61–93. Standards for Licensing Facilities for Chemically Dependent or Addicted Persons.

(Statutory Authority: 1976 Code §§ 44–7–260 et seq.)

Editor's Note

Unless otherwise noted, the following constitutes the history for 61–93, 101 to 3223.

HISTORY: Added by State Register Volume 12, Issue No. 2, eff February 26, 1988. Amended by State Register Volume 25, Issue No. 5, Part 1, eff May 25, 2001; State Register Volume 34, Issue No. 6, eff June 25, 2010; State Register Volume 39, Issue No. 6, Doc. No. 4464, eff June 26, 2015; SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

The Table of Contents appears as published in SCSR 44-6 Doc. No. 4954; there is no text for "504. Staffing for Withdrawal Management Programs (I)" or "2616. Seclusion Room (II)".

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SECTION 100. DEFINITIONS AND LICENSURE

101. Definitions.

For the purpose of this regulation, the following definitions shall apply:

A. Abuse. Physical abuse or psychological abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing infliction of physical injury on a Patient by an act or failure to act. Physical abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that of a therapeutic procedure prescribed by a licensed physician or other legally authorized healthcare professional. Physical abuse does not include altercations or acts of assault between Patients.

2. Psychological Abuse. The deliberate use of any oral, written, or gestured language or depiction that includes disparaging or derogatory terms to a Patient or within the Patient's hearing distance, regardless of the Patient's age, ability to comprehend, or disability, including threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Administering Medication. The acts of preparing and giving of a single dose of a medication to the body of a Patient by injection, ingestion, or any other means in accordance with the orders of a Physician or other Authorized Healthcare Provider.

C. Administrator. The staff member designated by the Licensee to have the authority and responsibility to manage the Facility and who is in charge of all functions and activities of the Facility.

D. Adult. A person eighteen (18) years of age or older.

E. Aftercare/Continuing Care. Services provided to Patients after discharge from a Facility that facilitates the Patient's integration or reintegration into society. Activities may include self-help groups, supportive work programs, and staff follow-up contacts and interventions.

F. Annual. A time period that requires an activity to be performed at least every twelve (12) months.

G. Assessment. A procedure for determining the nature and extent of the problems and needs of a Patient or potential Patient to ascertain if the Facility can adequately address those problems, meet those needs, and to secure information for use in the development of the Individual Plan of Care.

H. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina as a Physician, advanced practice registered nurse, or physician assistant to provide specific treatments, care, or services to Patients.

I. Blood Assay for *Mycobacterium tuberculosis* ("BAMT"). A general term to refer to in vitro diagnostic tests that assess for the presence of tuberculosis ("TB") infection with *Mycobacterium tuberculosis*. This term includes, but is not limited to, IFN-γ release assays ("IGRA").

J. Chemical Dependency. A disorder manifested by repeated use of alcohol or another substance to an extent that it interferes with a person's health, social, or economic functioning; some degree of habituation and dependence may be implied. May also be referred to as Substance Use Disorder.

K. Clinical Services Supervisor. The designated individual with responsibility for clinical supervision of treatment Staff and interpretation of program policy and standards.

L. Consultation. A meeting with a licensed Facility and individuals authorized by the Department to provide information to Facilities in order to enable Facilities to better comply with the regulations.

M. Contact Investigation. Procedures that occur when a case of infectious Tuberculosis is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent Tuberculosis Infection or Tuberculosis disease, and treatment of these persons, as indicated.

N. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act or the South Carolina Controlled Substances Act.

O. Counselor. An individual licensed by the South Carolina Department of Labor, Licensing and Regulation or certified as such by South Carolina Association of Alcoholism and Drug Abuse Counselors.

P. Department. The South Carolina Department of Health and Environmental Control.

Q. Dietitian. An individual currently licensed as a Dietitian by the South Carolina Department of Labor, Licensing and Regulation.

R. Direct Care Staff. Those individuals who provide care and services to the Patient.

S. Discharge. The point at which treatment, care, and services in a Facility are terminated and the Facility no longer maintains active responsibility for the care of the Patient, except for Continuing Care monitoring.

T. Elopement. An instance when a Patient who is physically, mentally, or chemically impaired wanders, walks, runs away, escapes, or otherwise leaves the Facility unsupervised or unnoticed.

U. Exploitation. (1) Causing or requiring a Patient to engage in an activity or labor that is improper, unlawful, or against the reasonable and rational wishes of a Patient. Exploitation does not include requiring a Patient to participate in an activity or labor that is a part of a written individual plan of care or prescribed or authorized by the Patient's attending physician; (2) an improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a Patient by an individual for the profit or advantage of that individual or another individual; or (3) causing a Patient to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the Patient through cunning arts or devices that delude the Patient and cause him or her to lose money or other property.

V. Facility for Chemically Dependent or Addicted Persons (Facility or Substance Use Disorder Facility). A Facility organized to provide Outpatient or Residential Services to Chemically Dependent or Addicted Persons and their families based on an Individual Plan of Care including diagnostic treatment, individual and group counseling, family therapy, vocational and educational development counseling, and referral services.

W. Follow-up. Intermittent contact with a Patient following discharge from the program, for assessment of Patient status and needs.

X. Health Assessment. An evaluation of the health status of a staff member/volunteer by a Physician, other Authorized Healthcare Provider, or a registered nurse. A registered nurse may complete the Health Assessment pursuant to standing orders approved by a Physician as evidenced by the Physician's signature. The standing orders shall be reviewed annually by the Physician, with a copy of the review maintained at the Facility.

Y. Individual Plan of Care. A written action plan based on assessment data that identifies the Patient's diagnosis and/or needs, the strategy for providing services to meet those needs, treatment goals and objectives, and the criteria for terminating the specified interventions.

Z. In-process Counselor. A counselor accepted by the South Carolina Association of Alcoholism and Drug Abuse Counselors as enrolled for certification.

AA. Inspection. A visit by the Department for the purpose of determining compliance with this regulation.

BB. Intake. The administrative and assessment process for admission to a program.

CC. Interdisciplinary Team. A group designated by the Facility to provide or supervise care, treatment, and services. The group normally includes but is not limited to the following persons: Counselors, social workers, Physicians and other Authorized Healthcare Providers, pharmacists, peer support specialists, etc.

DD. Investigation. A visit by Department representatives to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to statutory and regulatory compliance.

EE. Legend Medications.

1. A Controlled Substance, when under federal law, is required, prior to being dispensed or delivered to be labeled with any of the following statements:

a. "Caution: Federal law prohibits dispensing without prescription."

b. "Rx only"; or

2. A Controlled Substance which is required by any applicable federal or state law to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only;

3. Any Controlled Substance considered to be a public health threat, after notice and public hearing as designated by the South Carolina Board of Pharmacy; or

4. Any prescribed compounded prescription Controlled Substance within the meaning of the South Carolina Pharmacy Practice Act.

FF. License. The authorization to operate a Substance Use Disorder Facility as defined in this regulation and as evidenced by a certificate issued by the Department to a Facility.

GG. Licensed Nurse. A person to whom the South Carolina Board of Nursing has issued a license as a registered nurse or licensed practical nurse, or an individual licensed as a registered nurse or licensed practical nurse who resides in another state that has been granted multi-state licensing privileges by the South Carolina Board of Nursing and may practice nursing in any Facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.

HH. Licensee. The individual, corporation, organization, or public entity licensed pursuant to this regulation to provide dependency and Substance Use Disorder treatment services.

II. Medical Withdrawal Management Program. A program in a Residential Facility providing for medically-supervised Withdrawal Management, with the capacity to provide screening for medical complications of Substance Use Disorder, a structured program of counseling, if appropriate, and referral for further rehabilitation.

JJ. Medication. A substance that has therapeutic effects, including, but not limited to, Legend, Non-Legend, over-the counter, and nonprescription Medications, herbal products, vitamins, and nutritional supplements.

KK. Medication Unit. A Satellite location established as part of, but geographically separate, from a licensed Opioid Treatment Program to only administer Medications and conduct substance use screening.

LL. Methadone. A synthetic opioid Medication usually administered on a daily basis.

MM. Minor. Any person whose age does not meet the criteria indicated in Section 101.C.

NN. Neglect. The failure or omission of a direct care staff member to provide the care, goods, or services necessary to maintain the health or safety of a Patient including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Failure to provide adequate supervision resulting in harm to Patients, including altercations or acts of assault between Patients, may constitute neglect. Neglect may be repeated conduct or a single incident that has produced or could result in physical or psychological harm or substantial risk of death. Noncompliance with regulatory standards alone does not constitute neglect.

OO. Non-Legend Medications. A substance which may be sold without a prescription and which is labeled for use by the consumer in accordance with state and federal law.

PP. Opioid Treatment Program. A program within an Outpatient Facility providing services using Methadone or other opioid treatment Medication, and offering a range of treatment procedures and services for the rehabilitation of persons dependent on opium, morphine, heroin, or any derivative or synthetic Controlled Substance of that group.

QQ. Outpatient Facility. A Facility providing Outpatient Services.

RR. Outpatient Services. Non-Residential services for persons with Substance Use Disorder and/or their families.

SS. Patient. Any individual who receives Outpatient or Residential Services from a licensed Facility.

TT. Physical Examination. An examination of a Patient by a Physician or other Authorized Healthcare Provider which addresses those issues identified in Section 1100 of this regulation.

UU. Primary Counselor. An individual who is assigned by a Facility to develop, implement, and periodically review the Patient's Individual Plan of Care and to monitor a Patient's progress in treatment.

VV. Quality Improvement Program. The process used by a Facility to examine its methods and practices of providing care services, identify the ways to improve its performance, and take actions that result in improved quality of care for the Facility's Patients.

WW. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a twenty-four (24) month period.

XX. Residential Facility. A twenty-four (24) hour Facility offering Residential Treatment Program, Medical Withdrawal Management, and Social Withdrawal Management services in a Residential setting including services for parents with children.

YY. Residential Treatment Program. A program in a Residential Facility that is designed to improve the Patient's ability to structure and organize the tasks of daily living and foster recovery through planned clinical activities, counseling, and clinical monitoring in order to promote successful involvement or re-involvement in regular, productive daily activity, and, as indicated, successful reintegration into family living.

ZZ. Revocation of License. An action by the Department to cancel or annul a Facility License by recalling, withdrawing, or rescinding its authority to operate.

AAA. Satellite Facility. An approved Outpatient Facility at a location other than the main Outpatient Facility that is owned or operated by the same licensee.

BBB. Self-Administration. A procedure by which any Medication is taken orally, injected, inserted, or topically or otherwise administered by a Patient to himself or herself without prompting. The procedure is performed without assistance and includes removing an individual dose from a previously dispensed and labeled container (including a unit dose container), verifying it with the directions on the label, taking it orally, injecting, inserting, or applying topically or otherwise administering the Medication.

CCC. Social Withdrawal Management Program. A program in a Residential Facility providing supervised Withdrawal Management in which neither the Patient's level of intoxication nor physical condition is severe enough to warrant direct medical supervision or the use of Medications to assist in withdrawal, but which maintains medical backup and provides a structured program of counseling (if appropriate), educational services, and referral for further rehabilitation.

DDD. Staff. Those individuals who are employees (full and part-time) of the Facility, to include those individuals contracted to provide care and services for the Patients.

EEE. Substance Use Disorder. A recurrent use of alcohol or other substance causing clinically and functionally significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.

FFF. Suspension of License. An action by the Department requiring a Facility to cease operations for a period of time or to require a Facility to cease admitting Patients, until such time as the Department rescinds that restriction.

GGG. Tuberculosis Risk Assessment. An initial and ongoing evaluation of the risk for transmission of Mycobacterium Tuberculosis in a particular healthcare setting. To perform a risk assessment, the following factors shall be considered: the community rate of Tuberculosis, number of Tuberculosis Patients encountered in the setting, and the speed with which Patients with Tuberculosis disease are suspected, isolated, and evaluated. The Tuberculosis Risk Assessment determines the types of administrative and environmental controls and respiratory protection needed for a setting.

HHH. Volunteer. An individual who performs tasks that are associated with the operation of the Facility without pay and at the direction of the Administrator or his or her designee.

III. Withdrawal Management. A process of withdrawing a Patient from a specific psychoactive substance in a safe and effective manner.

102. License Requirements.

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, represent, advertise, or market itself as a Facility in South Carolina without first obtaining a License from the Department. No Facility shall admit Patients prior to the effective date of the License. When it has been determined by the Department that services for Substance Use Disorder are being provided at a location, and the owner has not been issued a License from the Department, the owner shall cease operation immediately and ensure the safety, health, and well-being of the Patients. Current and/or previous violations of the South Carolina Code or Department regulations may jeopardize the issuance of a License for the Facility or the licensing of any other Facility or addition to an existing Facility that is owned/operated by the licensee. The Facility

shall provide only the treatment, services, and care it is licensed to provide pursuant to the definition in Section 101.V. of this regulation. (I)

B. Compliance. An initial License shall not be issued to a proposed Facility until the Licensee has demonstrated to the Department that the proposed Facility is in substantial compliance with the licensing standards. In the event a current Licensee who already has a Facility or activity makes application for another Facility, the currently licensed Facility /activity shall be in substantial compliance with the applicable standards prior to the Department issuing a License to the proposed Facility or amended License to the existing Facility. A paper or electronic copy of the licensing standards shall be maintained at the Facility and accessible to all Staff members and Volunteers. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

C. Licensed Services. No Facility shall provide services outside the limits of the type Facility identified on the face of the License and/or which the Facility has been authorized to provide. (I)

D. Satellite Facilities.

1. Outpatient Satellite locations, other than Medication Units, are authorized only in the same county as the main Facility or in contiguous counties to the county in which the main Facility is located.

2. Medication Units. A Licensed Outpatient Facility providing an Opioid Treatment Program may establish a Medication Unit. A Medication Unit shall only administer Medications and conduct substance use screening. Other required services shall be provided at the licensed Facility's primary location. The Medication Unit shall meet the regulatory requirements for Medication administration, staffing, substance use screening, and construction.

a. Medication Units shall be opened no closer than forty-five (45) miles and no further than ninety (90) miles from the primary Opioid Treatment Program.

b. The Facility shall obtain a registration from the Department's Bureau of Drug Control and a Controlled Substances registration from the federal Drug Enforcement Administration for each Medication Unit.

c. The Facility shall not establish, operate, or maintain a Medication Unit without submitting an application to and receiving approval from the Department. The Facility's application for the Medication Unit shall include documentation from the Department evidencing that the applicant received either a Certificate of Need or a determination by the Department that Certificate of Need review is not required.

E. Licensed Bed Capacity. No Residential Facility that has been authorized to provide a set number of licensed beds, as identified on the face of the License, shall exceed the licensed bed capacity. No Facility shall establish new care or services or occupy additional beds or renovated space without first obtaining authorization from the Department. Licensed beds shall not be utilized by any individuals other than Facility Patients. (I)

F. Persons Received in Excess of Licensed Bed Capacity. No Residential Facility shall receive for treatment, care, or services persons in excess of the licensed bed capacity, except in cases of justified emergencies (See Section 1400). (I)

G. Living Quarters for Staff in Residential Facilities. In addition to Patients, only Staff members, Volunteers, or owners of the Facility and members of the owner's immediate family may reside in Facilities licensed under this regulation. Patient rooms shall not be utilized by any individuals other than Facility Patients, nor shall bedrooms of Staff members or family members of the owner or the Licensee be utilized by Patients. Staff members or family members of the owner or Licensee, or Volunteers shall not use Patient living rooms, recreational areas, or dining rooms unless they are on duty.

H. Issuance and Terms of License.

1. The License issued by the Department shall be posted by the Licensee in a conspicuous place in a public area within the Facility.

2. The issuance of a License does not guarantee adequacy of individual care, services, personal safety, fire safety, or the well-being of any Patient or occupant of a Facility.

3. A License is not assignable or transferable and is subject to revocation at any time by the Department for the Licensee's failure to comply with the laws and regulations of this state.

4. A License shall be effective for a specified Facility, at a specific location, for a specified period following the date of issue as determined by the Department. A License shall remain in effect until the Department notifies the Licensee of a change in the status.

5. Facilities owned by the same entity but which are not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, shall not be considered as dividing otherwise adjoining or contiguous property. For Facilities owned by the same entity, separate Licenses are not required for separate buildings on the same or adjoining grounds where a single type of service is provided.

6. Facilities providing Outpatient and Residential Services on the same premises shall be licensed separately even though owned by the same entity.

I. Facility Name. No proposed Facility shall be named nor shall any existing Facility have its name changed to the same or similar name as any other Facility licensed in South Carolina. The Department shall determine if names are similar. If the Facility is part of a "chain operation" it shall then have the geographic area in which it is located as part of its name.

J. Application. Applicants for a License shall submit to the Department a completed application on a form prescribed, prepared, and furnished by the Department prior to initial licensing. Applicants for a License shall file an application with the Department that includes an oath assuring the contents of the application are accurate and true and in compliance with this regulation.

K. Required Documentation. The application for initial licensure shall include:

1. Completed application;

2. Proof of ownership of real property on which the Facility is located or a rental or lease agreement allowing the Licensee to occupy the real property on which the Facility is located;

3. Verification of emergency evacuation plan (see Section 1401); and

4. Verification of Administrator's qualifications.

L. Licensing Fees. Each applicant shall pay a License fee prior to the issuance of a License.

1. The initial and annual License fee shall be seventy-five dollars ($75.00) for Outpatient Facilities. The initial and annual License fee for Outpatient Facility satellite locations shall be fifty dollars ($50.00) per Satellite Facility.

2. For Residential Facilities, the annual License fee shall be ten dollars ($10.00) per bed or seventy-five dollars ($75.00), whichever is greater.

M. Licensing Late Fees. Failure to submit a renewal application and fee to the Department by the License expiration date shall result in a late fee of seventy-five dollars ($75.00) or twenty-five percent (25%) of the licensing fee amount, whichever is greater, in addition to the licensing fee. Failure to submit the licensing fee and licensing late fee to the Department within thirty (30) days of the licensure expiration date shall render the Facility unlicensed. (II)

N. License Renewal. For a License to be renewed, applicants shall file an application with the Department, pay a License fee, and shall not be under consideration for, or undergoing, enforcement actions by the Department. Annual licensing fees shall also include any outstanding Inspection fees. All fees are non-refundable, shall be made payable by check or credit card to the Department or online, and shall be submitted with the application.

O. Amended License. No facility shall establish new care or services or occupy additional beds or renovated space without first obtaining authorization from the Department. A Facility shall request issuance of an amended License by application to the Department prior to any of the following circumstances:

1. Change of licensed bed capacity;

2. Change of Facility location from one geographic site to another;

3. Changes in Facility name or address (as notified by the post office); or

4. Change in Facility service type.

P. Change of Licensee. A Facility shall request issuance of a new License by application to the Department prior to any of the following circumstances:

1. A change in the controlling interest even if, in the case of a corporation or partnership, the legal entity retains its identity and name; or

2. A change in the type of the legal entity, for example, sole proprietorship to or from a corporation, partnership to or from a corporation, even if the controlling interest does not change.

Q. Variance. A variance is an alternative method that ensures the equivalent level of compliance with the standards in this regulation. The Facility may request a variance to this regulation in a format as determined by the Department. Variances shall be considered on a case by case basis by the Department. The Department may revoke issued variances as determined to be appropriate by the Department.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 200. ENFORCEMENT OF REGULATIONS

201. General.

The Department shall utilize Inspections, Investigations, Consultations, and other pertinent documentation regarding a proposed or licensed Facility in order to enforce this regulation.

202. Inspections and Investigations.

A. Inspections by the Department shall be conducted prior to initial licensing of a Facility and subsequent Inspections conducted as deemed appropriate by the Department.

B. All Facilities are subject to Inspection and/or Investigation at any time without prior notice by individuals authorized by the South Carolina Code of Laws. When Staff members and /or Patients are absent, the Facility shall post information at the entrance of the Facility to those seeking legitimate access to the Facility, including visitors. The posted information shall include contact information and the expected time of return of the Staff members and Patients. The contact information shall include the name of a designated contact and his or her telephone number. The telephone number for the designated contact shall not be the Facility's telephone number. (I)

C. Individuals authorized by South Carolina law shall be allowed to enter the Facility for the purpose of Inspection and/or Investigation and granted access to all properties and areas, objects, requested records, and documentation at the time of the Inspection or Investigation. The Department shall have the authority to require the Facility to make photocopies of those documents required in the course of Inspections or Investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. The physical area of Department Inspections and Investigations shall be determined by the Department based on the potential impact or effect upon patients. (I)

D. When there is noncompliance with the licensing standards, the Facility shall submit an acceptable plan of correction in a format determined by the Department. The plan of correction shall be signed by the Administrator and returned by the date specified on the report of Inspection and/or Investigation. The plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;

2. The actions taken to prevent recurrences (actual and similar); and

3. The actual or expected completion dates of those actions.

E. In accordance with South Carolina Code Section 44–7–270, the Department may charge a fee for Inspections.

1. Residential Facilities. The fee for initial, relocation, and routine Inspections shall be three hundred fifty dollars ($350.00), plus twenty-five dollars ($25.00) per licensed bed. The Inspection fee for a bed increase and/or service modification is two hundred dollars ($200.00), plus twenty-five dollars ($25.00) per licensed bed. The fee for all follow-up Inspections shall be two hundred dollars ($200.00), plus twenty-five dollars ($25.00) per licensed bed.

2. Outpatient Facilities. The fee for initial, relocation, and routine Inspections shall be four hundred fifty dollars ($450.00). The Inspection fee for service modification, including the establishment of a Satellite Facility, and follow-up Inspections is two hundred fifty dollars ($250.00).

F. The Licensee shall pay the following Inspection fees during the construction phase of the project. The plan Inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	**Fee**
< $10,001	$750
$10,001 - $100,000	$1,500
$100,001 - $500,000	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project cost
Site Inspection	
50% Inspection	$500
80% Inspection	$500
100% Inspection	$500

203. Consultations.

Consultations shall be provided by the Department as requested by the Facility or as deemed appropriate by the Department.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 300. ENFORCEMENT ACTIONS

301. General.

When the Department determines that a Facility is in violation of any statutory provision or regulation relating to the operation or maintenance of such Facility, the Department, upon proper notice to the Licensee, may deny, suspend, or revoke Licenses, or assess a monetary penalty, or both.

302. Violation Classifications.

A. Violations of standards in this regulation are classified as follows:

1. Class I violations are those that present an imminent danger to the health, safety, or well-being of the persons in the Facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods, or operations in use in a Facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

2. Class II violations are those, other than Class I violations, that have a negative impact on the health, safety, or well-being of persons in the Facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

3. Class III violations are those that are not classified as Class I or II in this regulation or those that are against the best practices. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

B. The notations, "(I)" or "(II)," placed within sections of this regulation, indicate those standards are considered Class I or II violations if they are not met, respectively. Failure to meet standards not so annotated are considered Class III violations.

C. In determining an enforcement action, the Department shall consider the following factors:

1. Specific conditions and their impact or potential impact on health, safety, or well-being of the Patients including, but not limited to:

a. Deficiencies in Medication management; critical waste water problems; housekeeping, or fire and life safety-related problems that pose a health threat to the Patients;

b. Power, water, gas, or other utility and/or service outages;

c. Patients exposed to air temperature extremes that jeopardize their health;

d. Unsafe condition of the building or structure;

e. Indictment of an Administrator for malfeasance or a felony, which by its nature indicates a threat to the Patients;

f. Direct evidence of Abuse, Neglect, or Exploitation;

g. Lack of food or evidence that the Patients are not being fed properly;

h. No Staff available at the Facility with Patients present;

i. Unsafe procedures and/or treatment being practiced by Staff; (I)

2. Repeated failure of the Licensee or Facility to pay assessed charges for utilities and/or services resulting in repeated or ongoing threats to terminate the contracted utilities and/or services; (II)

3. Efforts by the Facility to correct cited violations;

4. Overall conditions of the Facility;

5. History of compliance; and

6. Any other pertinent conditions that may be applicable to current statutes and regulations.

D. When imposing monetary penalties, the Department may invoke South Carolina Code Section 44–7–320(C) to determine the dollar amount or may utilize the following schedule:

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$ 500–1,500	$ 300–800	$100–300
2nd	1,000–3,000	500–1,500	300–800
3rd	2,000–5,000	1,000–3,000	500–1,500
4th	5,000	2,000–5,000	1,000–3,000
5th	5,000	5,000	2,000–5,000
6th	5,000	5,000	5,000

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 400. POLICIES AND PROCEDURES (II)

A. The Facility shall maintain and adhere to written policies and procedures addressing the manner in which the requirements of this regulation shall be met. The Facility shall be in full compliance with the policies and procedures.

B. The written policies and procedures shall include the following:

1. Staffing and training;

2. Reporting incidents, accidents, reportable diseases, closure and zero census;

3. Patient records;

4. Admission and Discharge;

5. Patient care, treatment, and services;

6. Medication management;

7. Maintenance including doors, windows, heating, ventilation, air conditioning, fire alarm, electrical, mechanical, plumbing, and for all equipment;

8. Infection control and housekeeping;

9. Quality Improvement Program; and

10. Fire Prevention;

C. The Facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented and signed by the Administrator. All policies and procedures shall be accessible to Facility staff, printed or electronically, at all times.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 500. STAFF AND TRAINING

501. General (II).

A. The Facility shall develop and implement policies and procedures to provide for appropriate Staff and/or Volunteers in numbers and training to suit the needs and condition of the Patients and meet the demands of effective emergency on-site action that might arise. Training requirements/qualifications for the tasks each performs shall be in compliance with all local, state, and federal laws, and current professional organizational standards.

B. The Facility shall maintain accurate information regarding all Staff and/or Volunteers of the Facility. The documentation shall include at least current address, phone number, health and work and/or training background, as well as current information. The Facility shall ensure all employees are assigned certain duties and responsibilities that shall be in writing and in accordance with the individual's capability. (II)

C. When a Facility engages a source other than the Facility to provide services normally provided by the Facility, the Facility shall maintain documentation of the written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to Patient care, services, and rights.

D. The Facility shall maintain documentation to ensure the Facility meets staffing requirements in Sections 503, 504, and 505.

502. Administrator (II).

A. Each Facility shall have a full-time Administrator who is responsible for the overall management and operation of the Facility and has at least a bachelor's degree in a related field.

B. A Staff member shall be designated by name or position, in writing, to act in the absence of the Administrator, for example, a listing of the lines of authority by position title, including the names of the individuals filling these positions.

503. Staffing for Residential Facilities (I).

A. All Staff members and/or Volunteers on duty shall be present, awake, and dressed at all times when Patients are present in the Facility. All Staff members and/or Volunteers shall know how to respond to Patient needs and emergencies.

B. Additional Staff shall be provided if it is determined that the minimum Staff requirements are inadequate to provide appropriate services and supervision to the Patients of a Facility.

C. Staffing for Residential Treatment Programs.

1. The number of Staff members that shall be maintained in all Facilities:

a. In each building, there shall be at least one (1) Staff member and/or Volunteer on duty for each ten (10) Patients or fraction thereof present from 7:00 am until 7:00 p.m.

b. In each building, there shall be at least one (1) Staff member and/or Volunteer for each twenty (20) Patients or fraction thereof from 7:00 p.m. until 7:00 a.m.

2. The Facility shall have at least one (1) Physician available during Facility operating hours, either in person or by telephone for consultation and for emergencies.

D. Staffing for Withdrawal Management Programs.

1. In each building, there shall be at least one (1) Direct Care or Counselor Staff member for each ten (10) Patients or fraction thereof on duty at all times.

2. In Residential Facilities providing Medical Withdrawal Management, Staff members and Volunteers shall be under the general supervision of a Physician or registered nurse; a Physician, Licensed Nurse, or other Authorized Healthcare Provider shall be present at all times.

505. Staffing for Opioid Treatment Programs (I).

A. The Opioid Treatment Program Physician shall have authority over all medical aspects of care and make treatment decisions in consultation with treatment Staff consistent with the needs of the Patient, clinical protocols, and research findings. The Facility shall have at least one (1) Physician available during dosing and Facility operating hours, either in person or by telephone for consultation and for emergencies.

B. The Facility shall have a pharmacist or other person licensed to dispense Opioid Treatment Program Medications pursuant to the South Carolina Code of Laws who is responsible for dispensing the amounts of Opioid Treatment Program Medications administered and shall record and countersign all changes in dosing schedules.

C. The Facility shall have one (1) Licensed Nurse present at all times Medications are being administered to Patients.

D. The Opioid Treatment Program shall have a least one (1) full-time counselor on staff for every fifty (50) Patients or fraction thereof. Counselors shall be qualified as specified in Section 508.

506. Inservice Training (II).

A. All Facilities shall provide Staff and Volunteers the necessary training to perform the duties for which they are responsible in an effective manner. The Facility shall require all Staff members and Volunteers to complete the necessary training to perform their duties and responsibilities. The Facility shall document all in-service training. Staff training shall be signed and dated by the individual providing the training and the person receiving the training. The signature for the individual providing the training may be omitted for online training.

B. All Facilities shall provide the following training to all Staff and Volunteers prior to Patient contact and at a frequency as determined by the Facility, but at least annually:

1. The nature of Substance Use Disorder, complications of Chemical Dependency, and withdrawal symptoms.

2. Confidentiality of Patient information and records and the protection of Patient rights.

C. All Residential Facilities shall provide the following training to all Staff and Volunteers prior to Patient contact and at a frequency as determined by the Facility, but at least annually:

1. Cardio-pulmonary resuscitation to ensure that there is at least one (1) certified individual present when Patients are in the Facility;

2. Basic first-aid to include emergency procedures as well as procedures to manage and/or care for minor accidents or injuries;

3. Procedures for checking and recording vital signs;

4. Management/care of persons with contagious and/or communicable disease;

5. Medication management;

6. Use of restraints and seclusion;

7. Seizure response training; and

8. OSHA standards regarding bloodborne pathogens.

D. All Opioid Treatment Programs shall provide opioid Medication treatment training to all Staff and Volunteers prior to Patient contact and at a frequency as determined by the Facility, but at least annually.

E. All Staff members and Volunteers shall have documented orientation to the purpose and environment of the Facility within twenty-four (24) hours of their first day on the job in the Facility.

507. Health Status (I).

A. All Staff and Volunteers who have contact with Patients, including food services Staff and Volunteers, shall have a Health Assessment, as defined in Section 101.X, within twelve (12) months prior to initial Patient contact. The Health Assessment shall include tuberculin skin testing as described in Section 1702.

B. For Staff members and/or Volunteers working at multiple Facilities operated by the same Licensee, the documented Health Assessment shall be accessible at each Facility, provided the information is in compliance with this regulation.

508. Counselors (II).

A. Each Facility shall have at least one (1) Staff Counselor who is fully-certified or licensed. All non-certified and/or licensed Counselors shall be under the direct supervision of an on-site fully-certified or licensed Counselor.

B. Staff and Volunteers providing clinical counseling services shall have one (1) of the following qualifications:

1. Certification:

a. Certification under the system administered by the South Carolina Association of Alcohol and Drug Abuse Counselors Certification Commission, or currently engaged, as verified and documented in the individual's personnel file, in the South Carolina Association of Alcohol and Drug Abuse Counselors certification process that is to be completed within a three (3)-year period from date of hire as a Counselor; or

b. Certification as a Counselor by:

(1) The National Association of Alcohol and Drug Abuse Counselors;

(2) An International Certification Reciprocity Consortium-approved certification board; or

(3) Any other South Carolina Department of Alcohol and Other Drug Abuse Services - approved credentialing or certification association or commission; or

2. Licensure:

a. Licensed as a Psychiatrist by the South Carolina Board of Medical Examiners;

b. Licensed as a Psychologist by the South Carolina Board of Examiners in Psychology;

c. Licensed as a Social worker by the South Carolina Board of Social Work Examiners; or

d. Licensed as a Counselor or therapist by the South Carolina Board of Examiners for Licensure of Professional Counselors, Marriage and Family Therapists, Addiction Counselors and Psycho-Educational Specialists, pursuant to Section 40–75–30, of the South Carolina Code of Laws, 1976.; or

3. Licensure as a Licensed Addiction Counselor Associate by the South Carolina Board of Examiners for Licensure of Professional Counselors, Marriage and Family Therapists, Addiction Counselors and Psycho-Educational Specialists, pursuant to Section 40–75–30, of the South Carolina Code of Laws, 1976, under appropriate supervision. Full licensure must be completed within a three (3)-year period from date of hire as a Counselor.

C. Counselors in Opioid Treatment Programs shall have one (1) of the following qualifications:

1. Any of the certifications or licensures in 508.B above; or

2. The American Academy of Health Care Providers in the Addictive Disorders; or

3. The National Board for Certified Counselors; or

4. Any other equivalent, nationally-recognized, and South Carolina Department of Alcohol and Other Drug Abuse Services-approved association or accrediting body that includes similar competency-based testing, supervision, educational, and substantial experience.

D. In Facilities providing prevention services, Counselors shall have one (1) of the following qualifications:

1. Certification by the South Carolina Association of Prevention Professionals and Advocates as a Prevention Professional or Senior Prevention Professional; or

2. In-process of becoming certified as a Prevention Professional. This certification shall be achieved within a thirty-six (36)-month period of time from the date of hire as a prevention Counselor.

E. Any individual employed as a direct Patient Counselor, Opioid Treatment Program Counselor, or prevention services professional, to include contracted Staff, who does not obtain his or her certification or licensing within the above time-periods, shall cease providing counseling services until that certification or licensing status is achieved.

F. The Facility shall verify and maintain documentation of each Counselor's qualifications in the individual's Staff record.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 600. REPORTING

601. Accidents and Incidents (II).

A. The Facility shall maintain a record of each accident and/or incident, including usage of mechanical and/or physical restraints, involving Patients, Staff members or Volunteers, occurring in the Facility or on the Facility grounds. The Facility shall retain all documented incidents reported pursuant to this section six (6) years after the Patient stops receiving services at the Facility.

B. The Facility shall report the following types of incidents to the next of kin or responsible party at the earliest practicable hour, not exceeding twenty-four (24) hours of the incident. The Facility shall report the following types of incidents to the Department immediately, not to exceed twenty-four (24) hours, via the Department's electronic reporting system or as otherwise determined by the Department. incidents requiring reporting include, but are not limited to:

1. Confirmed or Suspected Abuse, Neglect or Exploitation against a Patient by Facility Staff;
2. Crimes committed against Patients;
3. Death: For Residential Facilities, any Patient's death in the Facility or on the Facility grounds; for Opioid Treatment Programs, any Patient's death regardless of location;
4. Overdose reversal (naloxone);
5. Elopement (Residential Facility only);
6. Bone fracture or joint fracture;
7. Hospitalization as a result of accident and/or incident;
8. Medication Error;
9. Attempted Suicide; and
10. Severe injury involving use of restraint.

C. The Facility shall submit a separate written investigation report within five (5) days of every incident required to be immediately reported to the Department pursuant to Section 601.B via the Department's electronic reporting system or as otherwise determined by the Department. Reports submitted to the Department shall contain only: Facility name, License number, type of accident and/or incident, the date of accident and/or incident occurred, number of Patients directly injured or affected, Patient medical record identification number, Patient age and sex, number of Staff directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident and/or incident, internal investigation results if cause unknown, a brief description of the accident and/or incident including location where occurred, and treatment of injuries.

602. Fire and Disasters (II).

A. The Facility's Administrator or his or her designee shall notify the Department immediately via telephone, e-mail, or fax of any fire in the Facility. The Facility shall submit a complete written report to include fire reports within a time-period determined by the Facility, but not to exceed forty-eight (48) hours from the occurrence of the fire.

B. The Facility's Administrator, or his or her designee, shall notify the Department immediately of any natural disaster or fire that requires displacement of the Patients, or jeopardizes or potentially jeopardizes the safety of the Patients. The Facility shall submit a complete written report that includes the fire report from the local fire department within a time-period as determined by the Facility, but not to exceed forty-eight (48) hours.

603. Communicable Diseases and Animal Bites (I).

The Facility shall report all cases of diseases and animal bites that are required to be reported to the appropriate county health department in accordance with R.61–20, Communicable Diseases.

604. Administrator Change.

The Licensee shall notify the Department via email, or a means as otherwise determined by the Department within seventy-two (72) hours of any change in Administrator status. The Licensee shall provide the Department in writing within ten (10) days the name of the newly-appointed Administrator and the effective date of the appointment.

605. Joint Annual Report.

Residential Facilities providing a Medical Withdrawal Management Program and Outpatient Facilities providing an Opioid Treatment Program, shall complete and return a "Joint Annual Report" to

the South Carolina Revenue and Fiscal Affairs Office within the time-period specified by the Department.

606. Accounting of Controlled Substances (I).

Any Facility registered with the Department's Bureau of Drug Control and the federal Drug Enforcement Agency shall report any theft or loss of Controlled Substances to local law enforcement and to the Department's Bureau of Drug Control within seventy-two (72) hours of the discovery of the loss and/or theft. Any Facility permitted by the South Carolina Board of Pharmacy shall report the loss or theft of drugs or devices in accordance with Section 40–43–91 of the South Carolina Code of Laws.

607. Facility Closure.

A. Prior to the permanent closure of a Facility, the Licensee shall notify the Department in writing of the intent to close and the effective closure date. Within ten (10) days of the closure, the Facility shall notify the Department of the provisions for the maintenance of the records, the identification of those Patients displaced, the relocated site, and the dates. On the date of closure, the License shall be returned to the Department.

B. In instances where a Facility temporarily closes, the Licensee shall notify the Department in writing within fifteen (15) calendar days prior to temporary closure. In the event of temporary closure due to an emergency, the Facility shall notify the Department within twenty-four (24) hours of the closure via telephone, email, or fax. At a minimum this notification shall include, but not be limited to: the reason for the temporary closure, the location where the Patients have been and/or will be transferred, the manner in which the records are being stored, and the anticipated date for re-opening.

C. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards of the Facility prior to its reopening. If the Facility is closed for a period longer than one (1) year, and there is a desire to re-open, the Facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new Facility.

608. Zero Census.

In instances when there have been no Patients in a Facility for any reason for a period of ninety (90) days or more, the Facility shall notify the Department in writing that there have been no admissions, no later than the one hundredth (100th) calendar day following the date of departure of the last active Patient. At the time of that notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the Facility prior to any new and/or readmissions to the Facility. In the event the Facility is at zero census or temporarily closed, the Licensee is still required to apply and pay the licensing fee to keep the License active. If the Facility has no Patients for a period longer than one (1) year and there is a desire to admit a Patient, the Facility shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new Facility.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 700. PATIENT RECORDS

701. Content (II).

A. The Facility shall initiate and maintain a Patient record for every individual screened, assessed and/or treated. The record shall contain sufficient information to identify the Patient and the agency and/or person responsible for each Patient, support the diagnosis, justify the treatment, and describe the response and/or reaction to treatment. The record contents shall also include the provisions for release of information, Patient rights, consent for treatment (approval by parent and/or guardian of Patient), Medications prescribed and administered, and diet (Residential Facilities only), documentation of the course and results, and promote continuity of treatment among treatment providers, consistent with acceptable standards of practice. In Facilities providing services for Parents with children, the name and age of each child shall be maintained in the Facility. All entries shall be written legibly in ink, typed, or electronic media, and signed and dated or documented in the electronic medical record.

B. If the Facility permits any portion of a Patient's record to be generated by electronic or optical means, there shall be policies and procedures to prohibit the use or authentication by unauthorized users.

C. Specific entries and documentation shall include at a minimum:

1. Consultations by Physicians or other Authorized Healthcare Providers;

2. Signed and dated orders and recommendations for all Medication, care, services, and diet (Residential Facilities only) from Physicians or other Authorized Healthcare Providers, which shall be completed prior to, or at the time of admission, and subsequently, as warranted; (I)

3. Intake screening and initial physical assessment completed by the nurse or Counselor;

4. A signed and dated original consent for treatment; (I)

5. The report of the mental status examination and other mental health assessments as defined in Section 101.G. as appropriate;

6. Notes of counseling sessions and any other changes in the Patient's mental and physical condition; and

7. Medication management and administration, and treatment records.

8. Discharge summary, completed within a time-period as determined by the Facility, but no later than three (3) business days, and shall include at minimum:

a. Time and circumstances of Discharge or transfer, including condition at Discharge or transfer, or death; and

b. The recommendations and arrangements for further treatments, including Aftercare.

D. Electronic signatures may be used in the Patient record if they are in accordance with applicable laws and regulations, and require a signature. Electronic authorization shall be limited to a unique identifier (confidential code) used only by the individual making the entry to preclude the improper or unauthorized use of any electronic signature

702. Screening (I).

A. The Facility shall have written protocols for screening individuals presenting for admission. The Facility shall maintain documentation of the rationale for the denial of admission and referral of the individual as applicable.

B. All screening shall be documented for each individual presenting to the Facility.

C. For Facilities providing a Medical Withdrawal Management Program, the Intake screening shall be conducted by a Physician or other Authorized Healthcare Provider to determine the need for medical services or referral for serious medical complications.

D. For Facilities providing Social Withdrawal Management, the Intake screening shall be provided by Staff or Volunteers trained to monitor the Patient's physical condition.

E. For Facilities providing an Opioid Treatment Program, screening shall include:

1. Evidence of tolerance to an opioid;

2. History of physiological dependence for at least one (1) year prior to admission. The Opioid Treatment Program Physician may waive the one (1)-year history of dependence when the Patient seeking admission meets one (1) of the following criteria:

a. The Patient has been recently released from a penal or chronic care Facility with a high risk of relapse;

b. The Patient has been previously treated and is at risk of relapse;

c. The Patient is pregnant and does not exhibit objective signs of opioid withdrawal or physiological dependence;

3. Evidence of multiple and daily self-administration of an opioid;

4. Reasonable attempts to confirm that the applicant is not enrolled in one (1) or more other Opioid Treatments Programs;

5. Controlled Substance history to determine dependence on opium, morphine, heroin, or any derivative or synthetic controlled substance of that group. The substance history shall include:

a. Controlled Substance(s) utilized;

b. Frequency of use;

c. Amount utilized;

d. Duration of use;

e. Age when first utilized;

f. Route of administration;

g. Previous treatment(s);

h. Unsuccessful efforts to control use; and

i. Inappropriate use of prescribed opioids.

703. Assessment for Residential Treatment Programs (II).

A written assessment of the Patient in accordance with Section 101.G shall be conducted by a designated Counselor as evidenced by his or her signature and date within a time-period determined by the Facility, but no later than five (5) business days after admission.

704. Assessment for Withdrawal Management Programs (II).

A written clinical Assessment of the Patient completed by a Licensed Nurse as evidenced by his or her signature and date in accordance with Section 101.G shall be conducted prior to the delivery of treatment. The clinical Assessment shall include a review of the Patient's Controlled Substance misuse/usage and treatment history.

705. Bio-Psycho-Social Assessment for Opioid Treatment Program (II).

A comprehensive Bio-Psycho-Social Assessment shall be completed by the Patient's primary Counselor once the Patient is stabilized but not later than thirty (30) calendar days following admission. The Assessment shall include:

A. A description of the historical course of the Chemical Dependence to include substances of misuse such as alcohol and tobacco, amount, frequency of use, duration, potency, and method of administration, previous withdrawal from Opioid Treatment Program Medication and/or treatment attempts, and any psychological or social complication.

B. A health history regarding chronic or acute medical conditions, such as HIV, STDs, hepatitis (B, C, D), TB, diabetes, anemia, sickle cell trait, pregnancy, chronic pulmonary diseases, and renal diseases.

C. Information related to the family of the Patient.

706. Individual Plan of Care (II).

The Facility shall develop an Individual Plan of Care with participation by the Patient or responsible party and Interdisciplinary Team as evidenced by their signatures and dates. The Individual Plan of Care shall contain specific goal-related objectives based on the needs of the Patient as identified during the Assessment phase, including adjunct support service needs and other special needs. The Individual Plan of Care shall also include the methods and strategies for achieving these objectives and meeting these needs in measurable terms with expected achievement dates. The type and frequency of counseling, as well as Counselor assignment, shall be included. The criteria for terminating specified interventions shall be included in the Individual Plan of Care. Individual Plan of Care shall be reviewed on a periodic basis as determined by the Facility and/or revised as changes in Patient needs occur.

A. In Residential Treatment Programs, an Individual Plan of Care shall be completed no later than seven (7) calendar days after admission.

B. For a Residential Facility offering a Withdrawal Management Program, an Individual Plan of Care shall be completed for supervised withdrawal within a time-period determined by the Facility's policies and procedures, but no later than seven (7) business days after admission.

707. Individual Plan of Care for Opioid Treatment Program (II).

A. The Facility shall develop and document an Individual Plan of Care within thirty (30) calendar days of admission with participation by the Patient and the primary Counselor.

B. The primary Counselor shall review the Patient progress in treatment and accomplishment of Individual Plan of Care goals not less than every ninety (90) calendar days during the first year of treatment and every six (6) months thereafter. The Counselor and Patient or responsible party shall sign and date any changes.

708. Record Maintenance.

A. The Licensee shall provide accommodations, space, supplies, and equipment for the protection, storage, and maintenance of Patient records. Patient records shall be stored in an organized manner.

B. The Patient record is confidential and shall be made available only to individuals authorized by the Facility and in accordance with local, state, and federal laws, codes, and regulations. (II)

C. The Facility shall maintain records generated by organizations or individuals contracted by the Facility for care or services.

D. Upon Discharge of a Patient, the record shall be completed within thirty (30) calendar days and filed in an inactive or closed file maintained by the Licensee.

E. Records of adult Patients may be destroyed after six (6) years following Discharge of the Patient. Records of Minors shall be retained for six (6) years or until majority, whichever period of time is greater. Other regulation-required documents, e.g., Medication destruction, fire drills, etc., shall be retained for at least twelve (12) months or since the last Department routine Inspection, whichever is the longer period.

F. Records of current Patients are the property of the Facility and shall be maintained at the Facility and shall not be removed without court order.

G. In the event of change of ownership, all active Patient records or copies of active Patient records shall be transferred to the new owner(s).

H. When a Patient transfers from one licensed Facility to another within the provider network (same Licensee) the original record may follow the Patient; the sending Facility shall maintain documentation of the Patient's transfer and/or Discharge dates and identification information.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 800. ADMISSION (I)

801. General.

Individuals seeking admission shall be identified as appropriate for the level of care or services, treatment, or procedures offered. The Facility shall establish admission criteria that are consistently applied and comply with state and federal laws and regulations. The Facility shall admit only those persons whose needs can be met within the accommodations and services provided by the Facility.

802. Residential Facilities.

A. Residential Facilities shall not admit any person who, because of acute mental illness or intoxication, presents an immediate threat of harm to him or herself and/or others

B. Parental consent shall be obtained for all persons under eighteen (18) years of age prior to admission to a Residential Facility. If any court of competent jurisdiction declares a person under eighteen (18) years of age an emancipated Minor, such person may be admitted to the Facility without parental consent.

C. Residential Treatment Programs shall not admit any person needing Withdrawal Management services, hospitalization, or nursing home care.

D. Withdrawal Management Programs.

1. Appropriate admission to a Facility providing Withdrawal Management shall be determined by a licensed or certified Counselor and subsequently shall be authorized by a Physician or other Authorized Healthcare Provider in accordance with Section 1100.

2. Withdrawal Management Programs shall not admit any person needing hospitalization, Residential Treatment Program, or nursing home care.

3. Parental consent shall be obtained for all persons under eighteen (18) years of age prior to admission to a Residential Treatment Program. If any court of competent jurisdiction declares a

person under eighteen (18) years of age an emancipated Minor, then such person may be admitted to the program without parental consent.

803. Opioid Treatment Programs.

A. Persons shall not be admitted to the Opioid Treatment Program to receive opioids for pain management only. Appropriate referrals by the Opioid Treatment Program Physician shall be made as necessary, e.g., pain management specialist.

B. No person under eighteen (18) years of age shall be admitted to an Opioid Treatment Program unless a parent, legal guardian, or responsible adult consents in writing to such treatment.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 900. PATIENT CARE, TREATMENT, AND SERVICES

901. General.

A. The Facility shall provide Patient care and services, including routine and emergency medical care, as identified in the Patient record and as ordered by a Physician or other Authorized Health Care Provider. Care and services shall be provided and coordinated among those responsible during the treatment process and modified as warranted based on any changing needs of the Patient, and detailed in the Individual Plan of Care. (I)

B. Care, treatment, and services shall be rendered effectively and safely in accordance with orders from Physicians, other Authorized Healthcare Providers, and certified and/or licensed Counselors, and precautions taken for Patients with special conditions, e.g., pacemakers, wheelchairs, etc. (I)

C. The Facility shall document that Patients were offered the opportunity to participate in Aftercare and/or Continuing Care programs offered by the Facility or through referral. (II)

D. In the event of closure of a Facility for any reason, the Facility shall ensure continuity of treatment and/or care by promptly notifying the Patient's attending Physician or other Authorized Healthcare Provider or Counselor and arranging for referral to other Facilities at the direction of the Physician or other Authorized Healthcare Provider or Counselor. The facility shall document the notification and referral in the Patient's medical record.

902. Residential Facilities. (II)

A. Patients shall receive assistance in activities of daily living as documented in the Individual Plan of Care.

B. Patients shall be provided necessary items and assistance to maintain their personal hygiene.

C. Opportunities shall be provided for participation in religious services. Assistance in obtaining pastoral counseling shall be provided upon request by the Patient.

D. Precautions shall be taken for the protection of the personal possessions of the Patients, including their personal funds. The Facility may secure the personal funds of the Patient provided the Patient authorizes the Facility to do so. The Facility shall maintain an accurate accounting of the funds, including evidence of purchases by Facility on behalf of the Patients. No personal monies shall be given to anyone, including family members, without written consent of the Patient. If money is given to anyone by the Facility, a receipt shall be obtained.

E. Residential Treatment Programs shall document in the Patient's medical record that the Facility has provided or made available the following:

1. Specialized professional consultation, supervision, and direct affiliation with other levels of treatment;

2. Arrangements for appropriate laboratory and toxicology tests as needed;

3. Counselors to assess and treat Patients for Substance Use Disorders and obtain and interpret information regarding the needs of the Patients;

4. Counselors to provide a planned regimen of twenty-four (24) hour professionally-directed evaluation, care, and treatment services for persons with Substance Use Disorders and their families to include individual, group, and/or family counseling directed toward specific Patient goals indicated in his or her Individual Plan of Care;

5. Educational guidance and educational program referral when indicated; and

6. Vocational counseling for any Patient when indicated. For those not employed, Staff and/or Volunteers shall facilitate the Patient's pursuit of employment search;

F. Withdrawal Management Programs.

1. Facilities Offering a Medical Withdrawal Management Program shall document in the Patient's medical record that the facility has provided the following:

a. Continuing observation and monitoring of each Patient's condition to recognize and evaluate significant signs and symptoms of medical distress and take appropriate action. Each Patient's general condition, including vital signs, shall be documented at a frequency as determined by the Facility, but not less than three (3) times during the first seventy-two (72) hours of admission to the Facility;

b. A plan for supervised withdrawal, to be implemented upon admission;

c. Counseling designed to motivate Patients to continue in the treatment process and referral to the appropriate treatment modality.

2. Facilities offering a Social Withdrawal Management Program shall document in the Patient's medical record that the Facility has provided the following:

a. Development of an Individual Plan of Care for supervised withdrawal;

b. Continuing observation of each Patient's condition to recognize and evaluate significant signs and symptoms of medical distress and take appropriate action; and

c. Counseling designed to motivate Patients to continue in the treatment process.

3. Facilities providing a Withdrawal Management Program shall provide room, dietary service, care, and supervision necessary for the maintenance of the Patient.

903. Facilities Providing an Opioid Treatment Program.

A. Services (II).

1. Services shall be directed toward reducing or eliminating the use of illicit Controlled Substances, criminal activity, or the spread of infectious disease while improving the quality of life and functioning of the Patient. Opioid Treatment Programs shall follow rehabilitation stages in sufficient duration to meet the needs of the Patient. These stages include initial treatment, early stabilization, long-term treatment, medical maintenance, and immediate emergency treatment when needed.

2. The Opioid Treatment Program shall directly provide, contract, or make referrals, for services based upon the needs of the Patient.

3. As part of Substance Use Disorder rehabilitative services provided by the Opioid Treatment Program, each Patient shall be provided with individual, group, and family counseling as based on needs identified during the assessment. The frequency and duration of counseling provided to Patients shall be determined by the needs of the Patient and be consistent with the Individual Plan of Care. Counseling shall address, as a minimum:

a. Treatment and recovery objectives included in the Individual Plan of Care, as well as education regarding HIV, Hepatitis, and other infectious diseases. HIV testing shall be made available as appropriate, while maintaining Patient confidentiality;

b. Concurrent substance misuse;

c. Involvement of family and significant others with the informed consent of the Patient;

d. Providing treatment groups; and

e. Guidance in seeking alternative therapies, if applicable.

B. Support Services.

1. The Opioid Treatment Program shall ensure that a comprehensive range of support services, including, but not limited to, vocational, educational, employment, legal, mental health and family problems, medical, Substance Use Disorder, HIV or other communicable diseases, pregnancy and prenatal care, and social services are made available to Patients who demonstrate a need for such services. Support services may be provided either directly or by appropriate referral. Support services recommended and utilized shall be documented in the Patient record.

2. When appropriate, the Opioid Treatment Program shall link the Patient with an educational program, and vocational employment services. Deviations from compliance with these outcomes shall be documented in the Patient's record.

3. The Opioid Treatment Program shall establish and utilize formal linkages with community-based treatment services, through an established set of procedures for coordinating care with Physicians or other health or behavioral care providers when appropriate.

4. The Opioid Treatment Program shall establish linkages with the criminal justice system to encourage continuous treatment of individuals incarcerated or on probation and parole.

C. Services to Pregnant Patients in an Opioid Treatment Program (II).

1. The Facility shall make reasonable effort to ensure that pregnant Patients receive prenatal care by a Physician and that the Physician is notified of the Patient's participation in the Opioid Treatment Program when the Facility becomes aware of the pregnancy.

2. The Opioid Treatment Program shall provide, through in-house services or referral, and document in the Individual Plan of Care, appropriate services and interventions for the pregnant Patient to include:

a. Physician consultation at least monthly;

b. Nutrition counseling; and

c. Parenting training to include newborn care, health and safety, parent/infant interaction, and bonding.

3. The Facility shall maintain signed documentation of a Patient's acknowledgement of refusal of prenatal care.

4. Opioid Treatment Program FDA-approved Medication for opioid treatment dosage levels shall be maintained at an appropriate level for pregnant Patients as determined by the Opioid Treatment Program Physician and documented in the Patient's record. (I)

5. When a pregnant Patient chooses to discontinue participation in the Opioid Treatment Program, the program Physician, in coordination with the attending obstetrician, shall supervise the termination process.

904. Substance Use Testing for Opioid Treatment Programs (II).

A. Substance use testing shall be used as a clinical tool for the purposes of diagnosis and in the development of Individual Plans of Care.

B. Substance use testing for the presence of Opioid Treatment Program Medication, benzodiazepines, cocaine, opiates, marijuana, amphetamines, and barbiturates, as well as other substances, when clinically indicated by the Opioid Treatment Program Physician, shall be conducted at a frequency as determined by the Opioid Treatment Program.

C. Results of substance use testing shall be addressed by the primary Counselor with the Patient, in order to intervene in Controlled Substance use behavior.

D. The Opioid Treatment Program shall establish and implement written testing procedures, including random collection of substance testing samples, to effectively minimize the possibility of falsification of the sample, to include security measures for prevention of tampering.

E. Patients granted take home dosages shall undergo random substance use testing on a monthly basis. For Patients whose substance use testing reports indicate positive results for any illicit substances, non prescription Medications, or a negative result of Opioid Treatment Program Medication, the frequency for substance use testing shall be determined by the Opioid Treatment Program Physician or other Authorized Healthcare Provider. Documentation of the rationale for the frequency shall be documented in the Patient's medical record.

F. Only those laboratories certified in accordance with the federal Clinical Laboratories Improvement Amendments shall be utilized by the Opioid Treatment Program for urinalysis.

905. Orientation for Patients Admitted to an Opioid Treatment Program.

Patient orientation shall be accomplished within seven (7) calendar days of admission and documented in the Patient record. The orientation shall include:

A. Opioid Treatment Program guidelines, rules, and regulations;

B. Confidentiality;

C. Substance use testing procedure;

D. Administering Opioid Treatment Program Medication;

E. Signs and symptoms of an overdose and when to seek emergency assistance;

F. Discharge procedures;

G. Treatment phases;

H. HIV/AIDS information and education;

I. Patient rights (See Section 1000);

J. The nature of Substance Use Disorders and recovery including misunderstandings regarding methadone or other opioid treatment Medication; and

K. For pregnant Patients, risk to the unborn child.

906. Transportation.

Residential Facilities shall provide or assist in securing local transportation for Patients for emergent or non-emergent health reasons to health care providers such as, but not limited to, Physicians, dentists, physical therapists, or for treatment at renal dialysis clinics.

907. Safety Precautions and Restraints (I).

A. Periodic or continuous mechanical, physical, or chemical restraints during routine care of a Patient shall not be used, nor shall Patients be restrained for Staff convenience or as a substitute for care or services. However, in cases of extreme emergencies when a Patient is a danger to him or herself or others, mechanical and/or physical restraints may be used as ordered by a Physician or other Authorized Healthcare Provider, and until appropriate medical care can be secured. Only those devices specifically designed as restraints may be used.

B. Emergency restraint orders shall specify the reason for the use of the restraint, the type of restraint to be used, the maximum time the restraint may be used, and instructions for observing the Patient while restrained, if different from the Facility's written procedures. Patients certified by a Physician or other Authorized Healthcare Provider as requiring restraint for more than twenty-four (24) hours shall be transferred to an appropriate Facility.

C. During emergency restraint, Patients shall be monitored at least every fifteen (15) minutes and provided with an opportunity for motion and exercise at least every thirty (30) minutes. Prescribed Medications and treatments shall be administered as ordered, and Patients shall be offered nourishment and fluids and given bathroom privileges.

D. The use of mechanical restraints shall be documented in the Patient's record, and shall include the date and time implemented, the length of time restrained, observations while Patient is restrained.

908. Services for Minors (II).

A. In Residential Facilities, Minors shall be housed separately from adults except in Facilities providing services for Parents with children.

B. In those instances where Minors are served, the Facility shall ensure that the special needs of these Patients are addressed, including, but not limited to, education-related considerations.

C. The Facility shall ensure treatment and counseling are conducted to meet the physical, mental, and emotional developmental needs of the Minor.

D. The Facility shall refer Minors who require special medical needs to a Physician who has clinical experience with Minors and dependency. The Facility shall monitor Minors for treatment reactions that may be developmentally detrimental. A plan shall be in place in the event that special medical care is required.

909. Referral Services.

A. Referrals for care and/or services shall not be made to unlicensed Facilities if such Facilities are required to be licensed. (II)

B. The Facility shall provide information regarding appropriate self-help groups to Patients and encourage their participation in such activities, and document the information was provided in the Patient's record.

C. The facility shall maintain documentation of the rationale for the denial of admission and referral for services offered to the Patient as applicable.

D. A community resource file shall be developed, maintained, and used for proper Patient referral and placement. The file shall include a listing of services, fees, hours of operation, and contact person as well as material to be provided to the Patient. The Facility shall provide the Patient with information and offer referral for community resources such as transportation, hospital emergency services, and ambulance services.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1000. PATIENT RIGHTS AND ASSURANCES

1001. Informed Consent (II).

A. Upon admission, there shall be a written, signed, and dated informed consent between the Patient and the Facility. The informed consent shall include at least the following:

1. An explanation of the specific care, services, and/or equipment provided by the Facility, such as, administration of Medication, provision of special diet as necessary, assistance with bathing, toileting, feeding, dressing, and mobility;

2. Discharge and transfer provisions to include the conditions under which the Patient may be Discharged, and the agreement terminated, and the disposition of personal belongings; and

3. Documentation of the explanation of the Patient's rights (see Section 1002) and the grievance procedure.

4. Each person enrolling in an Opioid Treatment Program shall be notified of the autopsy provision in South Carolina Code Section 44–53–750 as a part of such person's informed consent.

B. The provision of care and services to Patients shall be guided by the recognition of and respect for cultural differences to ensure reasonable accommodations shall be made for Patients with regard to differences, such as, but not limited to, religious practice and dietary preferences.

1002. Patient Rights (II).

A. Patient rights shall be guaranteed and prominently displayed in a public area. Documentation of the explanation of the Patient's Bill of Rights shall be maintained in the Patient's medical record. The Patient rights shall include:

1. The opportunity to participate in the Individual Plan of Care;

2. Informed consent for treatment;

3. Grievance and/or complaint procedures, including the address and phone number of the Department, and a provision prohibiting retaliation should the grievance right be exercised;

4. Confidentiality of Patient records;

5. Respect for the Patient's property (Residential Facilities Only);

6. Freedom from Abuse, Neglect, and Exploitation; (I)

7. Privacy in visits unless contraindicated in the recovery and treatment process or as ordered by a Physician or other Authorized Healthcare Provider;

8. Privacy during treatment and while receiving personal care; and

9. Respect and dignity in receiving care, treatment, and services.

B. For Facilities providing Residential Services, the Patients shall be assured freedom of movement. Patients shall not be locked in or out of their rooms or any common usage areas, in the Facility, or in or out of the Facility building. (I)

C. Care and services and items provided by the Facility, the charge, and those services that are the responsibility of the Patient shall be delineated in writing and the Patient shall be made aware of such charges and services as verified by his or her signature.

D. The Facility shall comply with all current federal, state, and local laws and regulations related to discrimination, e.g., Title VII, Section 601 of the Civil Rights Act of 1964, ADA, and ensure that there is no discrimination with regard to source of payment in the recruitment, location of Patient, acceptance or provision of goods and services to Patients or potential Patients, provided that payment offered is not less than the cost of providing services.

E. In Residential Facilities, no care and/or treatment and/or services shall be provided to individuals who are not Patients of the Facility, except those services provided to family members as part of the Patient's recovery plan.

1003. Discharge and Transfer.

A. Unless a Patient is under court order or detained subject to a pending judicial process, a Patient may be transferred or Discharged only for medical reasons, the welfare of the Patient, the welfare of other Patients of the Facility, lack of progress or participation in treatment, or successful completion of the program. He or she shall be given written notice of Discharge except when the health, safety, or well-being of other Patients of the Facility would be endangered.

B. When a Patient is transferred from one Facility to another, a transfer summary, to include copies of relevant documents, shall be forwarded to the receiving Facility within a time-period as determined by the Facility but not to exceed seventy-two (72) hours from transfer. The Facility shall ensure that Medication, personal possessions and funds of the Patient are forwarded to the receiving Facility and/or site in a manner that ensures continuity of care and/or treatment and/or services and maximum convenience to the Patient.

C. A Patient transferring from another Opioid Treatment Program shall have a Physical Examination upon admission and have his or her dose determined by a Physician prior to receiving the first dosage.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020; SCSR 44–6 Doc. No. 4954, eff June 26, 2020 (errata).

SECTION 1100. PATIENT PHYSICAL EXAMINATION

A. Residential Facilities. A Physical Examination shall be completed by a Physician or other Authorized Healthcare Provider for Patients within thirty (30) calendar days prior to admission or two (2) business days of admission for Patients. Physical Examinations conducted by Physicians or other Authorized Healthcare Providers licensed in other states are permitted for new admissions under the condition that the Patient undergoes a second Physical Examination by a South Carolina licensed Physician or other Authorized Healthcare Provider within thirty (30) calendar days of admission to the Facility. The Physical Examination shall address:

1. The appropriateness of level of services;

2. Identification of special conditions and/or care required;

3. A tuberculin skin test, as described in Section 1702, unless there is a previously documented positive reaction;

4. If a Patient or potential Patient has a communicable disease, the Facility shall follow the recommendations made by a Physician or other Authorized Healthcare Provider in order to:

a. Ensure that the Facility has the capability of providing adequate care and preventing the spread of that condition, and that Staff and Volunteers are adequately trained; or

b. Transfer the Patient to an appropriate Facility, if necessary; and

5. A substance use test. Following the test, the Physician or Authroized Healthcare Provider shall determine the frequency of subsequent testing based on the Patient's clinical presentation.

B. In Facilities providing services for parents with children, there shall be a report of an examination for each child by a Physician or other Authorized Healthcare Provider attesting to the health status and special care needs that may impact the child, his/ or her parent, and/or others within the Facility. The examination shall be conducted not earlier than thirty (30) calendar days prior to the parent's admission or no later than forty-eight (48) hours after admission.

C. Opioid Treatment Program.

1. Physical Examination. A Physical Examination conducted by the Opioid Treatment Program Physician or other Authorized Healthcare Provider shall be completed within seventy-two (72) hours prior to the first dose of Opioid Treatment Program Medication and shall address the following at a minimum: (I)

a. Evidence of communicable or Infectious disease;

b. Pulmonary, liver, renal, and cardiac abnormalities;

c. Neurological issues;

d. Vital signs;

e. Evidence of clinical signs of dependency; and

f. Examination of head, ears, eyes, nose, throat, thyroid, chest (including heart, lungs and breast), abdomen, extremities, and skin.

2. Medical Laboratory Analysis. A medical laboratory analysis shall be conducted within seven (7) calendar days of admission and shall include:

a. Serological test for Infectious disease;

b. Initial substance use testing for Controlled Substance profile;

c. Liver profile; and

d. If indicated, an electrocardiogram, chest x-ray, and/or a biological pregnancy test.

3. In the event the medical staff are unable to obtain an adequate blood draw for the medical laboratory analysis on the first attempt, the Facility shall reattempt within the seven (7) days of admission. After three (3) documented attempts within the seven (7) days of admission, the Opioid Treatment Program Physician or other Authorized Healthcare Provider may waive the blood testing requirements. The Physician's decision shall be documented in the Patient's medical record. The Facility shall follow its policies and procedures related to infection control if the Physician waives the blood testing requirement.

D. In the event that a Patient transfers from one Residential Facility to another, an additional admission Physical Examination and/or tuberculin skin test shall not be necessary, provided the Physical was conducted not earlier than twelve (12) months prior to the admission of the Patient, and the Physical meets all other requirements specified in Section 1100.A.1, unless the receiving Facility has an indication that the health status of the Patient has changed significantly. In such instances of transfer, issues of appropriateness of level of treatment placement shall be addressed in the Patient record.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1200. MEDICATION MANAGEMENT

1201. General (I).

A. Medications, including Controlled Substances, medical supplies, and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal law and regulations, which includes the securing, storing, and administering, dispensing, and delivering of medications, medical supplies, and biologicals, their disposal when discontinued or outdated, and their disposition at Discharge, death, or transfer of a Patient. All Facilities that manage Medication of Patients shall comply with this section.

B. Applicable reference materials published within the previous three (3) years shall be available at the Facility in order to provide Staff and/or Volunteers with adequate information concerning Medications.

1202. Medication Orders (I).

A. Medication, including oxygen, shall be administered and delivered to Patients only upon orders of a Physician or other Authorized Healthcare Provider. Medications accompanying Patients at admission may be administered and/or delivered to Patients, provided the Medication is in the original container and the order/authorization is subsequently obtained as a part of the admission Physical Examination. If there are concerns regarding whether or not such Medications should be administered and/or delivered due to the condition or state of the Medication, e.g., old, expired, makeshift labels, or the condition or state of health of the newly-admitted individual, Staff and Volunteers shall consult with or make arrangements to have the Patient examined by a Physician or other Authorized Healthcare Provider, or at the local hospital emergency room prior to administering or delivering any Medications.

B. All orders (including verbal orders) shall be signed and dated by a Physician or other Authorized Healthcare Provider within a time-period as designated by the Facility, but no later than seventy-two (72) hours after the order is given.

C. In an Opioid Treatment Program, all orders shall be documented, signed, and dated by the Opioid Treatment Program Physician. The Opioid Treatment Program Physician shall determine the initial and subsequent dosage and schedule, and prescribe such dose and schedule to include changes by verbal or written order to the pharmacist and Licensed Nurse. However, the verbal order shall be documented, signed, and dated by the Opioid Treatment Program Physician within seventy-two (72) hours.

D. Orders for Controlled Substances shall be authenticated by the prescribing Physician or designee.

E. Medications and medical supplies ordered for a specific Patient shall not be administered and/or delivered to any other Patient.

1203. Administering Medication (I).

A. Doses of Medication shall be administered by the same Licensed Nurse who prepared them for administration. Preparation shall occur no earlier than one (1) hour prior to administering. Preparation of doses for more than one (1) scheduled administration shall not be permitted. Each Medication dose administered shall be recorded on the Patient's Medication administration record (''MAR'') as it is administered. Should an ordered dose of Medication not be administered, an explanation as to the reason shall be recorded on the MAR. The recording of Medication administration shall include: the medication name, dosage, mode of administration, date, time, and the signature of the individual administering or supervising the taking of the Medication. Initials in lieu of signatures are acceptable provided such initials can be readily identified on the MAR. If the ordered dosage is to be given on a varying schedule, for example, ''take two tablets the first day and one tablet every other day by mouth with noon meal,'' the number of tablets shall also be recorded.

B. When a Physician or other Authorized Healthcare Provider changes the dosage of a Medication, a new entry reflecting the change shall be documented in the Medication administration record (''MAR''). No dose shall be administered until the Patient's identity has been verified and the dosage compared with the currently ordered and documented dosage level. Ingestion shall be observed and verified by the person authorized to administer the Medication.

C. Opioid Treatment Program Only:

1. The Facility shall not administer a Patient's initial dose of Opioid Treatment Program Medication until the program Physician or other Authorized Healthcare Provider has determined that all admission criteria have been met, to include a completed Physical Examination by the program Physician or other Authorized Healthcare Provider and confirmation of current Medication regimen being taken by the applicant.

2. The initial dose of methadone shall not exceed thirty (30) milligrams and the initial total daily dose for the first day shall not exceed forty (40) milligrams unless the Opioid Treatment Program Physician or other Authorized Healthcare Provider justifies in the Patient record that forty (40) milligrams did not suppress the abstinence symptoms after three (3) hours of observation following the initial dose. There shall be written justification in the Patient record, signed and dated by the Opioid Treatment Program Physician or other Authorized Healthcare Provider, for doses in excess of one hundred (100) milligrams of methadone per day after the first day.

3. A Patient's scheduled dose may be temporarily delayed if necessary, e.g., to obtain a urine sample or for Counselor consultation. The dose shall not be withheld, however, for failure to comply with the Opioid Treatment Program rules or procedures unless the decision is made to terminate the Patient's participation in the Opioid Treatment Program. A dose may be withheld only when the Opioid Treatment Program Physician or other Authorized Healthcare Provider determines that such action is medically indicated.

4. When the Opioid Treatment Program Physician prescribes Controlled Substances other than Opioid Treatment Program Medications, such prescriptions shall not be administered to any Patient unless the Opioid Treatment Program Physician or other Authorized Healthcare Provider first examines the Patient and assesses his or her potential for misuse of such Medications.

D. Self-administration of Medications shall be allowed only on the specific written orders of a Physician or other Authorized Healthcare Provider. An appropriate Staff member delivering the Medication shall document the delivery. Such documentation shall include the date, time, and the signature of the individual delivering the Medication.

E. When Patients who cannot Self-Administer Medications leave the Facility for an extended time, the proper amount of Medications, placed into a prescription vial or bottle, along with dosage, mode, date, and time of administration, shall be given to a responsible person who will be in charge of the Patient during his or her absence from the Facility and properly documented in the Medication administration record. If there is no designated responsible party for the Patient, then the attending Physician or other Authorized Healthcare Provider shall be contacted for proper instructions.

F. The Medications prescribed for a Patient shall be protected from use by other Patients, visitors, and Staff and Volunteers. For those Patients who have been authorized by a Physician or other Authorized Healthcare Provider to Self-Administer Medications, such Medications (nitroglycerin, rescue inhalers, epinephrine auto-injectors) may be kept on the Patient's person, i.e., a pocketbook, pocket, or any other method that would enable the Patient to control the items.

1204. Pharmacy Services (I).

A. Any pharmacy within the Facility shall be provided by or under the direction of a licensed pharmacist in accordance with accepted professional principles and appropriate federal, state, and local laws and regulations.

B. Facilities that maintain stocks of Medications and biologicals for Patient use within the Facility shall obtain and maintain from the South Carolina Board of Pharmacy a valid, current, non-dispensing drug outlet permit that is displayed in a conspicuous location in the Facility.

C. Labeling of Medications dispensed to Patients shall be in compliance with local, state, and federal laws and regulations applicable to retail pharmacies.

1205. Medication Containers (I).

A. Medications for Patients shall be obtained from a permitted pharmacy or Authorized Healthcare Provider as allowed by law on an individual prescription basis. These Medications shall bear a label affixed to the container that reflects at least the following: name of pharmacy, name of Patient, name of the prescribing Physician or other Authorized Healthcare Provider, date and prescription number, directions for use, and the name and dosage unit of the Medication. The label shall be brought into accord with the directions of the Physician or other Authorized Healthcare Provider each time the prescription is refilled. Medication containers having soiled, damaged, incomplete, illegible, or make-shift labels shall be returned to the pharmacy for re-labeling or disposal.

B. Medications for each Patient shall be kept in the original container(s) including unit dose systems; there shall be no transferring between containers or opening blister packs to remove Medications for destruction or adding new Medications for administration, except under the direction of a pharmacist. In addition, for those Facilities that utilize the unit dose system or multi-dose system, an on-site review of the Medication program by a pharmacist shall be conducted on at least a quarterly basis to ensure the program has been properly implemented and maintained. For changes in dosage, the new packaging shall be available in the Facility no later than the next administration time subsequent to the order. This shall be documented and signed by the pharmacist.

C. Medications for Patients shall be obtained from a permitted pharmacy or prescriber on an individual prescription basis. These Medications shall bear a label affixed to the container that reflects at least the following: name of pharmacy, name of Patient, name of the prescribing Physician or dentist, date and prescription number, directions for use, and the name and dosage unit of the Medication.

D. When a Physician or other legally Authorized Healthcare Provider changes the dosage of a Medication, such information shall be documented in the Medication administration record and a label that does not obscure the original label shall be attached to the container that states, "Directions changed; refer to MAR and Physician or other Authorized Healthcare Provider orders for current administration instructions."

1206. Medication Storage (I).

A. Medications may be stored in a separate locked box within a refrigerator at or near the Medication storage area, either behind a locked door or the refrigerator shall be locked.

B. Controlled Substances and ethyl alcohol shall be stored in accordance with applicable state and federal laws. A record of the stock and distribution of all Controlled Substances shall be maintained in such a manner that the disposition of any particular item may be readily traced.

C. Medications shall be stored:

1. Separately from poisonous Controlled Substances or body fluids;

2. In a manner which provides for separation between topical and oral Medications, and which provides for separation of each individual Patient's Medication.

D. Stock Medications

1. Unless the Facility has a permitted pharmacy, stocks of Legend Medications shall not be stored except those specifically prescribed for individual Patients.

2. Non-legend Medications may be retained and labeled as stock in the Facility for administration as ordered by a Physician or other Authorized Healthcare Provider.

3. Stocks of naloxone may be stored for emergency overdose crises, with or without specific prescription for individual Patients.

4. If stock non-Patient specific Controlled Substances are to be used, a Controlled Substances registration from the Department's Bureau of Drug Control and a Controlled Substances registration from the federal Drug Enforcement Administration shall be obtained. The registrations shall be displayed in a conspicuous location within the Facility.

E. No Medications may be left in a Patient's room unless the Facility provides an individual cabinet/compartment that is kept locked in the room of each Patient who has been authorized to Self-Administer in writing by a Physician, or other Authorized Healthcare Provider. In lieu of a locked cabinet or compartment, a room that can be locked and is licensed for a capacity of one (1) Patient is acceptable provided the Medications are not accessible by unauthorized persons, the room is kept locked when the Patient is not in the room, the Medications are not Controlled Substances, and all other requirements of this section are met.

F. The Medications prescribed for a Patient shall be protected from use by other Patients, visitors and Staff and Volunteers. For those Patients who have been authorized by a Physician or other Authorized Healthcare Provider to self-administer Medications, such Medications may be kept on the Patient's person, i.e., a pocketbook, pocket, or any other method that would enable the Patient to control the items.

G. During nighttime hours in semi-private rooms, only Medications that a Physician or other Authorized Healthcare Provider has ordered in writing for emergency/immediate use, e.g., nitroglycerin, rescue inhalers, or epinephrine auto-injectors may be kept unlocked in or upon a cabinet or bedside table, and only when the Patient to whom that Medication belongs is present in the Patient room.

1207. Disposition of Medications (I).

A. The Facility shall release Medications to the Patient upon Discharge, unless specifically prohibited by the ordering Physician or Authorized Healthcare Provider.

B. Patient's Medications shall be destroyed by the Facility Administrator or his or her designee or returned to dispensing pharmacy when:

1. Medication has deteriorated or exceeded its safe shelf-life; and

2. Unused portions remain due to death, Discharge, or discontinuance of the Medications. Medications that have been discontinued by order may be stored for a period not to exceed thirty (30) calendar days provided they are stored separately from current Medications.

C. The destruction of Medication shall occur within five (5) days of the above-mentioned circumstances, be witnessed by the Administrator or his or her designee, and the mode of destruction indicated.

D. The destruction of controlled substances Medications shall be accomplished only by the Administrator or his or her designee on-site and witnessed by a Licensed Nurse or pharmacist, or by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

1208. Opioid Treatment Program Take-home Medication (II).

A. Opioid Treatment Program Medication, including guest and take-home doses, shall be administered to Patients in single doses. Take-home bottles shall be labeled in accordance with federal and state law and regulations and shall contain necessary cautionary statements; caps shall be childproof.

B. Take-home Opioid Treatment Program Medication may be given to Patients who demonstrate a need for a more flexible schedule in order to enhance and continue the rehabilitative process. However, since Opioid Treatment Program Medication is an opioid subject to misuse if not managed properly, precautions shall be taken to prevent its potential misuse. The Opioid Treatment Program Physician shall ensure that take-home Medication is given to those Patients who meet the following criteria for eligibility:

1. Adherence to Opioid Treatment Program rules, regulations, and policies;
2. Length of time in the Opioid Treatment Program and level of maintenance treatment;
3. Presence of Opioid Treatment Program Medication in substance use testing;
4. Potential complications from concurrent health problems;
5. Lengthy travel distance to the Facility; and
6. Progress in maintaining a stable lifestyle as evidenced by:
   a. Absence of misuse of opioids and non-opioids;
   b. Absence of alcohol misuse, or determination that the using alcohol and is in treatment for the alcohol misuse problem;
   c. Regularity of attendance at the Opioid Treatment Program, to include required counseling sessions;
   d. Absence of serious behavior problems, including loitering at the Opioid Treatment Program;
   e. Absence of known recent criminal activity;
   f. Employment, school attendance, or other appropriate activity; and
   g. Assurance that take-home Medication can be securely transported and stored by the Patient for his or her use only.

C. The decision to provide take-home Medication to Opioid Treatment Program Patients and the amount provided shall be based upon and determined by the reasonable clinical judgment of the Opioid Treatment Program Physician and appropriately documented and recorded in the Patient's file prior to the initiation of the take-home dose. The Opioid Treatment Program Physician shall document compliance by the Patient with all of the aforementioned requirements prior to providing the first take-home dose. (I)

D. The Patient's take-home status shall be reviewed and documented at least on a quarterly basis by the primary Counselor.

E. If a Patient, due to special circumstances, such as illness, personal or family crisis, travel, or other hardship, is unable to conform to the applicable treatment schedule, he or she may be permitted to receive up to a two (2)-week supply of Opioid Treatment Program Medication, based on the clinical judgment of the Opioid Treatment Program Physician. The justification for permitting the adjusted schedule shall be recorded in the Patient's record by the Opioid Treatment Program Physician.

F. One-time or temporary (usually not to exceed three (3) days) take-home Medication shall be approved by the Facility for family or medical emergencies or other exceptional circumstances.

G. A Patient transferring from another Opioid Treatment Program or readmitted after having left the Opioid Treatment Program voluntarily and who has complied with Facility rules and program policies and procedures may be granted an initial take-home schedule that is no greater than that allowed at the time of transfer or voluntary Discharge provided all criteria other than length of treatment are met.

H. A Patient discharged from another Opioid Treatment Program shall only be initially granted take-home privileges from the new admitting Opioid Treatment Program provided the requirements of Section 1209 are met.

I. Take-home Medication shall be labeled with the name of the Opioid Treatment Program, address, telephone number, and packaged in conformance with state and federal regulations.

J. A diversion control plan shall be established to assure quality care while preventing the diversion of Opioid Treatment Program Medication from treatment to illicit use. The plan shall include:

1. Clinical and administrative continuous monitoring;

2. Problem identification, correction and prevention;

3. Accountability to the Patient and community; and

4. Opioid Treatment Program Medication usage and amount accountability.

1209. Opioid Treatment Program Guest-Dosing (II).

A. When a Patient is separated from his or her Opioid Treatment Program for an extended period, and the Patient is in the vicinity of another Licensed Opioid Treatment Program, guest-dosing may occur provided there is: (I)

1. Authorization in writing from the sending Opioid Treatment Program Physician or other Authorized Healthcare Provider; and

2. Information from the sending Opioid Treatment Program to include at least the following: Patient name, identifying information, means of identity verification, dates of guest-dosing, amount of each day's dose, number of take-home doses (if any), urinalysis history, and any other information requested by the authorizing treatment Opioid Treatment Program.

B. Records of guest-dosing shall be maintained at the Opioid Treatment Program providing the guest-dosing.

C. Guest-dose status for a Patient shall not exceed twenty-eight (28) days unless there are special circumstances, and an extension of time is agreed upon by the two (2) Opioid Treatment Programs involved.

D. A Facility desiring to administer guest dosing for Patients from neighboring states in the event of a natural disaster or emergency shall:

1. Request that the Department concur that an emergency situation exists by contacting the Department;

2. Administer the guest-dosing only upon written orders from the Facility's Opioid Treatment Program physician; and

3. Maintain documentation of the physician's rationale for the dosing protocol and information utilized to make the decision.

1210. Security of Medications (I).

A. The areas where Opioid Treatment Program stock Medications are maintained or administered shall be secured. Access to Controlled Substances, which include Opioid Treatment Program Medications, shall be limited to persons licensed or registered to order, administer, or dispense those Medications.

B. Immediately after administering, the remaining contents of the containers shall be purged to prevent the accumulation of residual Opioid Treatment Program Medications. The Opioid Treatment Program shall ensure that take-home Medications bottles are returned to the Opioid Treatment Program. All used containers, as well as take-home bottles given to Patients, shall be made inaccessible to unauthorized individuals. Used containers shall be disposed of by the Opioid Treatment Program.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1300. MEAL SERVICE

1301. General (II).

A. All Facilities that prepare food on-site shall be approved by the Department, and shall be regulated, inspected, and graded pursuant to R.61–25, Retail Food Establishments. Facilities preparing food on-site, licensed for sixteen (16) beds or more subsequent to the promulgation of this regulation shall have commercial kitchens. Existing Facilities with sixteen (16) licensed beds or more may continue to operate with equipment currently in use; however, only commercial kitchen equipment shall be used when replacements are necessary. Those Facilities with fifteen (15) beds or less shall be regulated pursuant to R.61–25 with certain exceptions in regard to equipment (may utilize domestic kitchen equipment).

B. When meals are catered to a Facility, such meals shall be obtained from a food service establishment permitted by the Department, pursuant to R.61–25 and there shall be a written executed contract with the food service establishment on file in the Facility.

C. All food to be served to Patients shall be transported, received, stored, and handled in accordance with R.61–25. Washing and sanitation of all food contact and non-food contact surfaces, equipment, and utensils shall meet the standards required by R.61–25. A handwash lavatory shall be provided in the food service area equipped with liquid soap and a hand drying provision. Hand sanitizers shall not be used in lieu of liquid soap.

D. If food is prepared at a central kitchen and delivered to separate Facilities or separate buildings and/or floors of the same Facility, provisions shall be made and approved by the Department for proper maintenance of food temperatures and a sanitary mode of transportation.

E. Food shall be prepared by methods that conserve the nutritive value, flavor, and appearance. The food shall be palatable, properly prepared, and sufficient in quantity and quality to meet the daily nutritional needs of the Patients in accordance with written dietary policies and procedures. Efforts shall be made to accommodate the religious, cultural, and ethnic preferences of each individual Patient and consider variations of eating habits, unless the orders of a Physician or other Authorized Healthcare Provider contraindicate.

1302. Food and Food Storage (II).

Residential Facilities shall maintain at least a one (1)-week supply of staple foods and a two (2)-day supply of perishable foods on the premises. Supplies shall be appropriate to meet the requirements of the menu and special diets.

1303. Meals and Services.

A. Residential Facilities shall serve a minimum of three (3) nutritionally-adequate meals in each twenty-four (24)-hour period unless otherwise directed by the Patient's Physician or other Authorized Healthcare Provider. Not more than fourteen (14) hours shall elapse between the serving of the evening meal and breakfast the following day. (II)

B. Specific times for serving meals shall be established, documented on a posted menu, and followed.

C. Suitable food and snacks shall be available and offered between meals at no additional cost to the Patients. (II)

1304. Meal Service Personnel for Residential Facilities (II).

A. The health, disease control, and cleanliness of all those engaged in food preparation and serving shall be in accordance with R.61–25.

B. Dietary services shall be organized with established lines of accountability and clearly defined job assignments for those engaged in food preparation and serving. There shall be trained Staff and/or Volunteers to supervise the preparation and serving of the proper diet to the Patients. Patients may engage in food preparation in accordance with Facility guidelines; however, trained Staff and/or Volunteers shall supervise.

1305. Menus.

A. Menus shall be planned and written at a minimum of one (1) week in advance and dated as served. The current week's menu, including routine and special diets and any substitutions or changes made, shall be readily available or posted in one (1) or more conspicuous places in a public area. All substitutions made on the master menu shall be recorded in writing.

B. If the Facility accepts Patients in need of medically-prescribed special diets, the menus for such diets shall be planned by a professionally qualified Dietitian, or shall be reviewed and approved by a Physician or other Authorized Healthcare Provider. The Facility shall maintain documentation that each of these menus has been planned by a Dietitian, a Physician, or other Authorized Healthcare Provider. At a minimum, documentation for each Patient's special diet menu shall include the signature of the Dietitian, the Physician, or other Authorized Healthcare Provider, his or her title, and the date he or she signed the menu.

C. Records of menus as served shall be maintained for at least thirty (30) days.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1400. EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1401. Disaster Preparedness (II).

A. All Residential Facilities shall develop, by contact and consultation with their county emergency preparedness agency, a written plan for actions to be taken in the event of a disaster and implement the written plan for actions at the time of need. Prior to initial licensing of a Facility by the Department, the completed plan shall be submitted to the Department for review. At the time of each License renewal, a completed form prescribed and furnished by the Department addressing specific components of the plan shall be included with each application submitted to the Department. All Staff and Volunteers shall be made familiar with this plan and instructed as to any required actions. A copy of the plan shall be available for Inspection by the Patient and/or responsible party and the Department upon request. The plan shall be reviewed and updated Annually, and as appropriate. The Facility shall conduct and document a rehearsal of the emergency and disaster evacuation plan at least Annually and shall not require Patient participation.

B. The disaster plan for Residential Facilities shall include, but not be limited to:

1. A sheltering plan to include:

a. The licensed bed capacity and average occupancy rate;

b. Name, address, and phone number of the sheltering facility(ies) to which the Patients will be relocated during a disaster; and

c. A letter of agreement signed by an authorized representative of each sheltering facility that shall include: the number of relocated Patients that can be accommodated; sleeping, feeding, and medication plans for the relocated Patients; and provisions for accommodating relocated staff. The letter shall be updated annually with the sheltering facility and whenever significant changes occur. For those facilities located in Beaufort, Berkeley, Charleston, Colleton, Dorchester, Horry, Jasper, and Georgetown counties, at least one (1) sheltering facility must be located in a county other than these counties.

2. A transportation plan to include agreements with entities for relocating Patients that addresses:

a. The number and type of vehicles required;

b. How and when the vehicles are to be obtained;

c. Who (by name or organization) will provide drivers;

d. Procedures for providing appropriate medical support during relocation;

e. The estimated time to accomplish the relocation; and

f. The primary and secondary routes to be taken to the sheltering facility.

3. A staffing plan for the relocated Patients to include:

a. How care will be provided to the relocated Patients including the number and type of Staff;

b. Plans for relocating Staff or assuring transportation to the sheltering facility; and

c. Co-signed statement by an authorized representative of the sheltering facility if staffing will be provided by the sheltering facility.

4. A written, signed, and dated statement from the county emergency preparedness agency verifying the Facility's plan was developed and reviewed through contact and consultation with the county emergency preparedness agency.

C. During any emergent event, the Facility shall provide data, Facility and evacuation status, and other requested information as determined by the Department, and at a frequency as determined by the Department.

D. Evacuation is a temporary measure in order to evacuate Patients from potentially hazardous and/or harmful circumstances and shall not exceed seven (7) calendar days. In the event evacuated Patients are unable to return to the Facility within seven (7) days due to damage to the Facility or its components, the lack of electricity and/or water, or other similar reasons, the Facility shall endeavor to assess each Patient's current condition and identify each Patient's current needs and preferences. Based on the resources available, the Facility shall implement each Patient's Discharge plan. For Patients needing assistance or support following Discharge, the Facility shall coordinate the transfer of the Patients to their responsible parties or to appropriately licensed Facilities capable of meeting the

Patients' needs. Prior to the seventh (7th) day, if the Facility determines an extension of time is needed, the Facility may request approval from the Department.

1402. Licensed Capacity During an Emergency (II).

A. In the event that the Facility temporarily provides shelter for evacuees who have been displaced due to a disaster, then for the duration of that emergency, provided the health, safety, and well-being of any Patient is not compromised, it is permissible to temporarily exceed the licensed capacity for the Facility in order to accommodate these individuals.

B. A Facility desiring to temporarily admit Patients in excess of its licensed bed capacity due to an emergency shall:

1. Request that the Department concur that an emergency situation exists by contacting the Department;
2. Determine the maximum number of Patients to be temporarily admitted;
3. Establish an anticipated date for Discharge of the temporary Patients;
4. Outline how and where the temporary Patients will be housed; and
5. Contact the county emergency preparedness agency to advise them of additional Patients.

C. The Facility shall not require the Patients temporarily admitted during the emergency situation to undergo tuberculin screening or submit to an admission history and physical examination.

D. The Facility shall notify the Department when the Patient census has returned to, or moves below, normal bed capacity by Discharge or transfer to licensed beds.

E. If the event occurs after normal business hours, the Facility shall contact the Department promptly during the next business day.

F. The Facility shall resolve in advance all other issues related to the temporary Patients (for example, Staff, Physician orders, additional food, and handling of Medications) by memorandum of agreements, internal policies and procedures, and emergency planning documents

1403. Emergency Call Numbers (II).

Emergency call data shall be posted in a conspicuous place and shall include at least the telephone numbers of fire and police departments, an ambulance service, and the poison control center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of the Staff to be notified in case of emergency, and the Physician or other Authorized Healthcare Provider on-call.

1404. Continuity of Essential Services (II).

There shall be a written plan to be implemented to assure the continuation of essential Patient supportive services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the work force resulting from inclement weather or other causes.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1500. FIRE PREVENTION

1501. Arrangements for Fire Department Response (I).

A. Each Facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire.

B. Facilities located outside of a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the Facility and a copy shall be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department.

1502. Fire Response Training (I).

A. Each Staff member and Volunteer shall receive training within twenty-four (24) hours of his or her first day of employment in the Facility, and at least Annually thereafter, addressing at a minimum, the following:

1. The Facility fire plan including evacuation routes and procedures;
2. Reporting a fire;

3. Use of the fire alarm system, if applicable;

4. Location and use of fire-fighting equipment;

5. Methods of fire containment; and

6. Specific responsibilities, tasks, or duties of each individual.

B. Documentation of the fire response training shall be signed and dated by both the individual providing the training and the individual receiving the training, and maintained in the individual's Staff record.

1503. Fire Drills (I).

A. A plan for the evacuation of Patients, Staff members, and visitors, to include evacuation routes and procedures, in case of fire or other emergencies, shall be established and posted in conspicuous public areas throughout the Facility.

B. Patients shall be made familiar with the fire plan and evacuation plan upon admission. The Facility shall maintain documentation of the review of the fire plan and evacuation plan with the Patient in the Patient's record.

C. All Patients capable of assisting in their own evacuation shall be trained in the proper actions to take in the event of a fire.

D. For Residential Facilities only:

1. Unless otherwise mandated by statute or regulation, an unannounced fire drill shall be conducted at least quarterly for all shifts. Each Staff member and Volunteer shall participate in a fire drill at least once each year. Records of drills shall be maintained at the Facility, indicating the date, time, shift, description, and evaluation of the drill, and the names of Staff and Volunteers and number of Patients directly involved in responding to the drill.

2. All Patients at the time of the fire drill shall participate in the drill. In instances when a Patient refuses to participate in a drill, efforts shall be made to encourage participation, e.g., counseling, implementation of incentives rewarding patients for participation, specific Staff-to-Patient and Volunteer-to-Patient assignments to promote Patient participation. Continued refusal may necessitate implementation of the Discharge planning process to place the Patient in a setting more appropriate to their needs and abilities.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1600. MAINTENANCE

1601. General (II).

A. The Facility shall keep all equipment and building components (for example, doors, windows, lighting fixtures, plumbing fixtures) in good repair and operating condition. The Facility shall document preventive maintenance. The Facility shall comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility. (II)

B. If applicable, a documented and implemented procedure shall be developed for calibrating Medication-dispensing instruments consistent with manufacturer's recommendations to ensure accurate dosing and tracking.

1602. Preventive Maintenance of Emergency Equipment and Supplies (II).

Each Facility shall develop and implement a written preventive maintenance program for all fire alarm, electrical, mechanical, plumbing, fire protection systems and for all equipment and supplies including, but not limited to, all Patient monitoring equipment, isolated electrical systems, conductive flooring, Patient grounding systems, and medical gas systems. Facilities shall check and/or test this equipment at intervals ensuring proper operation and state of good repair. After repairs and/or alterations to any equipment or system, the Facility shall thoroughly test the equipment or system for proper operation before returning it to service. The Facility shall maintain records for each piece of emergency equipment to indicate its history of testing and maintenance.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1700. INFECTION CONTROL AND ENVIRONMENT

1701. Staff Practices.

Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for proper disposal of toxic and hazardous substances. These preventive measures and/or practices shall be in compliance with applicable guidelines of Bloodborne Pathogens Standard of the Occupational Safety and Health Act of 1970; the Centers for Disease Control and Prevention and R.61–105, Infectious Waste Management; and other applicable federal, state, and local laws and regulations.

1702. Tuberculosis Risk Assessment and Screening (I).

A. Tuberculosis Testing. The Facility may utilize either Tuberculin skin testing or Blood Assay for Mycobacterium tuberculosis (''BAMT'') for detecting Myobacterium tuberculosis infection:

1. Tuberculin skin testing. A small dose (0.1 mil) of purified protein derivative (PPD) tuberculin is injected just beneath the surface of the skin (by the intradermal Mantoux method), and the area is examined for induration (hard, dense, raised area at the site of the TST administration) forty-eight to seventy-two (48 to 72) hours after the injection (but positive reactions can still be measurable up to a week after administering the TST). The size of the indurated area is measured with a millimeter ruler and the reading is recorded in millimeters, including zero (0) millimeters to represent no induration. Redness and/or erythema is insignificant and is not measured or recorded. Authorized Healthcare Providers are permitted to perform tuberculin skin testing and symptom screening.

2. Blood Assay for Mycobacterium tuberculosis (''BAMT''). A general term to refer to in vitro diagnostic tests that assess for the presence of tuberculosis (''TB'') infection with Myobacterium tuberculosis. This term includes, but is not limited to, IFN-γ release assays (''IGRA'').

B. The Facility shall conduct an annual tuberculosis risk assessment in accordance with the Centers for Disease Control guidelines to guide the Facility's infection control policies and procedures related to the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

C. Baseline Status.

1. The Facility shall determine the baseline status of all staff according to current Centers for Disease Control and Departmental Tuberculosis guidelines.

2. Tuberculosis Screening. All staff within three (3) months prior to Patient contact shall have a baseline two-step Tuberculin Skin Test (''TST'') or a single Blood Assay for Mycobacterium tuberculosis (''BAMT''). If a newly employed staff or volunteer has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered and read to serve as the baseline prior to Patient contact.

D. Post Exposure. After known exposure to a person with potentially infectious tuberculosis disease without use of adequate personal protection, the tuberculosis status of all staff shall be determined in a manner prescribed in the Centers for Disease Control and Department's most current tuberculosis guidelines.

E. Annual Tuberculosis Training. All staff shall receive annual training regarding tuberculosis to include risk factors and signs and symptoms of tuberculosis disease. The annual tuberculosis training shall be documented in a staff record and maintained at the Facility.

F. Serial Screening. The Facility shall follow the Centers for Disease Control and Department's most current tuberculosis guidelines related to serial screening.

1703. Tuberculosis Screening for Patients (I).

A. At baseline, Patients in Residential Facilities shall have evidence of a two-step tuberculin skin test or single Blood Assay for Mycobacterium tuberculosis. If the Patient in a Residential Facility has a documented negative tuberculin skin test (at least single-step) within the previous twelve (12) months, the Patient shall have only one (1) tuberculin skin test or single Blood Assay for Mycobacterium tuberculosis to establish a baseline status.

B. Patients in Residential Facilities shall have at least the first step within thirty (30) days prior to admission and no later than forty-eight (48) hours after admission.

C. Patients in the Opioid Treatment Program shall receive the first step of the two-step tuberculin test within seventy-two (72) hours of admission to the Facility. The second step of the two-step tuberculin skin test must be administered within the next seven to fourteen (7 to 14) days.

D. Patients with Positive Tuberculosis Results.

1. Patients with a baseline positive or newly positive test result for Mycobacterium tuberculosis infection (i.e., tuberculosis skin test or Blood Assay for Mycobacterium Tuberculosis) or documentation of treatment for latent tuberculosis infection, tuberculosis disease or signs or symptoms of tuberculosis, e.g., cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude tuberculosis disease (or evaluate an interpretable copy taken within the previous three (3) months). Routine repeat chest radiographs are not required unless symptoms or signs of TB tuberculosis disease develop or unless recommended by a Physician. These Patients will be evaluated for the need for treatment of TB tuberculosis disease or latent tuberculosis infection and will be encouraged to follow the recommendations made by a Physician with tuberculosis expertise (i.e., the Department's Tuberculosis Control program).

2. Patients who are known or suspected to have tuberculosis disease shall be transferred from the Facility if the Facility does not have an Airborne Infection Isolation room, required to undergo evaluation by a Physician, and permitted to return to the Facility only with approval by the Department's Tuberculosis Control program.

1704. Housekeeping (II).

A. The Facility and its grounds shall be neat, clean, free of vermin, and free of offensive odors.

B. Interior housekeeping shall at a minimum include:

1. Cleaning each specific area of the Facility;

2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment's purpose or use;

3. Chemicals indicated as harmful on the product label, cleaning materials and supplies shall be in locked storage areas and inaccessible to Patients; and

4. During use of chemicals indicated as harmful on the product label, cleaning materials and supplies shall be in direct possession of the Staff member and monitored at all times.

C. Exterior housekeeping shall at a minimum include:

1. Cleaning of all exterior areas, such as porches and ramps, and removal of safety impediments such as water, snow, and ice; and

2. Keeping Facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin.

1705. Infectious Waste (I).

Accumulated waste, including all contaminated sharps, dressings, pathological, and/or similar infectious waste, shall be disposed of in a manner compliant with R.61–105, Infectious Waste Management, and the OSHA Bloodborne Pathogens Standard.

1706. Pets (II).

A. Healthy animals that are free of fleas, ticks, and intestinal parasites, and have been examined by a veterinarian prior to entering the Facility, have received required inoculations, if applicable, and that present no apparent threat to the health, safety, and well-being of the Patients, shall be permitted in the Facility, provided they are sufficiently fed, and cared for, and that the pets and their housing and food containers are kept clean.

B. Pets shall not be allowed near Patients who have allergic sensitivities to pets, or for other reasons, such as Patients who do not wish to have pets near them.

C. Pets shall not be allowed in the kitchen area. Pets shall be permitted in Patient dining and activities areas only during times when food is not being served. If the dining and activities area is adjacent to a food preparation or storage area, those areas shall be effectively separated by walls and closed doors while pets are present.

1707. Clean and Soiled Linen and Clothing for Residential Facilities (II).

A. Clean Linen and Clothing.

1. A supply of clean, sanitary linen and clothing shall be available at all times;

2. In order to prevent the contamination of clean linen and clothing by dust or other airborne particles or organisms, clean linen and clothing shall be stored and transported in a sanitary manner, for example, enclosed and covered; and

3. Clean linen and clothing shall be separated from storage for other purposes.

B. Soiled Linen and Clothing.

1. Soiled linen and clothing shall not be sorted, rinsed, or washed outside of the laundry service area;

2. Provisions shall be made for collecting, transporting, and storing soiled linen and clothing;

3. Soiled linen and clothing shall be kept in enclosed, covered, and leak proof containers; and

4. Laundry operations shall not be conducted in Patient rooms, dining rooms, or in locations where food is prepared, served, or stored. Patients may sort, rinse, and handwash their own soiled, delicate, personal items, e.g., pantyhose, underwear, socks, handkerchiefs, clothing, accessories, heirloom linens, needlepoint, crocheted, or knitted pillows or pillowcases, or other similar items personally owned and cared for by, in a private bathroom or sink, provided the practice does not create a safety hazard, e.g. water on the floor.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1800. QUALITY IMPROVEMENT PROGRAM (II)

A. Facilities shall maintain a written, implemented Quality Improvement Program that provides effective self-assessment and implementation of changes designed to improve the treatment/care/services provided by the Facility.

B. The Quality Improvement Program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively accomplished;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Establish ways to measure the quality of Patient care and Staff performance, as well as the degree to which the policies and procedures are followed;

5. Analyze the appropriateness of Individual Plans of Care and the necessity of treatment/care/services rendered;

6. Analyze the effectiveness of the fire plan;

7. Analyze all incidents and accidents to include Patient deaths;

8. Analyze any infection, epidemic outbreaks, or other unusual occurrences which threaten the health, safety, or well-being of the Patients; and

9. Establish a systematic method of obtaining feedback from Patients and other interested persons, e.g., family members and peer organizations, as expressed by the level of satisfaction with treatment/care/services received.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 1900. DESIGN AND CONSTRUCTION

1901. Codes and Standards.

All Facilities shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each Patient. Facility design shall be such that all Patients have access to required services.

1902. Local and State Codes and Standards (II).

A. Facilities shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the type of Facility. No Facility shall be licensed unless the Department has assurance that responsible local zoning and building officials have approved the Facility for code compliance.

B. All Facilities shall meet the construction codes and regulations for the building and its essential equipment and systems in effect at the time the License was issued unless specifically required otherwise in writing by the Department.

C. Facilities shall ensure all additions, alterations, or renovations meet the codes, regulations, and requirements in effect at the time of the plan's approval.

D. Any Facility that closes or has its License revoked and for which application for licensure is made at the same site shall be considered a new building and shall meet the current codes, regulations, and requirements for the building and its essential equipment and systems in effect at the time of application for licensing.

1903. Submission of Plans and Specifications (II).

A. Prior to construction for new buildings, additions, major alterations or replacement to existing buildings, when a building is licensed for the first time, when a building changes License type, or a Facility increases occupant load/licensed capacity, plans and specifications shall be submitted to the Department for review, unless otherwise agreed to with the Department. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. These submissions shall be made in at least three (3) stages: schematic, design development, and final. All plans shall be drawn to scale with the title, stage of submission, and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a construction plan approval has been received from the Department. During construction the owner and/or Licensee shall employ a registered architect and/or engineer for supervision and Inspections.

B. The Facility shall submit plans and specifications to the Department for review and approval for projects that have an effect on:

1. The function of a space;
2. The accessibility to or of an area;
3. The structural integrity of the Facility;
4. The active and/or passive fire safety systems;
5. Doors;
6. Walls;
7. Ceiling system assemblies;
8. Exit corridors;
9. Life safety systems; or
10. That increase the occupant load or capacity of the Facility.

C. Cosmetic changes utilizing paint, wall covering, floor covering, etc., that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications, kept on file at the Facility, and made available to the Department.

D. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review, and re-approval from the Department.

1904. Construction Inspections.

Construction work that violates applicable codes or standards shall be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction without a proper permit shall not be inspected by the Department.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2000. FIRE PROTECTION, PREVENTION, AND LIFE SAFETY (I)

A. Facilities with six (6) or more licensed Residential beds shall have a partial, manual, automatic, supervised fire alarm system. The Facility shall arrange the system to transmit an alarm automatically to a third party. The alarm system shall notify by audible and visual alarm all areas and floors of the

building. The alarm system shall shut down central recirculation systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. For Residential Facilities only, all fire, smoke, heat, sprinkler flow, and manual fire alarming devices shall be connected to and activate the main fire alarm system when activated.

C. The fire-resistive ratings for the various structural components shall comply with the applicable code(s) in Section 1900. Fire-resistive ratings of various materials and assemblies not specifically listed in the codes can be found in publications of recognized testing agencies such as Underwriters Laboratories - Building Materials List and Underwriters Laboratories - Fire Resistance Directory.

D. The Facility shall not have single and multi-station smoke alarms.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2100. Reserved.

HISTORY: Reserved by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2200. Reserved.

HISTORY: Reserved by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2300. Reserved.

HISTORY: Reserved by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2400. ELECTRICAL

2401. Receptacles (II).

A. Patient Room. Each Patient room shall have duplex grounding type receptacles located to include one (1) at the head of each bed.

B. Corridors. Duplex receptacles for general use shall be installed approximately fifty (50) feet apart in all corridors and within twenty-five (25) feet of the ends of corridors.

2402. Ground Fault Protection (I).

A. Ground fault circuit-interrupter protection shall be provided for all outside receptacles and bathrooms.

B. The Facility shall provide ground fault circuit-interrupter protection for any receptacles within six (6) feet of a sink or any other wet location. If the sink is an integral part of the metal splashboard grounded by the sink, the entire metal area is considered part of the wet location.

2403. Exit Signs (I).

A. In Facilities licensed for six (6) or more beds, required exits and ways to access thereto shall be identified by electrically-illuminated exit signs.

B. Changes in egress direction shall be marked with exit signs with directional arrows.

C. Exit signs in corridors shall be provided to indicate two (2) directions of exit.

2404. Emergency Electric Service (I).

Emergency electric services shall be provided as follows:

A. Exit lights, if required;

B. Exit access corridor lighting;

C. Illumination of means of egress; and

D. Fire detection and alarm system, if required.

2405. Emergency Generator Service.

A. Residential Facilities shall have an emergency generator and shall provide certification that construction and installation of emergency generator service complies with requirements of all adopted state, federal, or local codes, ordinances, and regulations.

B. Residential Facilities shall have an emergency generator that provides emergency electrical service during interruption of the normal electrical service and shall be provided to the distribution system as follows:

1. Exit lights and exit directional signs;

2. Exit access corridor lighting;

3. Lighting of means of egress and Staff work areas;

4. Fire detection and alarm systems;

5. In Patient care areas;

6. Signal system;

7. Equipment necessary for maintaining telephone service;

8. Elevator service that will reach every Patient floor when rooms are located on other than the ground floor;

9. Fire pump (if applicable);

10. Equipment for heating and cooling Patient rooms;

11. Public restrooms;

12. Essential mechanical equipment rooms;

13. Battery-operated lighting and a receptacle in the vicinity of the emergency generator;

14. Alarm systems, water flow alarm devices, and alarms required for medical gas systems; and

15. Patient records when solely electronically based.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2500. Reserved.

HISTORY: Reserved by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2600. PHYSICAL PLANT

2601. Facility Accommodations and Floor Area (II).

A. Residential Facilities shall provide sufficient living arrangements for all Patients, including quiet reading, study, relaxation, entertainment, or recreation.

B. Residential Facilities shall meet minimum square footage requirements as follows: (II)

1. Twenty (20) square feet per licensed bed of living and recreational areas combined, excluding bedrooms, halls, kitchens, dining rooms, bathrooms, and rooms not available to the Patients. In Facilities for parents with children, there shall be at least twenty (20) square feet per licensed bed and ten (10) square feet per child of living and recreational areas together.

2. Fifteen (15) square feet of floor space in the dining area per licensed bed. In Facilities for parents with children, dining space shall accommodate fifteen (15) square feet per licensed bed and seven and a half (7.5) square feet per child.

C. Residential Facilities shall not require Patients to ambulate from one site to another outside the building and shall not impede Patients from ambulating from one site to another due to the presence of physical barriers.

D. Residential Facilities shall make accommodations available to meet group needs of Patients and their visitors.

E. Residential Facilities shall ensure visual and auditory privacy between Patients and Staff and Volunteers.

2602. Design (I).

Facilities shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each Patient. Facility design shall be such that all Patients have access to required services. There shall be two hundred (200) gross square feet per licensed bed in Residential Facilities ten (10) beds or less, and an additional one hundred (100) gross square feet per licensed bed for each licensed bed over ten (10).

2603. Furnishings and Equipment (I).

A. Facilities shall ensure the physical plant is free of fire hazards and impediments to fire prevention.

B. Facilities shall not have any portable electric or unvented fuel heaters.

C. Facilities shall ensure that fireplaces and fossil-fuel stoves have partitions, screens, or other means to prevent burns. Facilities shall ensure that fireplaces are vented to the outside and shall prohibit "unvented" type gas logs. Facilities shall ensure that gas fireplaces have a remote gas shutoff within the room but not inside the fireplace.

2604. Exits (I).

A. If exit doors and cross-corridor doors are locked, the requirements under Special Locking Arrangements shall be met as applicable to the code listed in Section 1900.

B. Facilities shall maintain halls, corridors, and all other means of egress from the building free of obstructions.

C. Facilities shall not assign Patients needing physical or verbal assistance to exit the building to rooms located above or below the floor of exit discharge.

D. Facilities shall ensure that each Patient room opens directly to an approved exit access corridor without passage through another occupied space or has an approved exit directly to the outside at grade level and accessible to a public space free of encumbrances. When two (2) Patient rooms share a common "sitting" area, the "sitting" area shall open onto the exit access corridor.

2605. Water Supply and Hygiene (II).

Facilities shall ensure that Patient and Staff handwashing lavatories, and Patient showers and tubs are supplied with hot and cold water at all times.

2606. Temperature Control (I).

A. Facilities shall ensure that plumbing fixtures accessible to Patients and requiring hot water to have a water supply that is thermostatically controlled to a temperature of at least one hundred (100) degrees Fahrenheit and not to exceed one hundred and twenty (120) degrees Fahrenheit at the fixture.

B. Residential Facilities shall ensure that water heaters provide at least six (6) gallons of water per hour per bed at the above temperature range. (II)

C. Hot water supplied to the kitchen equipment/utensil washing sink shall be supplied at one hundred and twenty (120) degrees Fahrenheit provided all kitchen equipment/utensils are chemically sanitized. For those Facilities sanitizing with hot water, the sanitizing compartment of the kitchen equipment and utensil washing sink shall be capable of maintaining the water at a temperature of at least one hundred and seventy one (171) degrees Fahrenheit.

D. Hot water provided for washing linen and clothing shall not be less than one hundred and sixty (160) degrees Fahrenheit. Should chlorine additives or other chemicals which contribute to the margin of safety in disinfecting linen/clothing be a part of the washing cycle, the minimum hot water temperature shall not be less than one hundred and ten (110) degrees Fahrenheit, provided hot air drying is used. (II)

2607. Cross-connections (I).

Facilities shall ensure that there are no cross-connections in plumbing between safe and potentially unsafe water supplies. Facilities shall ensure water is delivered at least two (2) delivery pipe diameters above the rim or points of overflow to each fixture, equipment, and service unless protected against back-siphonage by approved vacuum breakers or other approved back-flow preventers. Facilities shall ensure that all faucets and fixtures which may be attached to a hose have an approved vacuum breaker or other approved back-flow preventer.

2608. Wastewater Systems (I).

A. Residential Facilities shall ensure the wastewater system for commercial kitchens is in accordance with R.61–25, Retail Food Establishments.

B. Facilities shall dispose of liquid waste in a wastewater system approved by the local authority.

2609. Electric Wiring (I).

Facilities shall ensure that a licensed electrician, registered engineer, or certified building inspector inspects the electric wiring at least annually.

2610. Panelboards (II).

Facilities shall label the panelboard directory to conform to the actual room numbers or designations and shall maintain clear access to the panelboard.

2611. Lighting.

A. Facilities shall maintain lighting in spaces occupied by persons, machinery, and equipment within buildings, approaches to buildings, and parking lots. (II)

B. Facilities shall provide artificial light with sufficient illumination for reading, observation, and activities.

C. Residential Facilities shall maintain general lighting in all parts of Patients' rooms, and shall provide at least one (1) light fixture for night lighting in each Patient room. Residential Facilities shall provide a reading light to each Patient.

D. Facilities shall maintain lighted hallways, stairs, and all other means of egress at all times.

2612. Heating, Ventilation, and Air Conditioning (II).

A. Facilities shall ensure that a certified or licensed technician inspects the heating, ventilation, and air conditioning system at least annually.

B. Facilities shall maintain a temperature between seventy-two (72) and seventy-eight (78) degrees Fahrenheit in Patient areas.

C. Facilities shall ensure that heating, ventilation, and air conditioning supplies and return grills are installed at least three (3) feet away from a smoke detector. (I)

D. Facilities shall ensure that heating, ventilation, and air conditioning grills are not installed in the floors.

E. Facilities shall ensure that intake air ducts are filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. Facilities shall ensure discharge from the heating, ventilation, and air conditioning system does not irritate Patients, Staff, and Volunteers.

F. Facilities shall have operable windows or approved mechanical ventilation in every bathroom and restroom.

G. Facilities shall ensure all kitchen areas are ventilated to prevent excessive heat, steam, condensation, vapors, smoke, and fumes.

2613. Patient Rooms.

A. Residential Facilities shall provide the following equipment in each Patient room for each Patient:

1. A comfortable single bed having a mattress with moisture-proof cover, sheets, blankets, pillow and pillowcases. Roll-away type beds, cots, bunkbeds, and folding beds are not permitted. Facilities are permitted to remove a Patient bed and place the mattress on a platform or pallet, or utilize a recliner, upon approval by the Physician or other Authorized Healthcare Provider and documentation is provided in the Individual Plan of Care. (II)

2. A closet or wardrobe, a bureau consisting of at least three (3) drawers, and a compartmentalized bedside table or nightstand to adequately accommodate each Patient's personal clothing, belongings, and toilet articles. Facilities are permitted to utilize built-in storage.

3. A comfortable chair for each Patient occupying the room. If the available square footage of the Patient room will not accommodate a chair for each Patient or if the provision of multiple chairs impedes Patient ability to freely and safely move about within their room, Facilities shall provide at least one (1) chair and make additional chairs available for temporary use in the Patient's room for visitors.

B. Facilities that use hospital-type beds shall maintain at least two (2) lockable casters on each bed, located either diagonally or on the same side of the bed.

C. Facilities shall not place beds in corridors, solaria, or other locations not designated as Patient room areas. (I)

D. Facilities shall ensure Patient rooms have a maximum of three (3) beds. Facilities with mothers with children shall ensure Patient rooms have a maximum of one (1) licensed bed and two (2) cribs or beds. (II)

E. Facilities shall not have any Patient rooms in a basement.

F. Facilities shall not provide access to a Patient room through another Patient room, toilet, bathroom or kitchen.

G. Facilities shall provide bed pans, urinals, hot water bottles, and any other equipment necessary to meet Patient needs. Facilities are permitted to have portable toilets in Patient rooms only at night or in case of temporary illness, and shall keep them stored at all other times. Facilities are permitted to permanently position a portable toilet at a Patient's bedside if the toilet is sanitary and the Patient room is private and of a sufficient size. (II)

H. Facilities are permitted to utilize side rails when required for safety and when ordered by a Physician or other Authorized Healthcare Provider. (II)

I. Facilities shall ensure privacy when personal care is being given to a Patient in a semi-private room.

J. Facilities shall consider Patient compatibility in the assignment of rooms for which there is multiple occupancy.

K. Facilities shall have at least one (1) private room available in the Facility in order to provide assistance in addressing Patient compatibility issues, Patient preferences, and accommodations for Patients with communicable disease.

2614. Patient Room Floor Area.

A. Except for Residential Facilities of five (5) beds or less, each Patient room is considered a tenant space and shall be enclosed by one (1)-hour fire-resistive construction with a twenty (20)-minute fire-rated door, opening onto an exit access corridor. (I)

B. Each Patient room shall be an outside room with an outside window or door for exit in case of emergency. This window or door may not open onto a common screened porch. (I)

C. The Patient room floor area is a usable or net area and does not include wardrobes (built-in or freestanding), closets, or the entry alcove to the room. The following allowance of floor space shall be as a minimum: (II)

1. Rooms for only one (1) Patient: one hundred (100) square feet;

2. Rooms for more than one (1) Patient: eighty (80) square feet per Patient.

3. In Facilities for mothers with children, rooms for Patient and child: eighty (80) square feet per licensed bed and forty (40) square feet per child with a maximum of two (2) children per Patient. When a bed is required in lieu of a crib for a child, the square footage shall be fifty (50) square feet per child.

D. Facilities shall maintain at least three (3) feet between beds. (II)

2615. Bathrooms and Restrooms (II).

A. Privacy shall be provided at toilets, urinals, bathtubs, and showers.

B. An adequate supply of toilet tissue shall be maintained in each bathroom.

C. There shall be at least one (1) handwash lavatory adjacent to each toilet. Liquid soap shall be provided in public restrooms and bathrooms used by more than one (1) Patient. Communal use of bar soap is prohibited. A sanitary individualized method of drying hands shall be available at each lavatory.

D. Easily cleanable receptacles shall be provided for waste materials. Such receptacles in toilet rooms for women shall be covered. The Facility shall ensure receptacles are non-combustible or fire resistant as required by building codes reference in Section 1900.

E. All bathroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surfaces to the highest level of splash.

F. There shall be a mirror above each bathroom lavatory for Patients' grooming.

G. In Residential Facilities:

1. Facilities shall provide an ample number of toilets to serve the needs of the Patients Staff members, Volunteers, and the public. Facilities shall provide Patients with a minimum of one (1) toilet for each six (6) licensed beds or fraction thereof.

2. All bathtubs, toilets, and showers used by Patients shall have approved grab bars securely fastened in a usable fashion.

3. There shall be one (1) bathtub or shower for each eight (8) beds or fraction thereof.

4. Separate bathrooms shall be provided for Staff members, Volunteers, and the public.

5. Toilet facilities shall be at or adjacent to the kitchen for kitchen employees.

6. Soap, bath towels, and washcloths shall be provided to each Patient as needed. Bath linens assigned to specific Patients may not be stored in centrally-located bathrooms. Provisions shall be made for each Patient to properly keep their bath linens in their room, such as, on a towel hook or bar designated for each Patient occupying that room, or bath linens to meet Patient needs shall be distributed as needed, and collected after use and stored properly, per Section 1707.

H. Facilities shall have bathrooms and restrooms equipped for handicapped persons as required by building codes referenced in Section 1900.

2617. Patient Care Unit and Station for Medical Withdrawal Management Programs (II).

A. Each Patient care unit shall have a Patient care station.

B. A Patient care unit shall contain not more than forty-four (44) licensed beds; and the Patient care station shall not be more than one hundred fifty (150) feet from a Patient room, and shall be located and arranged to permit visual observation of the unit corridor(s).

C. Each Patient care station shall contain separate spaces for the storage of wheelchairs and general supplies/equipment for that station.

D. There shall be at, or near each Patient care station, a separate medicine preparation room with a cabinet with one or more locked sections for Controlled Substances, work space for preparation of medicine, and a sink. As an alternative, a medicine preparation area with counter, cabinet space, and a sink shall be required on those units where there is:

1. A unit dose system in which final Medication preparation is not performed on the Patient care station; or

2. A twenty-four (24) hour pharmacy on the premises; or

3. Procedures that preclude Medication preparation at the Patient care station.

2618. Doors (II).

A. All Patient rooms and bathrooms and restrooms shall have opaque doors for the purpose of privacy.

B. All glass doors, including sliding or patio type doors shall have a contrasting or other indicator that causes the glass to be observable.

C. Bathroom and restroom door widths shall be not less than thirty-six (36) inches.

D. Doors to Patient occupied rooms shall be at least thirty-six (36) inches wide.

E. Doors that have locks shall be unlockable and openable with one action.

F. If Patient room doors are lockable, there shall be provisions for emergency entry. There shall not be locks that cannot be unlocked and operated from inside the room.

G. All Patient room doors shall be solid-core.

2619. Elevators (II).

Facilities shall ensure that a certified elevator inspector inspects and tests elevators upon installation prior to first use and annually thereafter.

2620. Screens (II).

Facilities shall equip windows, doors, and openings intended for ventilation with insect screens.

2621. Janitor's Closet (II).

Residential Facilities shall maintain a lockable janitor's closet equipped with a mop sink or receptor and space for the storage of supplies and equipment.

2622. Storage Areas.

A. Facilities shall provide adequate general storage areas for Patient and Staff and Volunteer belongings, equipment, and supplies.

B. Facilities shall ensure that areas used for storage of combustible materials and storage areas exceeding one hundred (100) square feet in area are equipped with a National Fire Protection Association-approved automatic sprinkler system. (I)

C. In storage areas provided with a sprinkler system, a minimum vertical distance of eighteen (18) inches shall be maintained between the top of stored items and the sprinkler heads. The tops of storage cabinets and shelves attached to or built into the perimeter walls may be closer than eighteen (18) inches below the sprinkler heads. In non-sprinklered storage areas, there shall be at least twenty-four (24) inches of space from the ceiling. (I)

D. All ceilings, floor assemblies, and walls enclosing storage areas of one hundred (100) square feet or greater shall be of not less than one (1) hour fire-resistive construction with three-fourths (3/4) hour fire-rated door(s) and closer(s). (I)

E. Facilities shall ensure that storage buildings on the premises meet the applicable code listed in Section 1900 regarding distance from the licensed building. An appropriate controlled environment shall be provided if necessary for storage of items requiring such an environment.

F. Facilities shall ensure that items stored in mechanical rooms are located away from mechanical equipment and are not a type of storage that might create a fire or other hazard. (I)

G. Facilities shall not store supplies and equipment directly on the floor. Facilities shall not store supplies and equipment susceptible to water damage and contamination under sinks or other areas with a propensity for water leakage.

H. Facilities licensed for more than fifteen (15) beds shall maintain a soiled linen storage room designed, enclosed, and used solely for that purpose and equipped with mechanical exhaust directly to the outside.

2623. Telephone Service.

A. Facilities shall provide at least one (1) telephone on each floor of the Facility with at least one (1) active main or fixed-line telephone service available.

B. Facilities shall provide at least one (1) telephone on each floor for Staff members and Volunteers to conduct routine business of the Facility and to summon assistance in the event of an emergency. The Facility shall ensure Patients have privacy when using the telephone.

2624. Location.

A. Facilities shall ensure that roads serving the Facility are passable at all times.

B. Facilities shall provide parking space to meet the needs of Patients, Staff, Volunteers, and visitors.

C. Facilities shall maintain adequate access to and around the building for firefighting equipment. (I)

D. Facilities providing an Opioid Treatment Program shall not operate within five hundred (500) feet of:

1. The property line of a church;
2. The property line of a public or private elementary or secondary school;
3. A boundary of any Residential district;
4. A public park adjacent to any Residential district; or
5. The property line of a lot devoted to Residential use.

2625. Outdoor Area.

A. Facilities shall ensure outdoor areas where unsafe, unprotected physical hazards exist are enclosed by a fence or a natural barrier of a size, shape, and density that effectively impedes travel to the hazardous area. (I)

B. Facilities shall protect mechanical and equipment rooms that open to the outside of the Facility from unauthorized individuals.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2700. SEVERABILITY

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, and they shall remain in effect, as if such invalid portions were not originally a part of this regulation.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

SECTION 2800. GENERAL

Conditions that have not been addressed in this regulation shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Amended by SCSR 44–6 Doc. No. 4954, eff June 26, 2020.

61–94. WIC VENDORS.

(Statutory Authority: S.C. Code Section 43–5–930, 1976, as amended.)

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SECTION 101. Definitions.

As used in these regulations, the following terms shall have the meaning specified:

(A) DHEC. The South Carolina Department of Health and Environmental Control.

(B) State Agency. The South Carolina Department of Health and Environmental Control.

(C) WIC Program. The Special Supplemental Nutrition Program for Women, Infants and Children.

(D) State WIC Program. Division of WIC Services. Bureau of Maternal and Child Health, South Carolina Department of Health and Environmental Control.

(E) Food Instrument. The document which is used by a participant to obtain supplemental foods.

(F) WIC Vendor. Any store or pharmacy approved for participation which has a valid, current WIC Vendor Agreement on file at the State WIC Program Office and continues to meet the minimum criteria for participation as listed in the agreement.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 201. Approval of Vendors.

(A) Only vendors authorized by the State Agency may redeem food instruments or otherwise provide supplemental foods to participants.

(B) To be authorized for participation as a WIC Vendor, a vendor must:

1. Request, in writing or by phone, a WIC Vendor application packet.

2. Submit a completed application packet to the State WIC Program Office, including the WIC Vendor Application, WIC Price Survey, Vendor Agreement, and an IRS W-9, Request for Taxpayer Identification and Certification form.

3. Be authorized to participate in the Supplemental Nutrition Assistance Program (SNAP). (Pharmacies are exempt from this requirement.)

4. Not be employed by the WIC program nor have a spouse, child, parent, or sibling who is employed by the WIC program serving the county in which the vendor applicant conducts business. The vendor applicant also shall not have an employee who handles, transacts deposits, or stores WIC food instruments who is employed by, or has a spouse, child, or parent who is employed by the WIC Program serving the county in which the vendor applicant conducts business.

5. Pass a pre-approval visit completed by the State WIC Program Office.

6. Inform and train cashiers and other staff on program requirements.

7. Ensure employees receive instruction regarding the WIC Program policies, procedures and requirements.

8. Maintain the minimum stock of WIC foods as required by the Vendor Agreement.

9. Comply with at least one established definition for store type within the four (4) Regions. Type 1 Chain, Type 2 Franchise, Type 3 Commissary, Type 4 Independent/Convenience and Type 5 Pharmacy.

10. Operate the store at a single, fixed location (no mobile/home delivery stores).

11. Purchase infant formula only from a state approved wholesaler, distributor or supplier.

12. Be located in South Carolina.

13. Must be open for business at least six (6) days a week for a minimum of eight (8) consecutive hours a day between the hours of 8 am - 10 pm.

14. Have no convictions or civil judgments within the last six (6) years that indicate a lack of business integrity on the part of the current owners, officers, or managers. Such activities include, but are not limited to: fraud, antitrust violations, embezzlement, theft, forgery, bribery, falsification of records, making false statements, receiving stolen property, making false claims, or obstruction of justice.

15. Provide to WIC participants only those foods authorized by the State WIC Program and in the exact quantities prescribed.

The following is a list of acceptable foods:

i) Infant formula must be iron-fortified, supply approximately twenty (20) kilocalories per fluid ounce, and not require the addition of any ingredient other than water.

ii) Infant cereal which contains a minimum of 45 milligrams of iron per 100 grams of dry cereal and contains no other ingredients, such as fruit, formula or DHA. No organic infant cereal.

iii) Infant juice which contains a minimum of 30 milligrams of Vitamin C per 100 milliliters of single strength or reconstituted frozen juice concentrate. Juice must be pasteurized, 100% unsweetened fruit or vegetable juice. No calcium-fortified or organic juice.

iv) Pasteurized fluid whole, fat free, lowfat or reduced fat milk which is unflavored and contains 400 international units of Vitamin D and 2000 international units of Vitamin A per fluid quart; or

v) Nonfat dry milk solids may be substituted on a reconstituted quart basis and must contain 400 international units of Vitamin D and 2000 international units of Vitamin A per reconstituted quart; or

vi) Quarts and 1/2 gallons of lactose-free milk (whole, reduced fat, low fat and fat free).

vii) Domestic cheese made from 100% pasteurized milk (American, Monterey Jack, Cheddar, & Mozzarella). Block style or sliced, lowfat, reduced fat, low cholesterol and/or low sodium are allowed.

viii) Cereal (hot or cold) which contains a minimum of 28 milligrams of iron per 100 grams of dry cereal and not more than 21.2 grams of sucrose and other sugars per 100 grams of cereal (no more than 6 grams of sugar per ounce). Half of the cereals authorized must have whole grain as the primary ingredient by weight and meet labeling requirements.

ix) Eggs, Grade A large, white only.

x) Peanut butter, with no added flavorings.

xi) Mature legumes or beans.

xii) Canned tuna or pink salmon packed in water or oil.

xiii) Infant fruits and vegetables include any variety of single ingredient, commercial infant food fruits or vegetables without added sugars, starches, or salt. No organic infant foods or foods with added DHA.

xiv) Infant meats include any variety of commercial infant food having meat or poultry as a single major ingredient, with added broth or gravy, and no added sugars, salt or DHA.

xv) Whole Grains include whole wheat bread, whole grain bread, brown rice, whole wheat or soft corn tortillas. Whole grain must be the primary ingredient by weight in all whole grain products and meet labeling requirements for making a health claim as a ''whole grain food with moderate fat content''.

(C) To retain authorization for participation a vendor must:

1. Renew the Vendor Agreement with the State WIC Program by the established renewal date.

2. Abide by the terms of the Agreement in effect.

3. Have prices which are competitive, based on the WIC Program definition, with similar type stores' prices.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 301. Redemption of Food Instruments.

In providing supplemental foods to participants, the Vendor shall:

(A) Only provide the supplemental foods as specified in the WIC Food Guide and only the types, sizes and quantities specified on the food instrument.

(B) Accept food instruments only from individuals who present a valid South Carolina WIC Program ID Card listing them as authorized to redeem the food instruments and receive the supplemental foods.

(C) Provide the supplemental foods at the current price or less than the current price charged to other customers, as indicated on individual food items or shelf labels indicating the price of the items.

(D) Accept food instruments from participants only within the allowed time period, as listed on each food instrument.

(E) Accept manual food instruments only if they have been stamped with a WIC Program stamp.

(F) Refuse to accept any food instruments on which the valid dates or food prescriptions have been altered in any way.

(G) Enter the date of purchase and total purchase amount (less tax) for the supplemental foods on the food instruments prior to obtaining the signature of the person authorized to receive the foods.

(H) Obtain the signature of the person receiving the supplemental foods and check that signature against the signature on the WIC Program ID Card.

(I) Offer WIC participants the same courtesies as other customers, including but not limited to:

1. Providing promotional specials such as reduced prices on items as advertised.

2. Allowing use of any open check-out line except for those indicated as ''cash only''.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 401. Submitting Food Instruments for Payment.

(A) The vendor must deposit food instruments into their local retail bank within thirty (30) days of the ''Void after Date''.

(B) Each food instrument must be stamped with the official WIC vendor stamp provided to the vendor by the State WIC Program Office prior to depositing.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 501. Payment of Food Instruments.

(A) The State Agency may reject food instruments improperly redeemed and may request reimbursement for payments already made for improperly redeemed food instruments. Reasons food instruments may be rejected include, but are not limited to:

1. Food instruments accepted prior to or after the valid dates.

2. Food instruments on which the date of purchase has not been entered.

3. Food instruments on which the purchase amount has not been entered.

4. Manual food instruments on which the local WIC Program stamp has not been applied.

5. Food instruments on which a valid WIC vendor stamp has not been applied.

6. Food instruments on which the serial number is illegible.

7. Food instruments on which a valid participant signature has not been applied.

8. Food instruments on which the valid dates or food prescription/quantities have been altered.

9. Food instruments accepted by a vendor which is not an authorized vendor as stipulated in Section 201 of these regulations.

10. Food instruments deposited more than thirty days (30) after the "Void after" date.

(B) The State WIC Program may delay payment or establish a claim if the Program determines the vendor has committed a violation that affects the payment to the vendor. The State WIC Program may offset any claim against current and subsequent amounts to be paid to the vendor. The vendor is responsible for any claim assessed by the State WIC Program.

(C) The State WIC Program, at its discretion, may allow the payment of a civil monetary penalty, in lieu of disqualification, as a result of the Program abuse.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 601. Correction of Rejected Food Instruments.

(A) Vendors shall have the opportunity to correct food instruments which are rejected for errors.

(B) Vendors must justify, correct or provide adequate proof that food instruments were accepted according to the procedures listed in Section 401 of these regulations.

(C) The State WIC Program has the authority to refuse payment for food instruments on which proper corrections have not been made or with which adequate proof of proper acceptance has not been received.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 701. Monitoring of Vendors.

(A) All vendors participating in the WIC Program agree to allow periodic monitoring of their business to assess compliance with Program requirements.

(B) During a monitoring visit, the vendor shall allow access to all food instruments accepted and located in the store at the time of the monitoring visit.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 801. Disqualifications and Sanctions.

(A) The State WIC Program may disqualify a vendor for Program abuse, failure to meet the requirements of the WIC Vendor Agreement, or other just causes.

(B) Mandatory Vendor Sanctions.

1. One (1) Year Disqualification. A vendor shall be disqualified from the WIC Program for a period of one (1) year for:

(a) A pattern of providing unauthorized food items in exchange for WIC food instruments, including charging for supplemental food provided in excess of those listed on the WIC check;

(b) A pattern of charging above the maximum allowable price for WIC items;

(c) Intentionally providing false information on the WIC Vendor Application;

(d) Intentionally providing false information on the Vendor Price Survey;

(e) Non-payment of any claim for overcharges to the WIC Program;

(f) Failure to allow monitoring of stores by a WIC Investigator or failure to provide WIC food instruments for review when requested by the WIC Investigator;

(g) Forging a signature on WIC food instruments;

(h) Failure to submit a WIC Vendor Price Survey; or

(i) Failure to attend WIC Vendor Training.

2. Three (3) Year Disqualification. A vendor shall be disqualified from the WIC Program for three (3) years for:

(a) One incident of the sale of alcoholic beverage or tobacco products in exchange for WIC food instruments;

(b) A pattern of claiming reimbursement for the sale of a specific supplemental food item which exceeds the store's documented inventory of that supplemental food item for a specific period of time, failing to supply store records, or failing to allow an audit of such records by the State WIC Program;

(c) A pattern of charging WIC participants more for supplemental food than non-WIC customers or charging participants more than the current shelf price;

(d) A pattern of receiving, transacting and/or redeeming WIC food instruments outside of authorized channels, including the use of an unauthorized vendor and/or an unauthorized person;

(e) A pattern of charging for supplemental food not received by the WIC participant; or

(f) A pattern of providing credit or non-food items, other than alcoholic beverages, tobacco products, cash, firearms, ammunition, explosives or controlled substances in exchange for WIC food instruments.

3. Six (6) Year Disqualification. A vendor shall be disqualified from the WIC Program for six (6) years for:

(a) One incident of buying or selling WIC food instruments for cash (trafficking);

(b) One incident of buying or selling firearms, ammunition, explosives or controlled substances as defined in 21 U.S.C. 802 in exchange for WIC food instruments.

4. Permanent Disqualification. A vendor shall be permanently disqualified from the WIC Program for any conviction of trafficking (buying or selling WIC food instruments for cash) or selling firearms, ammunition, explosives or controlled substances in exchange for a WIC food instrument. A vendor is not entitled to receive any compensation for revenues lost as a result of such violation.

(C) A vendor who has been disqualified from SNAP shall also be disqualified from the WIC Program. This disqualification shall be the same length of time as SNAP disqualification, and may begin at a later date than the SNAP disqualification. This disqualification shall not be subject to administrative or judicial review under the WIC Program.

(D) Second Mandatory Sanction. When a vendor, who has been sanctioned for violating any of the provisions listed in this section, receives a sanction for a second violation of these provisions, the second sanction shall be double the amount of the first.

(E) Third or Subsequent Mandatory Sanctions. When a vendor, who has been assessed two or more sanctions for violation of any of the provisions listed in this section, receives a third or subsequent sanction for a violation of these provisions, the third and all subsequent sanctions shall be double the amount of the immediately preceding sanction.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 901. Program Violations.

Each violation of program regulations has a set point value and a specific time period during which the points will remain on a vendor's record. If a vendor accumulates fifteen (15) or more violation points, the store will be disqualified from the WIC Program. The period of disqualification is determined by the nature of the violation(s), the number of violations and past disqualifications.

1. The following violations carry a point value of 8 and remain on a vendor's record for 18 months:

(a) Contacting WIC participants in an attempt to recoup funds for instruments not paid by the Program.

(b) Not providing "promotional specials" to WIC participants or not accepting cents-off coupons or store discount cards from WIC participants to reduce the amount charged to the program.

(c) Issuing "RAIN" checks.

(d) Requiring WIC participants to use special check-out lanes, not showing WIC participants the same courtesies as other customers, or engaging in any act of discrimination involving a WIC participant.

(e) Knowingly entering false information on food instruments.

(f) Requiring participants to make a cash purchase to redeem food instruments.

(g) Failure to stock between 4–8 food items as listed in the Vendor Agreement.

2. The following violations carry a point value of 5 and remain on a vendor's record for one (1) year:

(a) Allowing substitution for foods listed on the food instrument.

(b) Failure to stock between 1–3 food items as listed in the Vendor Agreement.

(c) Requiring participants to purchase a specific brand of WIC approved foods when more than one brand is available.

(d) Using a WIC stamp other than the one issued by the State WIC Program.

(e) Failure to properly redeem food instruments including but not limited to: not asking for I.D. cards, not completing date and purchase price on food instrument prior to obtaining participant's signature.

(f) Not marking WIC items with price labels or shelf tags.

(g) Collecting sales tax on WIC Purchases.

(h) Stocking WIC approved food outside of the manufacturer's expiration date.

(i) Providing (selling or giving) incentive items to WIC participants.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

SECTION 1001. Administrative Appeals.

All vendors have the opportunity to request a fair hearing (administrative review) regarding certain adverse actions taken by the State Agency. The vendor must provide the State Agency with a written fair hearing request within fifteen days (15) of the receipt of the notice of the adverse action. The written request must list the actions with which the vendor disagrees, as well as reasons the vendor disagrees with these actions. If the vendor does not request a hearing within the fifteen (15) day period following notification, the State Agency's decision becomes final.

If a timely request of final review is filed with the DHEC Clerk of the Board, the Clerk will provide additional information regarding review procedures. If the DHEC Board declines, in writing, to schedule a final review conference, the State Agency's decision becomes final and the vendor may request a contested case hearing before the Administrative Law Court within thirty (30) calendar days after notice is mailed informing the vendor that the Board declined to hold a final review conference.

HISTORY: Amended by State Register Volume 41, Issue No. 5, Doc. No. 4671, eff May 26, 2017.

61–95. Medicaid Nursing Home Permits.

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SECTION 101. DEFINITIONS.

For the purpose of these Regulations, the following definitions shall apply:

A. Department

"Department" means the Department of Health and Environmental Control.

B. Medicaid Nursing Home Permit

"Medicaid nursing home permit" means a permit issued in accordance with these regulations.

C. Medicaid-Participating Nursing Home Bed

"Medicaid-participating nursing home bed" means those nursing home beds certified for Medicaid (Title XIX) reimbursement, for which the nursing home has a Certificate of Need or grandfathered exemption for Title XIX participation.

D. Medicaid Patient

"Medicaid patient" means a person who is eligible for Medicaid (Title XIX) sponsored long-term care services.

E. Medicaid Patient Day

"Medicaid patient day" means a day of nursing home care for which a nursing home receives Medicaid reimbursement.

F. Medical Facilities Plan

The "Medical Facilities Plan" contains projections of nursing home bed need and sets priorities for the allocation of Medicaid beds; it is published annually by the Department and approved by the Board of Health and Environmental Control.

G. Nursing Home

"Nursing home" means a facility with an organized nursing staff to maintain and operate organized facilities and services to accommodate two or more unrelated persons over a period exceeding twenty-four hours, which is operated either in connection with a hospital or as a freestanding facility for the express or implied purpose of providing intermediate or skilled nursing care for persons who are not in need of hospital care.

SECTION 102. CONDITIONS.

A. No nursing home may provide care to Medicaid patients without first obtaining a Medicaid nursing home permit in the manner provided in Section 105.

B. A permit is issued pursuant to the provisions of Sections 44-7-80 through 44-7-90, 44-7-130, and 44-7-320 of the South Carolina Code of Laws of 1976, as amended. Such permit is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws of the State of South Carolina.

C. Effective Date and Term of Permit:

A permit shall be effective from the issuance date until the end of the State Fiscal Year in which the permit was issued.

D. Separate Permits:

Separate permits are required for each licensed facility.

E. Permitting Fees:

No annual fee is required to obtain a permit.

F. Inspections:

All nursing homes to which these requirements apply shall be subject to inspection at any time without prior notice by properly identified personnel of the Department. Documents required by these regulations shall be maintained and available for inspection.

G. Exceptions to Certificate of Need Conditions:

If a Certificate of Need (Section 44-7-320 of the 1976 Code) has been issued with specific conditions or restrictions attached, the Department may permanently remove Medicaid conditions or restrictions or waive them on an annual basis without requiring further review under the Certificate of Need program.

H. Change of Ownership, Name or Address:

A facility shall request issuance of an amended permit, by letter to the Department, prior to either of the following circumstances:

1. Change of ownership by purchase or lease.
2. Change of facility's name or address.

I. Involuntary Discharge or Transfer:

Nursing homes participating in Medicaid may not involuntarily discharge or transfer patients due to their Medicaid Status.

SECTION 103. PENALTIES.

A. The Department shall request quarterly reports from the State Health and Human Services Finance Commission, indicating the number of Medicaid patient days for which Medicaid reimbursement was received by each nursing home. Based on these reports, the Department will determine each nursing home's compliance with its Medicaid nursing home permit.

B. Nursing homes shall be subject to a penalty for violating these regulations. Violations include:

(1) a nursing home exceeding by more than ten (10) percent the number of Medicaid patient days stated in its permit;

(2) a nursing home failing to provide at least ninety (90) percent of the number of Medicaid patient days stated in its permit;

(3) the provision of any Medicaid patient days by a nursing home without a Medicaid nursing home permit.

C. Each Medicaid patient day above or below the allowable range is considered to be a separate violation. The Department may levy a fine not to exceed the facility's average rate per Medicaid patient day times each violation.

SECTION 104. WAIVER OF PERMIT REQUIREMENTS.

A nursing home may request a waiver of permit requirements from the Department if no Medicaid patients are waiting for admission to the nursing home, or if for some other reason a nursing home anticipates that the home cannot satisfy the Medicaid nursing home permit requirements. Applicants must document the reasons for such a waiver. Community Long Term Care (CLTC) waiting list data may be used as an indicator.

SECTION 105. APPLICATION.

A. Within sixty (60) days of the effective date of the annual appropriations act, all facilities desiring to serve Medicaid patients must apply to the Department for a Medicaid nursing home permit. Facilities failing to apply within the sixty-day time period will be ineligible to receive Title XIX reimbursement for the fiscal year covered by the annual appropriations act.

B. The application, to be filed upon forms provided by the Department, shall be forwarded to the Bureau of Health Facilities and Services Development, Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201. The application shall set forth at least the following:

(1) name of facility;

(2) address of facility;

(3) telephone number of facility;

(4) specific number of Medicaid patient days the nursing home proposes to provide;

(5) assurance of compliance with this Act;

(6) signature of the administrator.

SECTION 106. ALLOCATION.

A. Based upon the maximum number of Medicaid patient days authorized by the General Assembly in the annual appropriations act and the number of Medicaid patient days requested by the nursing homes, the Department will allocate the Medicaid nursing home permits as follows:

1. The first year that permits are issued, priority will be given to facilities (in existence, under construction, or issued a Certificate of Need) for beds that have been previously approved and/or certified to participate in the Medicaid program. The initial allocation will be for no more than the maximum number of patient days which can be provided in the beds previously approved and/or certified for Medicaid participation. Should there be more Medicaid patient days requested than Medicaid patient days authorized by the General Assembly, the number of Medicaid patient days allocated to each nursing home in its Medicaid nursing home permit shall be decreased by the same percentage as the percent reduction required to equal the authorized Medicaid patient days.

2. In following years, priority will be given to facilities to renew permits authorizing up to the same number of Medicaid patient days as allocated in the permit for the preceding year. Should the maximum number of Medicaid patient days authorized by the General Assembly be decreased from the previous year, the number of Medicaid patient days allocated to each nursing home in its Medicaid nursing home permit shall be decreased by the same percentage as the percent reduction in the number of patient days authorized by the General Assembly.

3. If there are still Medicaid patient days remaining to be allocated after priority is given in accordance with the above paragraphs, the Medicaid patient days will be allocated to licensed nursing homes by county based on the Medicaid county priority list published in the South Carolina Medical Facilities Plan in effect at the time the allocation is being made.

4. The Department shall not approve additional Medicaid patient days for beds which exceed the general long-term care bed need shown for a county in the Medical Facilities Plan unless all other licensed facilities which could provide Medicaid patient days in counties where a general long-term bed need is shown have been accounted for in the allocation of Medicaid patient days.

B. Should there be competing applications within a particular county for Medicaid patient days under Section 106 A.(3). above, the Department may make a partial allocation of Medicaid patient days to more than one facility or a full allocation to a single facility, if, in the best judgment of the Department, such allocation will better serve the needs of the Medicaid population.

C. The number of Medicaid patient days allocated to a nursing home will not be decreased from the previous year's allocation, unless either:

(1) the nursing home requests a lesser allocation; or

(2) the maximum number of Medicaid patient days in the appropriations act is decreased.

SECTION 107. ISSUANCE OF PERMIT.

A. Full Allocation

When a properly completed application is received by the Department and it is determined, using the methodology in Section 106, that the facility should receive the requested allotment of Medicaid patient days, a Medicaid nursing home permit shall be issued.

B. Partial Allocation

When it is determined that a facility should receive fewer Medicaid patient days than requested in the application, the Department shall notify the applicant of this determination, setting forth the reasons for the decision.

SECTION 108. APPEALS BY THE APPLICANT.

Should the Department determine to deny issuance of a Medicaid Nursing Home Permit, or permit only a portion of the Medicaid patient days requested, it shall send to the applicant a notice setting forth the particular reasons for the determination. The decision shall become final thirty (30) days after the mailing of the notice, unless the applicant, within such thirty-day period, shall give notice of his desire for an administrative hearing. If the applicant shall give such notice, he shall be given a hearing before the Board of Health and Environmental Control or its designee pursuant to Regulations promulgated by the Department.

HISTORY: Added by State Register Volume 13, Issue No. 5, eff May 26, 1989.

61–96. Athletic Trainers.

(Statutory Authority: Sections 44–75–10 et seq., S.C. Code of Laws, 1976, as amended)

Contents:

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A. Purpose, Administration and Definitions.

1. Purpose: The purpose of this regulation is to assure the highest degree of professional conduct by those engaged in offering athletic trainer services to the public and to safeguard the public's health, safety, and welfare by establishing minimum qualifications for those individuals wishing to offer athletic trainer services to the public.

2. Administration: All regulations pertaining to the administration of the "Athletic Trainers' Act of South Carolina", Sections 44–75–10 et seq., S.C. Code of Laws, 1976, as amended, shall be administered by the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina.

3. Definitions: For the purpose of these Standards, the following definitions shall apply:

a. "Law" as used in these rules shall mean the "Athletic Trainers' Act of South Carolina", Sections 44–75–10 et seq., S.C. Code of Laws, 1976, as amended.

b. "Board" shall mean the Board of the South Carolina Department of Health and Environmental Control.

c. "Department" means the South Carolina Department of Health and Environmental Control.

d. "Committee" shall mean the South Carolina Athletic Trainers' Advisory Committee.

e. "Athletic Trainer" means a person with specific qualifications as set forth in Section 44–75–50 of the Law who, upon the advice and consent of a licensed physician, carries out the practice of care, prevention, and physical rehabilitation of athletic injuries, and who, in carrying out these functions, may use physical modalities, including, but not limited to, heat, light, sound, cold, electricity, or mechanical devices related to rehabilitation and treatment.

f. "Certificate" means official acknowledgement by the Department that an individual has successfully completed the education and other requirements referred to in the "Athletic Trainers' Act of South Carolina", Sections 44–75–10 et seq., which entitles that individual to perform the functions and duties of an athletic trainer.

g. "Licensed Physician" means a physician licensed by the South Carolina State Board of Medical Examiners.

h. "Employment of Athletic Trainer" shall mean a person who is engaged as an athletic trainer if the person is employed on a salary or contractual basis by an educational institution, a hospital, rehabilitation clinic, professional organization, or other bona fide athletic organization and performs the duties of an athletic trainer as a major responsibility of this employment.

i. "Advice and Consent of a Licensed Physician" shall mean the general written or oral standing orders and/or protocol signed by a licensed physician.

B. Description of the Profession.

An athletic trainer is an individual who has successfully completed the college or university undergraduate degree and fulfilled the requirements for certification as established by the Board of Certification, Inc., in association with the National Athletic Trainers' Association (NATA), and successfully completed the Athletic Trainers Certification Examination as administered by the Board of Certification, Inc. Through a combination of formal classroom instruction and clinical experience, the athletic trainer is prepared to apply a wide variety of specific health care skills and knowledge within the domains/standards. The seven domains/standards of athletic training from which these specific tasks are measured in the examination are:

1. Direction: The athletic trainer renders services or treatment under the advice and consent of a licensed physician.

2. Prevention: The athletic trainer understands and uses preventative measures to assure the highest quality of care for every patient.

3. Immediate Care: The athletic trainer provides standard and immediate care procedures used in emergency situations, independent of setting.

4. Clinical Evaluation and Diagnosis: Prior to treatment the athletic trainer assesses the patient's level of function. The patient's input is considered as an integral part of the initial assessment. The athletic trainer follows the standards of clinical practice in an area of diagnostic reasoning and medical decision making.

5. Treatment Rehabilitation and Re-Conditioning: The athletic trainer develops the treatment program and determines the appropriate treatment, rehabilitation and/or reconditioning strategies. The treatment program objectives include long and short term goals and appraisal of those that the patient can realistically be expected to achieve from the program. This assessment measure determines effectiveness of the program and is incorporated into the program.

6. Program Discontinuation: The athletic trainer, in collaboration with the licensed physician, recommends discontinuation of athletic training services when the patient has received optimal benefit of the program. The athletic trainer, at the time of discontinuation, notes the final assessment of the patient's status.

7. Organization and Administration: All services are documented in writing by the athletic trainer and are part of the patient's permanent records. The athletic trainer accepts responsibility of recording details of the patient's health care status.

C. Certification.

1. Requirements: A person who seeks certification as an athletic trainer in the State of South Carolina must successfully complete the Athletic Trainer Certification Examination as administered by the Board of Certification, Inc., and satisfy the following requirements:

a. Meets the athletic training curriculum requirements of a college or university; and

b. Submits a certified transcript from the college or university along with the completed application.

2. Applications:

a. Each candidate for certification must file a written application on a form furnished upon request from the Department. The application must be completed in its entirety and must include all relative documents and fees.

b. An application must be completed by the applicant and reviewed by the Department within ninety (90) days of the date that the first document has been received by the Department. Any application not completed within this period will become void. Any consideration of certification after this date will require the applicant to submit a new application, new documents and appropriate fees. The applicant will be notified in writing of approval or denial of request for certification.

c. Once an application is reviewed by the Department, no refund of the application fee shall be issued.

d. Certification will remain current for two (2) years from the issue date.

3. Examination: The applicant must pass the Athletic Trainer Certification Examination as administered by the Board of Certification, Inc., in association with the National Athletic Trainers' Association before a certificate for South Carolina certification can be issued from the Department.

4. Renewal: With renewal being every two (2) years, the Department shall send a renewal application form, sixty (60) days prior to the renewal date, to the last address registered with the Department in the South Carolina Credentialing Information System (CIS), to the person to whom the certification was issued or renewed during the preceding renewal period. The athletic trainer shall then:

a. Complete the renewal application form;

b. Submit proof of continuing education credit as detailed in Section J, Continuing Education;

c. Enclose the renewal fee; and

d. File the above with the Department prior to the renewal date.

5. Failure to Renew: An athletic trainer who does not file with the Department his or her renewal application by the renewal date will be deemed to have allowed his or her certification to expire. Such certification may be reinstated by the Department, at its discretion, by the payment of an additional late renewal fee, provided the application is made within six (6) months of the renewal date. After six (6) months, an additional restoration fee will be charged to those individuals who wish to restore certification.

6. Reinstatement: A certificate which is revoked for failure to renew may be reinstated at the direction of the Department and the Committee within two (2) years of its expiration date. Any consideration for recertification will necessitate submission of a new application and will require the applicant to meet the then existing requirements.

D. Fees.

To be certified, athletic trainers practicing in the State of South Carolina must pay the fees according to the fee schedule listed below unless otherwise exempted by law. Appropriate fees must be made payable by credit card, check or money order to the South Carolina Department of Health and Environmental Control.

1. Fees:

(a) Application Fee: The application fee shall be fifty dollars ($50) due upon receipt of the application.

(b) Examination Fee: The examination fee will be the current examination fee of the Board of Certification, Inc. (BOC) in association with the National Athletic Trainers' Association. This fee is in addition to the application fee.

(c) Re-Examination Fee: The re-examination fee shall be the current BOC in association with the National Athletic Trainers' Association re-examination fee.

(d) Biennial Renewal Fee: The biennial renewal fee shall be forty dollars ($40) due on the anniversary date of the second year after the applicant is certified. Renewal fees will be due on the anniversary date every two years after that.

(e) Late Renewal Fees: An additional fifteen ($15) late renewal fee for a total of fifty-five ($55) will be charged to those individuals who renew with a six (6) month period after the biennial renewal date.

(f) Restoration Fee: An additional one-hundred ($100) restoration fee for a total of one-hundred forty dollars ($140) will be charged to those individuals who fail to renew within the six (6) month late renewal schedule.

2. Other Fees:

Duplicate Certificate and ID Certificate Card: Seven dollars ($7).

E. Reciprocity.

Certification by Reciprocity: A certificate may be issued by the Department to any qualified athletic trainer holding certification in any other state if such other state recognizes the certificate of South Carolina in the same manner. The applicant must meet the following requirements for reciprocal certification:

1. The applicant is currently certified to practice athletic training under the laws of another state or territory.

2. The requirements for said certification are equivalent to those required in South Carolina.

3. The applicant's certificate has not been, and is not presently, suspended or revoked.

F. Exemption from Certification.

No person shall represent him or herself as an athletic trainer unless he or she is certified by the Department, except as otherwise provided in this section. Exemptions apply as follows:

1. Licensed, registered, or certified professionals such as licensed physicians, nurses, physical therapists, and chiropractors practicing their professions are exempt if they do not assert to the public by any title or description as being athletic trainers.

2. A person rendering services that are the same as or similar to those within the scope of practice provided for in the Law is exempt as long as he or she is otherwise now employed or employed in the future as a faculty or staff member at the school in question and does not represent him or herself to be an athletic trainer.

3. Persons employed prior to June 19, 1984 by the State Department of Education, local boards of education, or private secondary or elementary schools for the treatment of injuries received by students participating in school sports activities are exempt.

4. A person serving as a student-trainer or in any similar position if the service is carried out under the supervision of a licensed physician or certified athletic trainer is exempt.

G. Grandfather Provision.

The Department may issue a certificate to an applicant who was actively engaged as an athletic trainer for a two-year period from June 19, 1979 to June 19, 1984. The applicant shall submit the following for documentation:

1. A notarized record of being employed on a salaried basis with an educational institute or bona fide athletic organization for the duration of the institution's school year, or the length of the athletic organization's season and performed the duties of an athletic trainer as the major responsibility of his employment.

2. A certified oath verifying that the documents submitted to the Department are "true and accurate".

3. Payment of an application fee as prescribed by the Department.

H. Change of Name and Address.

1. Change of Name: A request for a change of name from that under which the original certificate was issued shall be accompanied by a certified copy of a marriage certificate, court order or documentation of legal name change and appropriate fee. See fee schedule.

2. Change of Address: Each person who has a certificate shall keep the Department apprised in writing of his or her current name and address his or her contact information in CIS current at all times.

I. Professional Identification.

1. Titles and Abbreviations: A person certified by the Department to practice and perform athletic training in South Carolina may use the title, "State Certified Athletic Trainer and/or the abbreviation S.C.A.T.".

2. Production and Display of Certificate: A person certified by the Department to practice and perform athletic training in South Carolina shall carry said original card at all times, and show said original card when requested.

J. Continuing Education.

1. Definition and Philosophy: Each individual certified as an athletic trainer is responsible for service to the consumer and is accountable to the consumer, the employer, and the profession for evidence of maintaining high levels of skill and knowledge. Continuing education is defined as education beyond the basic preparation required for entry into the profession, directly related to the performance and practice of athletic training.

2. Requirements: Regulations set the requirement for attending and completing two courses during the two (2) year certification period. These courses are as follows:

a. A course in cardiopulmonary resuscitation (CPR) offered by the American Red Cross, or the American Heart Association, or any other CPR course approved by the South Carolina Athletic Trainers' Advisory Committee (SCATA).

b. A designated professional seminar offered yearly by the SCATA at the Association's annual conference.

c. A seminar shall mean two (2) designated courses within the scope of that year's conference.

d. The development of the course content and the monitoring of the courses will be under the supervision of the Committee.

e. At the completion of the appropriate courses during the seminar, a card will be issued to the athletic trainer by a member of the Committee.

f. Equivalent courses may be approved by the Committee.

g. The Committee will set the continuing education standards on an annual basis.

3. Reporting Procedures for Continuing Education: It is the responsibility of the athletic trainer to submit to the Department, by the renewal date of certification, proof of the completion of the continuing education requirements. Documentation shall include:

a. A photocopy of a current CPR card from either the American Red Cross or the American Heart Association or any other CPR course approved by SCATA; and

b. A photocopy of the SCATA professional seminar card, signed by a member of the committee.

4. Enforcement: Without documentation of the required continuing education, as outlined in J.2 and J.3 above, an athletic trainer's certification will not be renewed at the two-year renewal date. Documentation for the continuing education units must be current at the time of renewal.

5. Appeals: If the athletic trainer is unable to obtain the proper continuing education units by the time of renewal, he/she may submit a letter of appeal with the renewal application. This letter must document the reason(s) the athletic trainer was unable to obtain the necessary continuing education units. The Committee will recommend the course of action to be taken.

K. Revocation, Suspension and Denial of Certification; Penalties; Appeals Process.

1. Standards of Conduct: At the discretion of the Department, athletic trainers may have their certificates suspended or revoked at any time the Department determines that the holder of the certificate no longer meets the prescribed qualifications set forth by the Department or has committed any of the following acts:

a. Has engaged in any conduct considered by the Board or Department to be detrimental to the profession of athletic training;

b. Has used fraud or deceit in procuring or, attempting to procure, a certificate or renewal of a certificate to practice athletic training;

c. Has violated, aided, or abetted others in violation of any provision of the law, or these regulations;

d. Has practiced athletic training without a valid certificate.

2. Penalties:

Any person violating the provisions of Sections 44–75–10 et seq. is guilty of a misdemeanor and upon conviction must be punished by a fine of not less than twenty-five ($25) nor more than two hundred dollars ($200).

3. Actions: The Committee may recommend revocation or suspension of a certificate. Revocation may be for a period up to two years.

4. Appeals Process: Decisions to deny, suspend or revoke an athletic trainer's certification becomes the final agency decision fifteen (15) days after notice of the Department decision has been mailed to the applicant or holder of the certificate by certified mail, return receipt requested, unless a written request for final review is filed with the DHEC Board by the applicant or holder of the

certificate pursuant to Section 44–1–60 of the S.C. Code of Laws, 1976, as amended, and applicable law.

L. Athletic Trainers' Advisory Committee.

1. Organization: The South Carolina Athletic Trainers' Advisory Committee shall consist of nine members appointed by the Board. Two members must be from the Department, one must be from the State Board of Medical Examiners, four must be certified athletic trainers and two must be from the general public who are not certified or licensed in any health care fields and are not in any way associated with athletic trainers.

2. Officers: The Advisory Committee shall annually elect a chairman and vice-chairman from its membership. These two officers shall have all the privileges of re-election.

3. Meetings: The Committee must meet at least once a year. Additional meetings may be held on call of the chairman or at the written request of two Committee members. A record must be kept of all transactions which have been called for by the chairman and a written report shall be submitted for the minutes at the next regularly scheduled meeting. A quorum of two thirds of the Committee membership is required for any meeting of the Committee.

M. Responsibilities of the Department.

The South Carolina Department of Health and Environmental Control, with the advice of the Committee, shall:

1. Coordinate with the Committee chairman to develop and distribute an agenda for committee meetings.

2. Post public notices of upcoming Committee meetings per the Freedom of Information Act and notify the media of the meetings. The following statement shall be read by the chairman of the Committee at the beginning of each public meeting: "Let the minutes reflect that, as required by the provisions of the South Carolina Freedom of Information Act, Section 30–4–80(E) of the S.C. Code of Laws, 1976, as amended, notification of this meeting has been given to all persons, organizations, local news media and other news media which have requested such notification".

3. Assure that the Committee's address and telephone number is listed in the state telephone directory.

4. Take Committee meeting minutes, type, and send to the chairman for signature within two weeks after the meeting. The Department will distribute the minutes to committee members within one week after receiving a signature from the chairman.

5. Receive applications for athletic trainer certification and process for routine action. Unusual applications will be brought before the full Committee. If there is a problem, or if the Department needs additional information, the applicant is notified in writing of the delay by the Department.

6. Collect application fees, certification renewal fees, and other fees deemed necessary for the certification program. These fees are non-refundable to the applicant.

7. Maintain a record of each athletic trainer's certification expiration date.

8. Work with the Committee chairman to develop a formal budget for the Committee.

9. Develop and maintain an inquiry log to track all correspondence related to the athletic trainer's certification program and record all complaints.

10. Develop and update a rules and regulations manual for the certification program.

11. Investigate violations and complaints and follow-up with proper legal procedures.

HISTORY: Added by State Register Volume 13, Issue No. 6, eff June 23, 1989; Amended by State Register Volume 17, Issue No. 6, eff June 25, 1993; State Register Volume 34, Issue No. 5, eff May 28, 2010; State Register Volume 39, Issue No. 6, Doc. No. 4496, eff June 26, 2015.

61–97. Standards for Licensing Renal Dialysis Facilities.

(Statutory Authority: 1976 Code §§ 44–7–260 et seq.)

Editor's Note

Unless noted otherwise, the following constitutes the history for 61–97, Section 101 to App. A.

HISTORY: Added by State Register Volume 13, Issue No. 5, eff May 26, 1989; Amended by State Register Volume 17, Issue No. 2, eff February 26, 1993; State Register Volume 34, Issue No. 6, eff June 25, 2010.

The Table of Contents appears as published in SCSR 44-6 Doc. No. 4953; there is no text for "103. Requirements for Issuance of License".

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SECTION 100. DEFINITIONS AND LICENSURE

101. Definitions.

For the purpose of these standards, the following definitions shall apply:

A. Abuse. Physical abuse or psychological abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing infliction of physical injury on a patient by an act or failure to act. Physical abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that of a therapeutic procedure prescribed by a licensed physician or other legally authorized healthcare professional. Physical abuse does not include altercations or acts of assault between patients.

2. Psychological Abuse. The deliberate use of any oral, written, or gestured language or depiction that includes disparaging or derogatory terms to a patient or within the patient's hearing distance, regardless of the patient's age, ability to comprehend, or disability, including threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Administering Medication. The acts of preparing and giving a single dose of a medication to the body of a Patient by injection, ingestion, or any other means in accordance with the orders of a physician or other Authorized Healthcare Provider.

C. Administrator. The staff member designated by the Licensee to have the authority and responsibility to manage the Facility and oversees all functions and activities of the Facility.

D. Annual. A time period that requires an activity to be performed at least every twelve (12) months.

E. Assessment. A procedure for determining the nature and extent of the problems and needs of a Patient, or potential Patient, to ascertain if the Facility can adequately address those problems and needs, and to secure information for use in the development of the Individual Plan of Care.

F. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina as a physician, advanced practice registered nurse, or physician assistant to provide specific treatments, care, or services to Patients.

G. Consultation. A meeting with a licensed Facility and individuals authorized by the Department to provide information to Facilities to enable/encourage Facilities to better comply with the regulations.

H. Continuous Ambulatory Peritoneal Dialysis. A continuous manual exchange of dialysate into and from the peritoneal cavity (usually every four to six hours).

I. Continuous Cycling Peritoneal Dialysis. The use of a machine to warm and cycle the dialysate in and out of the peritoneal cavity (usually every four hours).

J. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act or the South Carolina Controlled Substances Act.

K. Department. The South Carolina Department of Health and Environmental Control.

L. Designee. A staff member designated by the Administrator to act on his or her behalf.

M. Dialysis. A process by which dissolved substances are removed from a Patient's body by diffusion from one fluid compartment to another across a semipermeable membrane.

N. Dietitian. An individual currently licensed as a Dietitian by the South Carolina Department of Labor, Licensing and Regulation.

O. Direct Care Staff. Those individuals who are employees (full- and part-time) of the Facility providing direct treatment, care, and services to Patients, and those individuals contracted to provide treatment, care, and services to Patients.

P. Discharge. The point at which treatment, care, and services in a Facility are terminated and the Facility no longer maintains active responsibility for the treatment, care, and services of the Patient.

Q. End-Stage Renal Disease. That stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

R. End-Stage Renal Disease Service. The type of care or services furnished to an End-Stage Renal Disease Patient. Such types of care are: transplantation service; Dialysis service and Home Dialysis training.

S. Exploitation. 1) Causing or requiring a Patient to engage in an activity or labor that is improper, unlawful, or against the reasonable and rational wishes of a patient. Exploitation does not include requiring a patient to participate in an activity or labor that is a part of a written Individual Plan of Care or prescribed or authorized by the patient's attending physician; 2) an improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a patient by an individual for the profit or advantage of that individual or another individual; or 3) causing a patient to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the patient through cunning arts or devices that delude the patient and cause him or her to lose money or other property.

T. Health Assessment. An evaluation of the health status of a staff member or volunteer by a Physician, other Authorized Healthcare Provider, or a registered nurse, A registered nurse may complete the Health Assessment pursuant to standing orders approved by a Physician as evidenced by the Physician's signature. The standing orders shall be reviewed annually by the physician, with a copy of the review maintained at the Facility.

U. Home Dialysis. Dialysis performed by a Patient and/or individuals who assist Patients at home. The Patient and individuals who assist patients are trained and supervised by licensed nurses to do dialysis treatments on their own.

V. Home Dialysis Training. A program that trains and provides support services to End-Stage Renal Disease Patients and individuals who assist them in performing Home Dialysis with little or no professional assistance.

W. Individual Plan of Care. A documented regimen of appropriate care and services or written action plan prepared by the Facility for each Patient, based on the Patient's needs and preferences, and which is to be implemented for the benefit of the Patient.

X. Interdisciplinary Team. A group designated by the Facility to provide or supervise care and services provided by the facility. The group may include the following persons: physician or other Authorized Healthcare Provider, licensed nurse, dietary, social services, and direct care staff members.

Y. Inspection. A visit by Department representatives for the purpose of determining compliance with current statutes and regulations.

Z. Investigation. A visit by Department representatives to a licensed Facility or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to statutory and regulatory compliance.

AA. Legend Drug.

1. A drug when, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only";

2. A drug which is required by any applicable federal or state law to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only;

3. Any drug products considered to be a public health threat, after notice and public hearing as designated by the S.C. Board of Pharmacy; or

4. Any prescribed compounded prescription drug within the meaning of the S.C. Pharmacy Practice Act.

BB. License. The authorization to operate a Facility as defined in this regulation and as evidenced by a current certificate issued by the Department to a Facility.

CC. Licensed Capacity. The number of dialysis stations that the Facility is authorized to operate to include chronic hemodialysis and home hemodialysis training stations.

DD. Licensed Nurse. A person to whom the South Carolina Board of Nursing has issued a license as a registered nurse or licensed practical nurse, or a person granted multi-state licensing privileges by the South Carolina Board of Nursing and who may practice nursing in any Facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.

EE. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care and services at the Facility and with whom rests the ultimate responsibility for compliance with the current regulation.

FF. Medical Director. A physician currently licensed in South Carolina who is responsible for the medical direction of the End-Stage Renal Disease Services.

GG. Medication. A substance that has therapeutic effects including, but not limited to, Legend, Non-Legend, herbal products, over-the counter, nonprescription, vitamins, and nutritional supplements.

HH. Neglect. The failure or omission of a direct care staff member to provide the care, goods, or services necessary to maintain the health or safety of a Patient including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Failure to provide adequate supervision resulting in harm to patients, including altercations or acts of assault between patients, may constitute neglect. Neglect may be repeated conduct or a single incident that has produced or could result in physical or psychological harm or substantial risk of death. Noncompliance with regulatory standards alone does not constitute neglect.

II. Non-Legend Drug. A drug that may be sold without a prescription and that is labeled for use by the consumer in accordance with state and federal law.

JJ. Patient. A person who receives care, treatment, or services from a Facility licensed by the Department.

KK. Physical Examination. An examination of a Patient that meets the requirements set forth in Section 1100 of this regulation by an Authorized Healthcare Provider.

LL. Quality Improvement Program. The process used by a Facility to examine its methods and practices of providing care and services, identify the ways to improve its performance, and take actions that result in higher quality of care and services for the Facility's Patients.

MM. Quarterly. A time period that requires an activity to be performed every three (3) months.

NN. Registered Health Information Administrator. An individual who holds a professional certification as a Registered Health Information Administrator from the American Health Information Management Association.

OO. Registered Health Information Technician. An individual who holds a professional certification as a Registered Health Information Technician from the American Health Information Management Association in the United States.

PP. Renal Dialysis Equipment Technician. An individual who cleans, sterilizes, sets up, monitors, adjusts, and tests dialysis machines and accessory equipment used in the treatment of Patients with End- Stage Renal Disease.

QQ. Renal Dialysis Facility (Facility). An outpatient Facility which offers staff-assisted Dialysis or Home Dialysis Training and support services to -End-Stage Renal Disease Patients. A Facility may be composed of one or more fixed buildings, mobile units, or a combination.

RR. Revocation of License. An action by the Department to cancel or annul a Facility License by recalling, withdrawing, or rescinding the Facility's authorization to operate.

SS. Social Worker. A person licensed as a social worker by the South Carolina Board of Social Work Examiners.

TT. Station. An individual Patient treatment area that provides sufficient space to accommodate the dialysis equipment and supplies needed for Dialysis. Includes Stations specifically for chronic Hemodialysis, Home Hemodialysis Training, and Peritoneal Dialysis.

UU. Suspension of License. An action by the Department requiring a Facility to cease operations for a period of time or to require a Facility to cease admitting Patients, until such time as the Department rescinds that restriction.

VV. Tuberculosis Risk Assessment. An initial and ongoing evaluation of the risk for transmission of Mycobacterium tuberculosis in a particular healthcare setting.

102. Licensure. (II)

A. No person, partnership, corporation, private or public organization, political subdivision or other governmental agency shall establish, operate, maintain, or represent itself (advertise or market) as a Renal Dialysis Facility in South Carolina without first obtaining a License from the Department. The Facility shall not admit Patients prior to the effective date of the License. When it has been determined by the Department that treatment, care, or services are being provided at a location, and the owner has not been issued a license from the Department to provide such treatment, care and services the owner shall cease operation immediately and ensure the safety, health, and well-being of the Patients. Current or previous violations of South Carolina Code or Department regulations may jeopardize the issuance of a License for the Facility or the licensing of any other Facility, or addition to an existing Facility that is owned and/or operated by the Licensee. The Facility shall provide only the treatment, care, and services it is licensed to provide pursuant to the definition in Section 101.QQ. (I)

B. A Renal Dialysis Facility License shall not be required for, nor shall such a License be issued to:

1. Facilities operated by the federal government.

2. Renal dialysis services provided in licensed hospitals (such services remain within the purview of R.61–16, Minimum Standards for Licensing Hospitals and Institutional General Infirmaries).

C. Compliance. An initial License shall not be issued to a proposed Facility until the Licensee applicant has demonstrated to the Department that the proposed Facility is in substantial compliance with this regulation. In the event a Licensee who already has a Facility or activity licensed by the Department makes application for another Facility or an increase in Licensed Capacity, the currently licensed Facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a License to the proposed Facility or an amended License to the existing Facility. A copy of licensing standards shall be maintained at the Facility and accessible to all staff members and volunteers. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

D. Licensed Dialysis Stations. No Facility that has been authorized to provide a set number of licensed stations, as identified on the face of the License, shall exceed the Licensed Capacity. No Facility shall establish new care or services or occupy additional Stations or renovated space without first obtaining authorization from the Department.

E. Issuance and Terms of License.

1. The License issued by the Department shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, services, personal safety, fire safety, or the well-being of any patient or occupant of a facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this state.

4. A license shall be effective for a specified facility, at a specific location, for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but which are not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, shall not be considered as dividing otherwise adjoining or contiguous property. For facilities owned by the same entity, separate licenses are not required for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

6. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

F. Facility Name. No proposed Facility shall be named, nor shall any existing facility have its name changed to, the same or similar name as any other facility licensed in South Carolina.

G. Application. Applicants for a License shall submit to the Department a complete and accurate application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application shall be signed by the owner(s) if an individual or partnership; by two (2) officers if a corporation; or by the head of the

governmental department having jurisdiction if a governmental unit. Corporations or limited partnerships, limited liability companies or any other organized business entity shall be registered with the S.C. Secretary of State's Office if required to do so by state law. (II)

H. The application for initial licensure shall include:

1. The application shall set forth the full name and address of the Facility for which the License is sought and of the owner in the event his or her address is different from that of the Facility, and the names of the persons in control of the Facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with this regulation;

2. The applicant's oaths assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation;

3. Proof of ownership of real property in which the Facility is located, or lease agreement allowing the Licensee to occupy the real property in which the Facility is located;

4. Verification of Administrator's qualifications;

5. Name of director of nursing services; and

6. Number of renal dialysis Stations.

I. Licensing Fees. Each applicant shall pay an Annual License fee prior to issuance of a License. The Annual fee shall be two hundred dollars ($200.00) for the first ten (10) Stations and twenty dollars ($20.00) for each additional Station. Annual licensing fees shall also include any outstanding inspection fees. All fees are non-refundable, shall be made payable by check or credit card to the Department or online, and shall be submitted with the application. (II)

J. Licensing Late Fee. Failure to submit a renewal application and fee to the Department by the license expiration date shall result in a late fee of seventy-five dollars ($75.00) or twenty-five percent (25%) of the licensing fee amount, whichever is greater, in addition to the licensing fee. Failure to submit the licensing fee and licensing late fee to the Department within thirty (30) days of the license expiration date shall render the Facility unlicensed. (II)

K. License Renewal. For a License to be renewed, applicants shall submit a complete and accurate application on a form prescribed and furnished by the Department, shall pay the License fee, and shall not have pending enforcement actions by the Department. If the License renewal is delayed due to enforcement actions, the renewal License shall be issued only when the matter has been resolved by the Department, or when the adjudicatory process is completed, whichever is applicable.

L. Amended License. A Facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

1. Addition of Renal Dialysis Station or any part thereof; including:

a. Chronic Hemodialysis Stations;

b. Home Hemodialysis Training Stations; or

c. Peritoneal Stations;

2. Change of Facility location from one geographic site to another;

3. Change in Facility name or address (if notified by post office the address has changed)

M. Change of Licensee. A Facility shall request issuance of a new License by application to the Department prior to a change of the legal entity, for example, sole proprietorship to or from a corporation, or partnership to or from a corporation, even if the controlling interest does not change.

N. The licensee shall notify the Department, in a means as determined by the Department, of a change in controlling interest even if, in the case of a corporation or partnership, the legal entity retains its identity and name.

O. Variance. A variance is an alternative method that ensures the equivalent level of compliance with the standards in this regulation. The Facility may request a variance to this regulation in a format as determined by the Department. Variances shall be considered on a case by case basis by the Department. The Department may revoke issued variances as determined to be appropriate by the Department.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 200. ENFORCEMENT OF REGULATIONS

201. General.

The Department shall utilize Inspections, Investigations, Consultations, and other pertinent documentation regarding a proposed or licensed Facility in order to enforce this regulation.

202. Inspections and Investigations.

A. A Facility shall undergo Inspection by the Department prior to initial licensing and is subject to subsequent Inspections as deemed appropriate by the Department. (I)

B. The Facility shall allow all individuals authorized by South Carolina law to enter the Facility for the purpose of Inspection and/or Investigation and granted access to all properties and areas, objects, requested records, and documentation at the time of the Inspection or Investigation. The Department shall have the authority to require the Facility to make photocopies of those documents required in the course of Inspections or Investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. The physical areas of Inspections and Investigations shall be determined by the Department based on the potential impact or effect upon Patients. (I)

C. When there is noncompliance with the licensing standards, the Facility shall submit an acceptable plan of correction in a format determined by the Department. The plan of correction shall be signed by the Administrator and returned by the date specified on the report of Inspection or Investigation. The plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar); and
3. The actual or expected completion dates of those actions.

D. The Facility shall make available to the public copies of reports of Inspections or Investigations conducted by the Department, including the Facility response, upon written request with redactions of names of individuals in the report as provided by S.C. Code Sections 44–7–310 and 44–7–315.

E. The Facility shall pay a fee of three hundred fifty dollars ($350.00) plus twelve dollars ($12.00) per licensed Station for initial and routine Inspections. The fee for Station increase Inspections and follow-up inspections is two hundred dollars ($200.00) plus twelve dollars ($12.00) per licensed Station.

F. The Licensee shall pay the following inspection fees during the construction phase of the project. The plan inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	**Fee**
< $10,001	$750
$10,001 - $100,000	$1,500
$100,001 - $500,000	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project cost
Site Inspection	
50% Inspection	$500
80% Inspection	$500
100% Inspection	$500

203. Consultations.

Consultations may be provided by the Department as requested by the Facility or as deemed appropriate by the Department.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 300. ENFORCEMENT ACTIONS

301. General.

When the Department determines that a Facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such Facility, the Department, upon proper notice to the Licensee, may deny, suspend, or revoke Licenses, or assess a monetary penalty, or both.

302. Violation Classifications.

Violation of standards in this regulation are classified as follows:

A. Class I violations are those that present an imminent danger to the health, safety, or well-being of the persons in the Facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a Facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that have a negative impact on the health, safety or well-being of persons in the Facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in this regulation or those that are against the best practices. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

D. The notations "(I)" or "(II)," placed within sections of this regulation, indicate those standards are considered Class I or II violations if they are not met, respectively. Failure to meet standards not so annotated are considered Class III violations.

E. In determining an enforcement action the Department shall consider the following factors:

1. Specific conditions and their impacts or potential impacts on health, safety, or well-being of the Patients including, but not limited to: deficiencies in medication management; critical waste water problems; housekeeping, maintenance, or fire and life safety-related problems that pose a health threat to the Patients; power, water, gas, or other utility and/or service outages; Patients exposed to air temperature extremes that jeopardize their health; unsafe condition of the building or structure; indictment of an administrator for malfeasance or a felony, which by its nature indicates a threat to the Patients; direct evidence of abuse, neglect, or exploitation; no staff available at the Facility with Patients present; unsafe procedures and/or treatment being practiced by staff; (I)

2. Repeated failure of the Licensee or Facility to pay assessed charges for utilities and/or services resulting in repeated or ongoing threats to terminate the contracted utilities and/or services; (II)

3. Efforts by the Facility to correct cited violations;

4. Overall conditions of the Facility;

5. History of compliance; and

6. Any other pertinent conditions that may be applicable to current statutes and regulations.

F. When imposing a monetary penalty, the Department may invoke S.C. Code Section 44–7–320(C) to determine the dollar amount or may utilize the following schedule:

FREQUENCY VIOLATION	OF CLASS I	CLASS II	CLASS III
1st	$500.–1,500	$300–800	$100–300
2nd	1,000–3,000	500–1,500	300–800
3rd	2,000–5,000	1,000–3,000	500–1,500
4th	5,000	2,000–5,000	1,000–3,000
5th	5,000	5,000	2,000–5,000

6th	5,000	5,000	5,000

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 400. POLICIES AND PROCEDURES

A. The Facility shall maintain and adhere to written policies and procedures addressing the manner in which the requirements of this regulation shall be met. The Facility shall be in full compliance with the policies and procedures. (II)

B. The written policies and procedures shall include the following: (II)

1. Staffing and training
2. Reporting incidents, accidents, reportable diseases, closure and zero census
3. Patient records
4. Patient care and services
5. Patient rights and assurances
6. Medication management
7. Admissions and discharge
8. Fire prevention
9. Maintenance including doors, windows, HVAC, fire alarm, electrical, mechanical, plumbing, and for all equipment
10. Infection control and housekeeping
11. Water supply
12. Quality Improvement Program

C. The Facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented and signed by the Administrator. All policies and procedures shall be accessible to Facility staff, printed or electronically, at all times.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 500. STAFF AND TRAINING

501. General.

A. The Facility shall maintain accurate and current information regarding all staff members of the Facility, to include at least address, phone number, date of hire, date of initial Patient contact, and personal, work, and training background.

B. The Facility shall assign all staff members duties and responsibilities in writing and in accordance with the individual's capability. The Facility shall maintain a personnel file for each staff member. The file shall contain a health assessment, laboratory test results, resumÉs of training and experience, and current job description that reflects the staff member's responsibilities and work assignments, orientation, and periodic evaluations. (II)

502. Administrator. (II)

A. The Facility shall employ a full-time Administrator who shall be responsible for the management and administration of the Facility. The Administrator shall hold at least a bachelor's degree or have a minimum of an associate degree in a health-related field with at least two (2) years of experience in End-Stage Renal Disease within the past five (5) years. The Director of Nursing may serve as the Administrator.

B. Designee. A staff member shall be designated in writing to act in the absence of the Administrator.

C. The Facility shall notify the Department in writing within seventy-two (72) hours of any change in Administrator status and shall provide the Department the name of the newly-appointed Administrator and the effective date of the appointment.

503. Director of Nursing.

The Facility shall have a licensed registered nurse to act as Director of Nursing. The Director of Nursing shall have the following:

A. At least twelve (12) months of experience in clinical nursing, and an additional six (6) months of experience in nursing care for patients with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the Dialysis process; or

B. Eighteen (18) months of experience in nursing care of a patient on dialysis, or in nursing care of a patient with a kidney transplant, including training in and experience with the dialysis process.

C. If responsible for Home Dialysis Training, at least three (3) months of the total required End-Stage Renal Disease experience shall be in training patients in Home Dialysis.

504. Staffing. (I)

A. Each Facility shall have the following minimum staffing to provide services:

1. A registered nurse who shall serve as charge nurse (the Director of Nursing may act in this role);

2. At least one (1) registered nurse shall be on duty during hours of operation for every ten (10) Patients or fraction thereof. The charge nurse may serve in this capacity; and

3. If the Facility provides Home Dialysis training, such training shall be provided by a registered nurse who has had at least twelve (12) months experience in dialysis. At least three (3) months of the total required End-Stage Renal Disease experience shall be in training patients in Home Dialysis.

B. In addition to nursing staff, Direct Care Staff shall be in the building and immediately available to ensure a ratio of one (1) Direct Care Staff to each four (4) Patients or fraction thereof. (I)

C. The Facility shall maintain documentation to ensure the Facility meets Sections 504.A and 504.B.

505. Medical Staff.

A. If more than one (1) physician practices in a Facility, they shall be organized as a medical staff with appropriate bylaws approved by the governing body. The medical staff shall meet at least Quarterly and the Facility shall maintain minutes of such meetings.

B. The Facility shall have a licensed physician to serve as Medical Director of the End-Stage Renal Diseases services.

C. The Medical Director shall be responsible for the execution of Patient care policies and medical staff bylaws and rules and regulations. (II)

D. A licensed physician or nephrologist with demonstrated experience in the care of Patients with End-Stage Renal Disease shall be on-call to respond to Dialysis-related Patient issues during all times of clinical operations.

E. The Facility shall maintain a contact list for all on-call personnel, to include name, telephone number, and dates on-call. The Facility shall update the contact list as changes in personal occur, but not less that annually.

506. Job Descriptions.

A. The Facility shall maintain written job descriptions that describe the duties of every position. Each job description shall include position, title, authority, specific responsibilities, and minimum qualifications.

B. Job descriptions shall be signed by each staff member when assigned to the position and when revised.

507. Orientation. (II)

A. The Facility shall develop and execute a written orientation program to familiarize all new staff members with the Facility, its policies, and the staff members' job responsibilities. Documentation of orientation shall include training source, duration, and shall be signed and dated by the trainer and trainee. All required orientation shall be completed prior to Patient contact.

B. For Direct Care Staff, the orientation program shall contain at least the following subject content:

1. Fluid and electrolyte balance;

2. Kidney disease and treatment;

3. Dietary management;

4. Principles of Dialysis;

5. Dialysis technology;

6. Venipuncture technique;

7. Care of Dialysis Patients; and

8. Prevention of Hepatitis and other infectious diseases.

508. Training. (I)

A. Documentation of all in-service training shall be signed and dated by both the individual providing the training and the individual receiving the training. The following training shall be provided to all Direct Care Staff prior to Patient contact and at a frequency determined by the Facility, but at least annually unless otherwise specified by certificate, e.g., cardiopulmonary resuscitation (CPR):

1. Basic first aid;

2. Confidentiality of Patient information;

3. Patient's rights and assurances;

4. End-Stage Renal Disease care;

5. Cardiopulmonary resuscitation for designated staff members to ensure that there is a certified staff member present whenever residents are in the Facility.

B. Each equipment technician shall have completed a training course. Documentation of the training course shall be maintained in the staff file. The training shall include the following:

1. Prevention of Hepatitis via Dialysis equipment;

2. The safety requirements of dialysate delivery systems;

3. Bacteriologic control;

4. Water quality standards; and

5. Repair and maintenance of Dialysis and other equipment.

C. Facilities may allow Licensed Practical Nurses to perform intravenous (IV) push medication therapy. Prior to any Licensed Practical Nurse performing IV push medication therapy the Facility shall secure and maintain in the individual staff file the following:

1. Documentation of completion of an intravenous (IV) therapy course to include didactic and skill competency verification as required by current state and federal regulations;

2. Documentation of competency of performing IV push medication therapy, and annually thereafter, to include:

a. Administration of set prescribed dose routine and chronic medications;

b. Lab value parameters;

c. Technical administration process monitoring;

d. Emergency plan according to Facility policy and procedures; and

e. All Medications to be administered, to include appropriate dosage, actions, side effects, and contraindications.

509. Health Assessment.

A. All Direct Care Staff shall have a documented Health Assessment within twelve (12) months prior to initial Patient contact. The Health Assessment shall include tuberculin skin testing as described in Section 1704.

B. For staff members working at multiple Facilities operated by the same Licensee, copies of the documented Health Assessment shall be accessible at each Facility.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 600. REPORTING

601. Incidents.

A. The Facility shall document every incident, and include an incident review, investigation, and evaluation as well as corrective action taken, if any. The Facility shall retain all documented incidents reported pursuant to this section for six (6) years after the Patient involved is last discharged. For the first year following discharge, these records shall be kept on site and readily available at that Facility.

B. The Facility shall report following types of incidents to the responsible party or emergency contact for each affected individual at the earliest practicable hour, not exceeding twenty-four (24) hours of the incident. The Facility shall notify the Department immediately, not to exceed twenty-four (24) hours, via the Department's electronic reporting system or as otherwise determined by the Department. Incidents requiring reporting include:

1. Confirmed or suspected crimes against Patients;
2. Confirmed or suspected Abuse, Neglect, or Exploitation;
3. Use of wrong dialyzer on Patient;
4. Blood spills of more than one hundred (100) milliliters;
5. Adverse reactions to Hemolytic transfusion;
6. Adverse reactions to dialyzers;
7. Medication errors with the potential for adverse impact;
8. Hospitalization or death resulting from the incident;
9. Severe hematoma or laceration requiring medical attention or hospitalization;
10. Bone or joint fracture;
11. Severe injury;
12. Fire;
13. Natural disaster

C. The Facility shall submit a separate written investigation report within five (5) days of every incident required to be reported to the Department pursuant to Section 601.B via the Department's electronic reporting system or as otherwise determined by the Department. Reports submitted to the Department shall contain only: Facility name, License number, type of accident and/or incident, the date of accident and/or incident occurred, number of Patients directly injured or affected, Patient medical record identification number, Patient age and sex, number of Staff directly injured or affected, number of visitors directly injured or affected, witness(es) name(s), identified cause of accident/incident, internal investigation results if cause unknown, a brief description of the accident/incident including location where occurred, and treatment of injuries

D. The Facility shall notify the Patient's Physician and responsible party or emergency contact within twenty-four (24) hours of significant changes in a Patient's condition and shall document the significant changes and notification in the Patient's record. (I)

602. Reportable Diseases and Infections. (II)

A. Reportable Diseases. The Facility shall report cases of reportable diseases in accordance with Regulation 61–20, Communicable Diseases, and any occurrences, such as epidemic outbreaks or poisonings or other unusual occurrence, which threaten the welfare, safety or health of Patients or personnel shall be reported immediately to the local health director and to the Bureau of Health Facilities Licensing.

B. Reports of infections such as abscesses, septicemia, hepatitis, or other communicable diseases observed during admission or follow-up (or return) visit of the Patient shall be made and kept as a part of the Patient's medical records. Efforts shall be made to determine the origin of any such infection and if the dialysis procedure was found to be related to acquiring the infection, remedial action shall be taken to prevent recurrence.

603. Closure and Zero Census.

A. The Facility shall notify the Department and Patients, or Patients' representatives when appropriate, in writing prior to permanent closure of the Facility and shall provide the effective closure date. The Facility shall return its License to the Department on the date of closure.

B. The Facility shall notify the Department in writing within fifteen (15) days prior to a temporary closure. or within forty-eight (48) hours if the temporary closure is due to an emergency. The

notification shall include the reason for the temporary closure, records maintenance plan, anticipated reopening date, and documentation of Patient notification. Facilities that are temporarily closed longer than one (1) year shall reapply for licensure with the Department and be subject to all applicable licensing and construction requirements for new Facilities.

C. The Facility shall notify the Department in writing if there have been no Patients in the Facility for any reason for ninety (90) days or more no later than one hundred (100) days after the last Patient is discharged. Facilities that are zero census longer than one (1) year shall reapply for licensure with the Department and be subject to all applicable licensing and construction requirements for new Facilities.

D. Prior to the closing of a Facility for any reason, the Licensee shall arrange for preservation of records to ensure compliance with this regulation. The Facility shall notify the Department in writing within ten (10) days of closure of the provisions for records maintenance describing the arrangements and the location of the records.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 700. PATIENT RECORDS

701. Content.

A. The Facility shall maintain an organized medical record for each Patient. All entries shall be permanently written, typed, or electronic media, authenticated by the author, and dated.

B. The medical record shall be current and contain: (II)

1. Face sheet;

a. identification data (name, date of birth, gender);

b. diagnosis;

c. primary care physician's name and phone number;

d. Responsible person or other individual to be contacted in case of emergency and phone number;

e. Patient's address and phone number; and

f. date of admission;

2. Orders from Physicians and other Authorized Healthcare Providers for at least one (1) year. Standing orders shall be updated on an Annual basis;

3. Documentation of Physician or other Authorized Healthcare Provider visits for at least one (1) year. Physician or other Authorized Healthcare Provider visits shall be made at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the patient is receiving in-facility dialysis. The Facility shall document each visit missed by the Patient;

4. Physician progress notes for Home Dialysis Patients shall be documented monthly;

5. Lab and x-ray reports;

6. Annual history and physical;

7. Social worker initial assessments, updates, and quarterly progress notes;

8. Dietary initial assessments, updates, and monthly progress notes;

9. Miscellaneous consultations, hospitalizations;

10. Current Individual Plan of Care;

11. Nurses' progress notes each time of dialysis for one (1) month;

12. Nurse's initial admission assessment;

13. Signed consent forms.

702. Authentication. (II)

Facilities employing electronic signatures or computer-generated signature codes shall ensure authentication and confidentiality. If the Facility permits any portion of a Patient's record to be generated by electronic means, there shall be policies and procedures to prohibit the use or authentication by unauthorized users.

703. Individual Plan of Care.

A. The Interdisciplinary Team shall develop an Individual Plan of Care for each Patient to ensure appropriate modality of care. The Interdisciplinary Team shall develop the Individual Plan of Care either within the first thirty (30) calendar days of care or within the first thirteen (13) treatments. Individual Plans of Care shall be based on Patient's needs.

B. The Interdisciplinary Team shall review the Individual Plan of Care at least monthly for unstable Patients, and Annually for stable Patients and as changes in Patient needs occur. The Facility shall document participation of the Interdisciplinary Team, Patient and/or Patient's responsible party as appropriate, as evidenced by their signatures and date. The Individual Plan of Care shall include the following care areas:

1. Medical;
2. Psychological;
3. Social;
4. Dietary needs;
5. Stability of Patients;
6. Diagnosis;
7. Type of dialysis treatment;
8. Determination of stability of Patient (stable or unstable);
9. Indication whether candidate for transplantation or home dialysis;
10. Psychological needs, goals, and interventions; and
11. Dietary needs and interventions.
12. The course of action to be taken, the response and reaction to the care, and results of the treatment, and/or services provided.

704. Record Maintenance.

A. The Licensee shall provide accommodations, space, supplies, and equipment for the protection, storage, and maintenance of Patient records. Patient records shall be stored in an organized manner.

B. The Patient record is confidential and shall be made available only to individuals authorized by the Facility and/or the South Carolina Code of Laws. (II)

C. Copies of records generated by organizations or individuals contracted by the Facility for care or services shall be maintained by the Facility.

D. Upon Discharge of a Patient, the record shall be closed within thirty (30) calendar days and filed in an inactive or closed file maintained by the Licensee.

E. The Facility shall designate a staff member to serve as supervisor of Patient records. The Facility-designated staff member shall be a Registered Health Information Administrator or a Registered Health Information Technician. If the designated staff member is not a Registered Health Information Administrator or a Registered Health Information Technician the staff member shall receive consultation from a Registered Health Information Administrator or a Registered Health Information Technician. (II)

F. The Facility shall safeguard information in the medical record against loss, tampering, or use by unauthorized persons.

G. Records of current Patients shall be the property of the Facility. The records of current Patients shall be maintained at the Facility and shall not be removed without court order.

705. Record Retention.

A. When a Patient is transferred to an emergency Facility, a transfer summary to include, at a minimum, the diagnosis shall accompany the Patient to the receiving Facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the Facility's Patient record. (I)

B. Records generated by organizations or individuals contracted by the Facility for care, treatment, procedures, surgery, and/or services shall be maintained by the Facility that has admitted the Patient. Appropriate information shall be provided to assure continuity of care.

C. The Facility shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by Facility staff, as needed, and for regulatory compliance Inspections.

D. Records of Patients shall be maintained for at least six (6) years following the discharge of the Patient. For the first year following discharge, these records must be kept on site and readily available at that Facility. Other documents required by the regulation, e.g., fire drills, shall be retained at least twelve (12) months or until the next Department Inspection, whichever is longer.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 800. Reserved.

HISTORY: Reserved by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 900. PATIENT CARE AND SERVICES

901. Dietary Services.

Each Facility shall employ or contract with a Dietitian(s) to provide for the dietary needs of each Patient. The Dietitian, in consultation with the physician or other Authorized Healthcare Provide, shall be responsible for assessing the nutritional and dietetic needs of each Patient, recommending therapeutic diets, counseling Patients and their families on prescribed diets, and monitoring adherence and response to diets. Each Patient shall be evaluated as to his or her nutritional needs by the attending physician or other Authorized Healthcare Provider and a Dietitian.

902. Laboratory Services. (II)

A. Laboratory services shall be provided under contract to meet the needs of the Patient. Hematocrits, clotting times, and blood glucoses may be done by the Facility's staff. Such staff shall be qualified by education and experience to perform such duties under the direction of a physician.

B. Controls. There shall be a Quarterly constant packing time performed on all centrifuges used for hematocrits. Records of performed constant packing time shall be maintained.

C. Administration of Blood. A Facility administering blood to Patients shall comply with the following:

1. Blood must be transported from the laboratory processing the blood to the Facility in a container that will ensure maintenance of a temperature of one to ten (1 to 10) degrees centigrade. Temperature must be recorded upon arrival.

2. If blood is not administered immediately upon arrival, it must be stored in a refrigerator at one to six (1 to 6) degrees centigrade. The temperature of the refrigerator must be monitored and recorded.

D. All expired laboratory supplies shall be disposed of in accordance with Facility policy and procedures.

903. Social Services.

Each Facility shall employ or contract with a social worker to meet the social needs of Patients. The Social Worker shall document and conduct psycho-social evaluations, participate in team review of Patient progress, and document recommended changes in treatment based on the Patient's current psycho-social needs. (II)

904. Home Dialysis.

Home Dialysis Services shall include the following: (II)

A. Hemodialysis:

1. Surveillance of the Patient's home adaptation, including provisions for visits to the home or the Facility;

2. Consultation for the Patient with a Social Worker and Dietitian;

3. A record keeping system which ensures continuity of care;

4. Installation and maintenance of equipment;

5. Testing and appropriate treatment of the water; and

6. Ordering of supplies on an ongoing basis.

B. Continuous Ambulatory Peritoneal Dialysis:

1. Consultation for the Patient with a licensed Social Worker and a licensed Dietitian;

2. A record keeping system which ensures continuity of care; and

3. Ordering of supplies on an ongoing basis.

C. Continuous Cycling Peritoneal Dialysis:

1. Surveillance of the Patient's home adaptation, including provisions for visits to the home or the Facility;

2. Consultation for the Patient with a licensed Social Worker and a licensed Dietitian;

3. A record keeping system which ensures continuity of care;

4. Installation and maintenance of equipment; and

5. Ordering of supplies on an ongoing basis.

905. Transfer Agreement.

A. The Facility shall have in effect a written transfer agreement, signed by the Administrator, with one or more hospitals, for the provision of inpatient care and other hospital services.

B. The Dialysis Facility shall transfer a Patient to a hospital whenever a transfer or referral is determined as medically necessary by the attending physician.

C. There shall be an exchange of information, within one (1) business day, of medical and other information necessary or useful in the care and treatment of Patients transferred to a hospital or any other inpatient medical facility, or to another End-Stage Renal Disease Facility.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1000. PATIENT'S RIGHTS AND ASSURANCES

A. The following rights shall be guaranteed to the Patient, and, at a minimum, the Facility shall provide the Patient and any guardians, next of kin, or sponsoring agencies a written and oral explanation of these rights:

1. Fully informed of these rights and responsibilities, and of all rules and regulations governing Patient conduct and responsibilities;

2. Fully informed of services available in the Facility and provided an explanation any out of pocket expenses to the patient within fifteen (15) calendar days of admission and any time there are changes to their insurance coverage;

3. Informed by a Physician of their medical condition as documented in the Patient's medical record unless the medical record documents a contraindication;

4. Afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

5. Be transferred or discharged only for medical reasons, at the Patient's request, or for the welfare of the Patient, other Patients, or Facility Staff, or for nonpayment of fees and given notice to ensure orderly transfer or discharge; and

6. Treated with consideration, respect and full recognition of their individuality and personal needs, including the need for privacy in treatment.

B. The Facility shall maintain written documentation evidencing the Patient has had his or her rights explained.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1100. PATIENT PHYSICAL EXAMINATIONS

A. A Physical Examination shall be completed for Patients within thirty (30) calendar days prior to admission and at least Annually thereafter. A Physical Examination included in a discharge summary from a healthcare facility licensed by the Department, completed within thirty (30) calendar days, is acceptable as the admission Physical Examination. The Facility's physician shall attest to the Physical Examination's accuracy by countersigning it.

B. Physical examinations by physicians licensed in states other than South Carolina are permitted for new admissions under the condition that residents obtain an attending physician licensed in South Carolina and undergo a second (2nd) physical examination by that physician within thirty (30) calendar days of admission to the facility.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1200. MEDICATION MANAGEMENT

1201. General.

A. Medications, including Controlled Substances, medical supplies, and those items necessary for the rendering of first aid, shall be properly managed in accordance with federal, state, and local laws and regulations. Such management shall address the securing, storing, and administering of Medications, medical supplies, first aid supplies, and biologicals, their disposal when discounted or expired, and their disposition at discharge, death, or transfer of a Patient.

B. Applicable reference materials published within the previous three (3) years shall be available at the Facility in order to provide staff members or volunteers with adequate information concerning Medications. (II)

1202. Medication Orders.

A. Medications, to include oxygen, shall be administered in the Facility to Patients only upon orders of a physician or other Authorized Healthcare Provider.

B. All other orders shall be received only by Licensed Nurses or Authorized Healthcare Providers and shall be authenticated and dated by a physician or other Authorized Healthcare Provider pursuant to the Facility's policies and procedures, but no later than fourteen (14) calendar days after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and identification of the physician or other Authorized Healthcare Provider and the individual receiving the order.

C. Medications and medical supplies ordered for a specific Patient shall not be provided to or administered to any other Patient.

1203. Medicine Storage.

A. Medication and drugs maintained in the Facility for daily administration shall be properly stored and safeguarded in enclosures of sufficient size and that are not accessible to unauthorized persons. Refrigerators used for storage of Medications shall maintain an appropriate temperature as determined by the requirements established on the label of Medications. A thermometer accurate to plus or minus three (3) degrees shall be maintained in these refrigerators. Only authorized personnel shall have access to storage enclosures. Controlled Substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws. Expired or discounted Medications shall not be stored with current Medications. (I)

B. Medicine Preparation Area. Medicines and drugs shall be prepared for administration in an area that contains a counter and a sink. This area shall be located in such a manner to prevent contaminations of medicines being prepared for administration. (II)

C. Stock Medications.

1. Unless the Facility has a permitted pharmacy, stocks of Legend Medications shall not be stored except those specifically prescribed for individual Patients.

2. Non-legend Medications may be retained and labeled as stock in the Facility for administration as ordered by a Physician or other Authorized Healthcare Provider.

3. Stocks of naloxone may be stored for emergency overdose crises, with or without specific prescription for individual Patients.

4. If stock non-Patient specific Controlled Substances are to be used, a Controlled Substances registration from the Department's Bureau of Drug Control and a Controlled Substances registration from the federal Drug Enforcement Administration shall be obtained. The registrations shall be displayed in a conspicuous location within the Facility. Records shall be kept of all stock supplies of Controlled Substances giving an accounting of all items received and/or administered. (I)

D. Poisonous Substances. All poisonous substances shall be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration. (I)

E. Review of Medications. A Physician, pharmacist, or Licensed Nurse shall document review at least monthly all Medications prescribed by the Facility's physician for each Patient, for potential adverse reactions, allergies, interactions, etc. (II)

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1300. Reserved.

HISTORY: Reserved by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1400. EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1401. Disaster Preparedness. (II)

A. The Facility shall develop and maintain a written plan for actions to be taken in the event of a disaster or an emergency evacuation. The plan shall be implemented as necessary and at the time of need. The plan shall be evaluated, updated at least Annually, and available upon request by Patients, Patients' families, and the Department.

B. During any emergent event the Facility shall provide data, Facility and evacuation status, and other requested information as determined by the Department, and at a frequency as determined by the Department.

1402. Continuity of Essential Services. (II)

There shall be a plan to be implemented to ensure the continuation of essential Patient services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the work force resulting from inclement weather or other causes.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1500. FIRE PREVENTION

1501. Arrangements for Fire Department Response and Protection. (I)

A. Each Facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, such as fire plan and evacuation plan.

B. Facilities located outside of a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the Facility and a copy shall be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department.

1502. Tests and Inspections. (I)

Fire protection and suppression systems shall be maintained and tested in accordance with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility.

1503. Fire Response Training. (I)

All Facility staff shall complete Annual fire response training in accordance with specific duties and responsibilities outlined in their job description. Training shall be documented in a staff record and maintained in the Facility.

A. Fire response training shall address, at a minimum, the following:

1. Reporting a fire;
2. Use of the fire alarm system, if applicable;
3. Location and use of fire-fighting equipment;
4. Methods of fire containment; and
5. Specific responsibilities, tasks, or duties of each individual.

B. A plan for the evacuation of Patients, staff members, and visitors, to include evacuation routes and procedures, in case of fire or other emergencies, shall be established and posted in a conspicuous public area.

C. All Patients capable of self-evacuation shall be trained in the proper actions to take in the event of a fire, for example, actions to take if the primary escape route is blocked.

D. Patients shall be made familiar with the fire plan and evacuation plan upon admission and this plan will be reinforced during subsequent Fire Drills.

1504. Fire Drills.

A. An unannounced fire drill shall be conducted at least Quarterly for all shifts. Each staff member shall participate in a fire drill at least once each year. Records of drills shall be maintained at the Facility, indicating the date, time, shift, description, and evaluation of the drill, and the names of staff members, volunteers, and Patients directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, then the mandated statute or regulation requirements supersede the requirements of this regulation, and the Facility shall comply with the provisions of the statute or regulation.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1503 above.

C. All Patients shall participate in fire drills. In instances when a Patient refuses to participate in a drill, efforts shall be made to encourage participation, for example, counseling, implementation incentives rewarding Patients for participation, specific staff-to-Patient assignments to promote Patient participation. Continued refusal may necessitate implementation of the discharge planning process to place the Patient in a setting more appropriate to his or her needs and abilities.

1505. Fire Extinguishers, Standpipes, and Automatic Sprinklers.

The Facility shall provide fire-fighting equipment such as fire extinguishers, standpipes, and automatic sprinklers as required by the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility. The Facility shall ensure extinguishers are sized, located, installed, and maintained in accordance with National Fire Protection Association No. 10. The Facility shall install suitable fire extinguishers in all hazardous areas. The Facility shall comply with all state and local fire and safety provisions. (I)

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1600. MAINTENANCE

1601. General Maintenance.

The Facility shall keep all equipment and building components including, but not limited to, doors, windows, lighting fixtures, and plumbing fixtures in good repair and operating condition. The Facility shall document preventive maintenance. The Facility shall comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility. (II)

1602. Equipment Maintenance.

A written preventive maintenance program for all fire alarm, electrical, mechanical, plumbing, fire protection systems, and for all equipment used in dialysis and related procedures including, but not limited to, all Patient monitoring equipment, isolated electrical systems, conductive flooring, Patient ground systems, and medical gas systems shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment or system, the equipment or system shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (II)

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1700. INFECTION CONTROL

1701. Staff Practices.

Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for proper disposal of toxic and hazardous substances. These preventive measures and/or practices shall be in compliance with applicable guidelines of the Blood borne Pathogens Standard of the Occupational Safety and Health Act of 1970; the Centers for Disease

Control and Prevention; R.61–105, Infectious Waste Management; and other applicable federal, state, and local laws and regulations.

1702. Committee.

A. The Facility shall have an infection control committee composed of at least the Administrator, a Physician, and a registered nurse that shall be responsible for writing and enforcing policies and procedures for preventing and controlling hepatitis and other infections.

B. The policies and procedures for preventing and controlling hepatitis and other infections shall include, but not be limited to: (II)

1. appropriate procedures for prevention of hepatitis and other infectious diseases, to include the utilization of universal precautions for prevention of transmission of bloodborne pathogens currently recommended by the Centers for Disease Control;

2. appropriate procedures for surveillance and reporting of infections to include infection rates;

3. housekeeping;

4. handling and disposal of waste and contaminants;

5. sterilization and disinfection of equipment;

6. prevention of contamination by blood and other body fluids of units outside of the dialysis and Dialyzer reprocessing areas including toilet facilities, staff lounge, etc.;

7. protection of Patient clothing during the time when blood lines are opened or needles inserted or withdrawn; and

8. investigation of infections.

1703. Tuberculosis Risk Assessment and Screening. (I)

A. Tuberculosis Testing. The Facility may utilize either Tuberculin skin testing or Blood Assay for Mycobacterium tuberculosis (''BAMT'') for detecting Mycobacterium tuberculosis infection:

1. Tuberculin skin testing (''TST''). A small dose (0.1 mil) of purified protein derivative (''PPD'') tuberculin is injected just beneath the surface of the skin (by the intradermal Mantoux method), and the area is examined for induration (hard, dense, raised area at the site of the TST administration) forty-eight to seventy-two (48 to 72) hours after the injection (but positive reactions can still be measurable up to a week after administering the TST). The size of the indurated area is measured with a millimeter ruler and the reading is recorded in millimeters, including zero (0) mm to represent no induration. Redness and/or erythema is insignificant and is not measured or recorded. Authorized Healthcare Providers are permitted to perform tuberculin skin testing and symptom screening.

2. Blood Assay for Mycobacterium tuberculosis (''BAMT''). A general term to refer to in vitro diagnostic tests that assess for the presence of tuberculosis (''TB'') infection with Mycobacterium tuberculosis. This term includes, but is not limited to, IFN-γ release assays (''IGRA'').

B. The Facility shall conduct an Annual tuberculosis risk assessment in accordance with the Centers for Disease Control guidelines to guide the Facility's infection control policies and procedures related to the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

C. Baseline Status.

1. The Facility shall determine the baseline status of all staff according to the Centers for Disease Control and the Department's most current tuberculosis guidelines.

2. Tuberculosis Screening. All staff within three (3) months prior to Patient contact shall have a baseline two-step Tuberculin Skin Test (''TST'') or a single Blood Assay for Mycobacterium tuberculosis (''BAMT''). If a newly employed staff or volunteer has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered and read to serve as the baseline prior to Patient contact.

D. Post Exposure. After known exposure to a person with potentially infectious tuberculosis disease without use of adequate personal protection, the tuberculosis status of all staff shall be determined in a manner prescribed in the Centers for Disease Control and Department's most current tuberculosis guidelines.

E. Annual Tuberculosis Training. All Direct Care staff shall receive Annual training regarding tuberculosis to include risk factors and signs and symptoms of tuberculosis disease. The Annual tuberculosis training shall be documented in a staff record and maintained at the Facility.

F. Serial Screening. The Facility shall follow the Centers for Disease Control and Department's most current tuberculosis guidelines related to serial screening.

1704. Staff Hepatitis Screening.

A. All Direct Care Staff shall have been vaccinated or have evidence of immunity for hepatitis B prior to Patient contact, unless contraindicated or offered and declined. The Facility shall maintain records of all Direct Care Staff hepatitis B vaccinations in each individual staff file. The HBsAG status of all Direct Care Staff shall be known to identify those individuals who are (1) HBsAg-positive and therefore potential sources of infection to others; (2) anti-HBs-positive and therefore, immune; and (3) HBV-seronegative and therefore susceptible to hepatitis B virus.

B. The Facility shall offer hepatitis B vaccinations to unvaccinated or partially vaccinated new direct care staff members (who do not already exhibit immunity) prior to patient contact. The decision to receive or decline a vaccination shall be documented in the individual staff file.

1. Each Direct Care Staff member who elects vaccination shall start the initial dose of the hepatitis B series within ten (10) days of Patient contact and complete the series within six (6) months. The Facility shall conduct and document routine post-vaccination testing according to the Centers for Disease Control guidelines for response to the vaccination.

2. The Facility shall consider the individuals declining vaccinations as hepatitis B virus susceptible, and follow the Centers for Disease Control guidelines in the event of a reported blood or bodily fluid exposure.

C. For staff members whose status has been determined to be HBsAg-positive, the Facility shall refer to current Centers for Disease Control guidelines and Facility policies and procedures.

1705. Patient Hepatitis Screening.

A. All Patients shall be screened within thirty (30) calendar days prior to admission to the Facility to determine the hepatitis B virus serological status (HBsAg, anti-HBc, and anti-HBs). The HBsAg status of all Patients shall be known to identify those individuals who are (1) HBsAg-positive and therefore potential sources of infection to others; (2) anti-HBs-positive and therefore immune; and (3) HBV-seronegative and therefore susceptible to hepatitis B virus. A status result from hepatitis B testing shall be maintained in the Patient's record.

B. The Facility shall make available to Patients literature describing the risks and benefits of the hepatitis B vaccination. The Facility shall offer hepatitis B vaccinations to unvaccinated and/or susceptible Patients. The Facility shall maintain all Patient vaccination records in each Patient record.

1. Each Patient who elects vaccination shall start the initial dose of the hepatitis B vaccine series within ten (10) days of admission and complete the series within six (6) months according to Centers for Disease Control guidelines for pre-exposure vaccination. The Facility shall conduct and document routine post-vaccination testing according to the Centers for Disease Control guidelines for response to the vaccination.

2. The Facility shall consider the individuals declining vaccinations as hepatitis B virus seronegative, and follow the Centers for Disease Control guidelines for routine testing.

C. For Patients whose status has been determined to be HBsAg positive, the Facility shall refer to current Center for Disease Control guidelines and Facility policies and procedures.

D. The Facility shall conduct routine hepatitis B testing per current Centers for Disease Control guidelines.

1706. Isolation Room.

All Facilities accepting hepatitis B surface antigen positive Patients shall provide a separate isolation Dialysis room. (II)

1707. Housekeeping. (II)

A. The Facility and its grounds shall be clean, and free of vermin and offensive odors.

B. Interior housekeeping shall, at a minimum, include:

1. Cleaning each specific area of the Facility;

2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area appropriate to the area and the equipment's purpose or use;

3. For chemicals indicated as harmful on the product label, cleaning materials and supplies shall be in locked storage areas and inaccessible to Patients; and

4. During use of chemicals indicated as harmful on the product label, cleaning materials and supplies shall be in direct possession of the staff member and monitored at all times.

C. Exterior housekeeping shall, at a minimum, include:

1. Cleaning of all exterior areas, such as, porches and ramps, and removal of safety impediments such as snow and ice;

2. Keeping the Facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin; and

3. Safe storage of chemicals indicated as harmful on the product label, equipment, and supplies inaccessible to Patients.

D. Paper towels or air hand dryers and soap dispensers with soap must be provided at all lavatories in the Facility. (II)

1708. Linen.

A. All reusable linens, including those used as sterilizing wrappers, must be laundered before re-use.

B. Clean linens shall be handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

C. The Facility shall have available at all times a quantity of linen essential for proper care and comfort of Patients.

D. Used linens shall be kept in closed and covered containers while being stored or transported.

1709. Refuse and Waste Disposal. (II)

A. All garbage and waste shall be collected, stored, and disposed of in a manner to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable-type containers shall not be reused.

B. Containers for garbage and refuse shall be covered and stored outside in durable, rust-resistant, non-absorbent, watertight, rodent-proof, easily cleanable containers placed on an approved platform to prevent overturning by animals, the entrance of flies or the creation of a nuisance. All solid waste shall be disposed of at frequencies in a manner so as not to create a rodent, insect, or other vermin problem.

C. Containers for garbage shall be cleaned and free of debris.

D. All sewage and liquid waste shall be disposed of in a manner not to create a public health hazard and by a sanitary method approved by the Department.

E. A Sharps disposal system shall be utilized and appropriately covered. (II)

1710. Outside Areas.

All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for vermin. Outside stairs, walkways, ramps, and porches shall be maintained free from accumulations of water, ice, snow, and other impediments.

1711. Toxic and Hazardous Substances.

The Facility shall have policies and procedures for dealing with toxic and hazardous substances. Such policies and procedures shall conform to current Occupational Safety and Health Administration standards regarding formaldehyde, renalin, or any other sterilizing agents. (II)

A. The Facility shall develop procedures to cover at a minimum:

1. Formaldehyde vapor concentration;

2. Fire prevention;

3. Solution exposure;

4. Leaks from machines;

5. Large and small spills; and

6. Solution contact with eyes, skin and/or clothing (appropriate eyewash stations shall be provided in all Facilities).

B. The Facility shall conduct and document routine monitoring of vapor concentration in accordance with current Occupational Safety and Health Administration guidelines.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1800. QUALITY IMPROVEMENT PROGRAM

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care and services provided by the Facility.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively accomplished;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Analyze the appropriateness of Individual Plans of Care and the necessity of care and services rendered;

5. Analyze all incidents and accidents, to include all medication errors and Patient deaths;

6. Analyze any infection, epidemic outbreaks, or other unusual occurrences which threaten the health, safety, or well-being of the Patients; and

7. Establish a systematic method of obtaining feedback from Patients and other interested persons, as expressed by the level of satisfaction with care and services received.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 1900. DESIGN AND CONSTRUCTION

1901. General.

A Facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each Patient. Facility design shall be such that all Patients have access to required services.

1902. Codes and Standards.

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the Facility.

B. Unless specifically required otherwise by the Department, all Facilities shall comply with the adopted construction codes and construction provisions effective at the time its initial License was issued.

1903. Submission of Plans and Specifications.

A. Plans and specifications shall be submitted to the Department for review and approval for new construction, additions or alterations to existing buildings, replacement of major equipment, buildings being licensed for the first time, buildings changing license type, and for Facilities increasing occupant load or Licensed Capacity. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. Unless directed otherwise by the Department, plans shall be submitted at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission, and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction, the owner shall employ a registered architect and/or engineer for observation and inspections. Periodic inspections shall be conducted by the Department throughout each phase of a project.

B. Plans and specifications shall be submitted to the Department for review and approval for projects involving Dialysis systems that are periodically replaced, reverse osmosis systems, or that have an effect on:

1. The function of a space;
2. The accessibility to or of an area;
3. The structural integrity of the Facility;
4. The active and/or passive fire safety systems;
5. Doors;
6. Walls;
7. Ceiling system assemblies;
8. Exit corridors;
9. Life safety systems; or
10. That increase the occupant load or Licensed Capacity of the Facility.

C. The Facility shall submit all subsequent addenda, change orders, field orders, and documents altering the Department's review. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, etc. that are required to have a flame-spread rating or to satisfy other safety criteria shall be documented with copies kept on file at the Facility and made available to the Department.

1904. Code and Standards Compliance and Inspections.

Construction work which violates codes or standards will be required to be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction performed without proper permitting shall not be inspected by the Department.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 2000. FIRE PROTECTION, PREVENTION, AND LIFE SAFETY

A. Facilities shall have a partial, manual, automatic, supervised fire alarm system. The Facility shall arrange the system to transmit an alarm automatically to a third party. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculation systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. All fire, smoke, heat, sprinkler flow, and manual fire alarming devices shall be connected to and activate the main fire alarm system when activated. (I)

C. Facilities shall not have single and multi-station smoke alarms.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 2100. GENERAL CONSTRUCTION

A. Gases, flammable and nonflammable, shall be handled and stored in compliance with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

B. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place. In "Smoke-Free" Facilities, "No Smoking" signs shall not be required provided all four (4) of the following conditions are met:

1. Smoking is prohibited;
2. The Facility nonsmoking policy is strictly enforced;
3. "Smoke-Free" signs are strategically placed at all major entrances; and
4. A facility shall have "No Smoking" signs where oxygen is stored. (I)

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 2200. Reserved.

HISTORY: Reserved by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 2300. WATER SUPPLY

A. Water Supply. Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the Facility and shall be adequate in volume and pressure for all purposes. (II)

B. The Facility shall enter into an agreement with the water district or similar authority whereby the Facility is regularly notified of situations occurring outside the Facility that may adversely impact water quality including, but not limited to: (I)

1. changes in treatment methods and source;
2. municipal water treatment equipment failure;
3. damage to the distribution system; and
4. chemical spills.

C. Water used for dialysis purposes shall be analyzed for bacteriological quality at least monthly and chemical quality at least Quarterly and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Water used to prepare a dialysate shall not contain concentrations of elements or organisms in excess of those specified below: (I)

ELEMENTS	LIMIT IN MILLIGRAMS PER LITER
Aluminum	.01
Arsenic	.005
Barium	.100
Cadmium	.001
Calcium	2.0
Chloramines	.001
Chlorine	.500
Chromium	.014
Copper	.100
Fluorides	.200
Lead	.005
Magnesium	4.0
Mercury	.0002
Nitrates (Nitrogen)	2.0
Potassium	8.0
Selenium	.090
Silver	.005
Sodium	70.0
Sulfates	100.0

Zinc	.100
Bacteria	200 colonies per milliliter

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 2400. ELECTRICAL

2401. General. (I)

A. The Facility shall equip all buildings containing Chronic Hemodialysis Stations with either:

1. An emergency generator with automatic transfer switch(s) that feeds the building and power requirements in Section 2401.B; or

2. An exterior building connection and automatic transfer switch(s) to receive a portable emergency generator that is under contract for delivery and connection. The portable emergency generator shall feed the building and power requirements in Section 2401.B.

B. Facilities subject to Section 2401.A shall meet the following building and power requirements:

1. All power and lighting in the reverse osmosis system, the Chronic Hemodialysis Stations, and the nurse station;

2. Nurse call system supporting the Chronic Hemodialysis Stations;

3. Emergency communication systems;

4. Heating, ventilating, and air conditioning systems for the reverse osmosis system and the Chronic Hemodialysis Stations;

5. Elevator banks serving the Chronic Hemodialysis Stations;

6. All exit lights with backup battery packs;

7. All exit access corridor lighting with backup battery packs;

8. All illumination of means of egress with backup battery packs;

9. All fire detection and alarm systems, if installed;

10. All sprinkler systems, if installed; and

11. Emergency generator run time of at least forty-eight (48) hours.

2402. Lighting and Electrical Services.

A. All electrical and other equipment used in the Facility shall be maintained free of defects that could be a potential hazard to Patients or personnel. The Facility shall provide safe lighting for individual activities as required by applicable codes.

B. The Facility shall maintain all electrical installations and equipment in a safe, operable condition in accordance with the applicable codes.

C. The Facility shall maintain documentation of Annual electrical system inspection by a certified or licensed technician.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 2500. HEATING, VENTILATION, AND AIR CONDITIONING (HVAC)

A. The Facility shall maintain documentation of annual Heating, Ventilation, and Air Conditioning system inspection by a certified or licensed technician. (II)

B. The Facility shall maintain a temperature of between seventy-two (72) and seventy-eight (78) degrees Fahrenheit in Patient areas. (II)

C. No Heating, Ventilation, and Air Conditioning supply or return grille shall be installed within three (3) feet of a smoke detector. (I)

D. Heating, Ventilation, and Air Conditioning grilles shall not be installed in floors. (II)

E. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in such a manner that would be an irritant to the Patients, staff, or volunteers. (II)

F. Each bathroom and/or restroom shall have either operable windows or have approved mechanical ventilation. (II)

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 2600. PHYSICAL PLANT

2601. General.

A. The dialysis unit(s) shall be separate from other activities and shall be located in an area free of traffic by non-unit staff or Patients. (II)

B. The nursing station shall be located in an area that provides adequate visual surveillance of Patients on dialysis machines. (I)

C. Treatment areas shall be designed and equipped to provide proper and safe treatment as well as privacy and comfort for Patients. Sufficient space shall be provided to accommodate emergency equipment and staff to move freely to reach Patients in emergencies. (I)

D. At least two (2) acceptable exits shall be provided for each Facility. (II)

E. If the Facility is located on the ground floor there must be one (1) exit to the outside for ambulance and/or handicapped use. (II)

F. If the dialysis units are located above the ground floor, the Facility must have an elevator sized to accommodate a stretcher. (II)

G. Dialysis units shall be at least three (3) feet apart with cubicle curtains or other means to provide complete privacy for each Patient as needed. (II)

H. All rooms shall open onto a corridor leading to an exit and all corridors used by Patients shall be at least four (4) feet wide. (II)

I. A waiting room shall be provided with sufficient seating for Patients and visitors.

J. Storage rooms shall be provided for supplies and equipment. Storage room floor space shall total at least ten (10) square feet per station.

K. A clean work area that contains a work counter, handwashing sink, and storage facilities for the storage of clean and sterile supplies shall be provided. (II)

L. A soiled work area that contains a work counter, handwashing sink, storage cabinets, and waste receptacle shall be provided. (II)

M. Patient toilet facilities shall be provided.

N. A separate staff toilet and personal storage space shall be provided within the unit.

O. Separate storage space shall be provided for oxygen cylinders if a piped system is not provided. (II)

P. A janitor's closet shall be provided adjacent to and for the exclusive use of the dialysis Facility.

2602. Ground Fault Protection.

All electrical and other equipment used in the Facility shall be maintained free of defects that could be a potential hazard to Patients or personnel. There shall be sufficient safe lighting for individual activities, including suitable lighting for corridors and baths. Lighting in work areas shall never be less than fifty (50) foot-candles. (II)

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

SECTION 2700. SEVERABILITY

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, and they shall remain in effect as if such invalid portions were not originally a part of this regulation.

HISTORY: Amended by SCSR 44–6 Doc. No. 4953, eff June 26, 2020.

61–98. State Underground Petroleum Environmental Response Bank (SUPERB) Site Rehabilitation and Fund Access Regulation.

(Statutory Authority: 1976 Code § 44–2–10)

Unless otherwise noted, the following constitutes the history for 61–98, Section I to Section V.
HISTORY: Added by State Register Volume 19, Issue No. 2, eff February 24, 1995; Amended by State Register Volume 20, Issue No. 6, Part 1, eff June 28, 1996; State Register Volume 21, Issue No. 5, eff May 23, 1997.

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SECTION I. Scope and Definitions.

A. Scope. This regulation, promulgated pursuant to the State Underground Petroleum Environmental Response Bank Act (SUPERB), sets forth certain requirements for site rehabilitation for releases from underground storage tanks (USTs) governed under the SUPERB Act and Regulation 61-92; accessing the SUPERB account; certification of site rehabilitation contractors and suspension and decertification of site rehabilitation contractors by the Department of Health and Environmental Control (the Department).

B. Definitions.

1. Active Remediation. Physical actions taken to reduce the concentrations of chemicals of concern.

2. Affiliate. Persons are affiliates of each other if, directly or indirectly, either one controls or has the power to control the other, or a third person controls or has the power to control both. Indicia of control include, but are not limited, to: interlocking management or ownership, identity of interest among family members, shared facilities and equipment, common use of employees, or a business entity organized following the suspension or debarment of a person which has the same or similar management, ownership or principal employees as the suspended, debarred, or voluntarily excluded person.

3. Attenuation. The reduction in concentrations of chemicals of concern in the environment with distance and time due to processes that include, but are not limited to, diffusion, dispersion, and absorption.

4. Carcinogen. Substances which have been classified for human carcinogenic risk by the U.S. Environmental Protection Agency.

5. Certification. An action taken by the Department in accordance with this regulation to authorize a contractor to perform site rehabilitation under the SUPERB Act.

6. Chemicals of Concern. Specific constituents that are identified for evaluation in the risk assessment process.

7. Civil Judgment. The disposition of a civil action by any court of competent jurisdiction, whether entered by verdict, decision, settlement, stipulation, or otherwise.

8. Corrective Action. A subset of site rehabilitation activities conducted to protect human health, safety, and the environment. These activities include recovery of free-product, evaluating risks, evaluating and implementing intrinsic remediation, making no further action decisions, implementing institutional controls, active remediation, designing and operating cleanup systems and equipment, and monitoring of progress.

9. Corrective Action Plan. A document outlining proposed corrective actions.

10. Direct Exposure Pathway. An exposure pathway where the point of exposure is at the source without a release to any other medium (for example, inhalation of vapors or dermal contact with free-product).

11. Engineering Controls. Modifications to a site, such as capping or water treatment at the point of use, to reduce or eliminate the potential for exposure to chemicals of concern.

12. Engineering Report. A document outlining the proposed technical equipment specifications of a corrective action system.

13. Exposure. Contact of a receptor(s) with chemicals of concern. Exposure is quantified as the amount of the chemical of concern available at the exchange boundaries, such as skin or lungs, and available for absorption by the human body.

14. Exposure Assessment. The determination or estimation, qualitative or quantitative, of the magnitude, frequency, duration, and route of exposure.

15. Exposure Factor. An intake variable value, either established by the Environmental Protection Agency or based on site-specific data, used to estimate an exposure concentration.

16. Exposure Pathway. The course chemicals of concern take from the source area(s) to an exposed organism. An exposure pathway describes a unique mechanism by which a receptor(s) is exposed to chemicals of concern. A complete exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure media (e.g., ground water) is included.

17. Exposure Point. The point at which it is assumed that a receptor, either potential or actual, can come into contact, either now or in the future, with the chemicals of concern. Maximum contaminant levels or other existing water quality standards must be met at the exposure point.

18. Exposure Route. The manner in which chemicals of concern come in contact with an organism (i.e., ingestion, inhalation, dermal contact).

19. Familial Relationship. A connection or association by family or relatives, in which a family member or relative has a material interest. Family or relatives include: father, mother, son, daughter, brother, sister, uncle, aunt, first cousin, nephew, niece, husband, wife, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, stepfather, stepmother, stepson, stepdaughter, stepbrother, stepsister, half brother, half sister, grandparent, great grandparent, grandchild, great grandchild, step grandparent, step great grandparent, step grandchild, step great grandchild, or fiancee.

20. Financial Relationship. A connection or association through a material interest of sources of income which exceed five percent of annual gross income from a business entity.

21. Hazard Index. The sum of two or more hazard quotients for multiple regulated substances and/or multiple exposure pathways which impact the same target organ or act by the same method of toxicity.

22. Hazard Quotient. The ratio of a single substance exposure level over a specific time period to a reference dose for that substance derived from a similar exposure period.

23. Indirect Exposure Pathways. An exposure pathway with at least one intermediate release to any media between the source and the point of exposure (for example, leaching of chemicals of concern from soils to ground water).

24. Institutional Controls. The restriction on use of or access to a site to eliminate or minimize potential exposure to chemicals of concern.

25. Intrinsic Remediation. The verifiable reduction of concentrations of chemicals of concern through naturally occurring microbial activity or attenuation mechanisms.

26. Legal Proceedings. Any criminal proceedings or any civil judicial proceedings to which the Federal, State, or Local government or quasi-governmental authority is a party. The term includes appeals from such proceedings.

27. Maximum Contaminant Level. A standard for drinking water established by U.S. Environmental Protection Agency under the Safe Drinking Water Act which is the maximum permissible level of chemicals of concern in water which is used as a drinking water supply.

28. Non-Carcinogen. Substances shown either through epidemiological studies or through laboratory studies to cause adverse health effects other than cancer.

29. Notice. A written communication served in person or sent by certified mail, return receipt requested, or its equivalent, to the last known address of a party, its identified counsel, its agent for service of process, or any partner, officer, director, owner, or joint venturer of the party. Notice, if undeliverable, shall be considered in effect five days after being properly sent to the last address known by the Department.

30. Person. An individual, partnership, corporation, or other legal entity organized or united for a business purpose, or a governmental agency.

31. Point(s) of Compliance. A location(s) selected between the source area and the exposure point(s) where chemicals of concern must be at or below the determined target levels in specific media (e.g., soil, ground water, air).

32. Proposal. A plan, request, invitation to consider or similar communication outlining cost, labor, or equipment estimates by or on behalf of a person seeking to directly or indirectly participate or to receive a benefit, directly or indirectly, from site rehabilitation.

33. Reasonably Anticipated Future Use. Future land use which can be predicted given current use, local government planning, and zoning.

34. Reasonable Maximum Exposure. Combination of upper-bound and mid-range exposure factors to be used in dose estimation equations to provide a result which represents an exposure scenario that is both protective and reasonable; not the worst case.

35. Receptors. Persons, structures, utilities, surface water, sensitive habitats, water supply wells, or other living organisms that are, or may be, affected by a release.

36. Related Interest. Affiliated companies, principal owners of the client company, or any other party with which the client deals where one of the parties can influence the management or operation policies of the other.

37. Release. Means any spilling, leaking, emitting, discharging, escaping, leaching or disposing from an underground storage tank into subsurface soils, ground water, or surface water.

38. Risk. The probability that a chemical of concern, when released into the environment, will cause an adverse effect in exposed humans or other living organisms.

39. Risk Assessment. An analysis of the potential for adverse health effects caused by chemicals of concern to determine the need for corrective action. Also used to develop target levels where remedial action is required.

40. Risk Reduction. The lowering or elimination of the level of risk posed to human health or the environment through initial response action, corrective action, or institutional or engineering controls.

41. Risk-Based Screening Levels. Risk based, non site-specific, corrective action target levels for chemicals of concern.

42. Sensitive Habitat. Fresh and salt water fisheries, fish habitats including shellfish areas, coastal and inland wetlands, and habitats of threatened or endangered species.

43. Site. Includes all land, regardless of ownership considerations or property boundaries, which is directly affected by the chemicals of concern.

44. Site Classification. A qualitative evaluation of a site based on known or readily available information.

45. Site Conceptual Exposure Model. An analysis of the current and reasonably potential future pathways based on reasonably anticipated receptors and current and reasonably anticipated future use to identify complete exposure pathways. The analysis should be documented in a flow chart or diagram, or other appropriate format, to depict the complete exposure pathways. The site conceptual exposure model should be updated as additional information is obtained for the site.

46. Site Rehabilitation. Cleanup actions taken in response to a release from a UST which includes, but is not limited to, assessment, investigation, evaluation, planning, design, engineering, construction, or other services put forth to investigate or cleanup affected subsurface soils, ground water or surface water.

47. Site Rehabilitation Contractor. An individual or corporation, other than the owner/operator, who performs site rehabilitation under the SUPERB Act and this regulation.

48. Site-Specific Target Level. Risk-based corrective action target levels for chemicals of concern developed for a particular site under the Tier 2 and Tier 3 evaluations.

49. Source Area. Either the location of free-phase hydrocarbons or the location of highest soil and ground-water concentration of the chemicals of concern.

50. Tier 1 Evaluation. A risk-based analysis where non-site-specific values based on conservative exposure factors (i.e., risk-based screening levels), potential exposure pathways, and land use are evaluated to determine appropriate actions.

51. Tier 2 Evaluation. A risk-based analysis applying the risk-based screening levels at the exposure point, development of site-specific target levels for potential indirect exposure pathways based on site-specific conditions, and establishment of points of compliance.

52. Tier 3 Evaluation. A risk-based analysis to develop values for potential direct and indirect exposure pathways at the exposure point based on site-specific conditions.

53. UST. Underground Storage Tank, as defined in Regulation 61-92.280.12.

54. Wellhead Protection Area. A Department approved area surrounding public water supply wells that is designed to protect the wells from threats by: 1) direct introduction of chemicals of concern in the immediate well area, 2) microbial contaminant, and 3) chemicals of concern.

SECTION II. Site Rehabilitation Risk–Based Corrective Action Procedures.

Risk-Based corrective action procedures outlined in this Section shall apply to all petroleum and petroleum product releases from underground storage tanks.

A. General Site Rehabilitation Requirements.

1. UST owners or operators shall implement site rehabilitation activities based on this regulation and on performance standards and criteria developed by the Department. Alternate approaches that accomplish the same goals as the performance standards will also be approvable. The UST owner or operator shall, upon Department approval, begin site rehabilitation activity and monitor, evaluate, and report the results of the activity in accordance with a schedule and in a format approved by the Department.

2. The current use and reasonably anticipated future use of sites shall be considered in making risk-based decisions including, but not limited to, the development of site conceptual exposure models, establishment of exposure points, and corrective actions. The reasonably anticipated future use of sites shall be determined based on factors such as: the current use of the site; zoning laws; comprehensive community master plans; population growth patterns and projections; accessibility of the site to existing infrastructure such as transportation and public utilities; site location in relation to urban, residential, commercial, industrial, agricultural, and recreational areas; Federal/State land use designation; historical or recent development patterns; and location of Wellhead Protection Areas.

3. UST owners or operators must take actions to prevent further releases, control fire and explosion hazards, and remove free product pursuant to the UST Control Regulations, R.61-92, Section 280.

B. Site Priority System, Risk Evaluation, and Corrective Action for Releases of Petroleum and Petroleum Products.

1. UST releases, regardless of its time of occurrence, shall be classified using this priority system.

a. Releases are placed in Classification 1 if any one of the following conditions exists:

(1) an emergency situation;

(2) a fire or explosion hazard;

(3) vapors or free product in a structure or utility;

(4) concentrations of chemicals of concern have been detected in a potable water supply or surface water supply intake;

(5) free product exists on surface water;

(6) chemicals of concern exist in surface water.

b. Releases are placed in Classification 2a if any one of the following conditions exists:

(1) a significant near term (zero to one year) threat to human health, safety, or sensitive environmental receptors;

(2) potable supply wells or surface water supply intakes are located less than one year ground-water travel distance downgradient of the source area.

c. Releases are placed in Classification 2b if any one of the following conditions exists:

(1) free product in a monitoring well measured at greater than one foot thickness;

(2) potable supply wells or surface water supply intakes are located less than 1000 feet downgradient of the source area (where ground-water velocity data is not available).

d. Releases are placed in Classification 3a if any one of the following conditions exists:

(1) a short term (one to two years) threat to human health, safety, or sensitive environmental receptors;

(2) potable supply wells or surface water supply intakes are located greater than one year and less than two years ground-water travel distance downgradient of the source area;

(3) sensitive habitats or surface water exist less than one year ground-water travel distance downgradient of the source area and the ground water discharges to the sensitive habitat or surface water.

e. Releases are placed in Classification 3b if any one of the following conditions exists:

(1) free product in a monitoring well measured at greater than 0.01 foot thickness and less than one foot thickness;

(2) concentrations of chemicals of concern above the risk-based screening levels have been detected in a non-potable water supply well;

(3) concentrations of chemicals of concern in surface soil (less than three feet below grade) in areas that are not paved;

(4) sensitive habitats or surface water used for contact recreation are less than 500 feet downgradient of the source area (where ground-water velocity and discharge location data are not available);

(5) the site is located in a sensitive hydrogeologic setting, determined based on the presence of fractured or carbonate bedrock hydraulically connected to the impacted aquifer;

(6) ground water is encountered less than 15 feet below grade and the site geology is predominantly sand or gravel.

f. Releases are placed in Classification 4a if any one of the following conditions exists:

(1) a long term (greater than two years) threat to human health, safety, or sensitive environmental receptors;

(2) potable supply wells or surface water supply intakes are located greater than two years and less than five years ground-water travel distance downgradient of the source area;

(3) non-potable supply wells are located less than one year ground water travel distance downgradient of the source area.

g. Releases are placed in Classification 4b if any one of the following conditions exists:

(1) free product exists as a sheen in any monitoring wells;

(2) non-potable supply wells are located less than 1000 feet downgradient of the source area (where ground-water velocity data is not available);

(3) the ground water is encountered less than 15 feet and the site geology is predominantly silt or clay.

h. Releases are placed in Classification 5 if any one of the following conditions exists:

(1) there is no demonstrable threat, but additional data are needed to show that there are no unacceptable risks posed by the site;

(2) assessment data for the site indicate concentrations of chemicals of concern are above the risk-based screening levels or site-specific target levels, as appropriate, and further assessment is needed;

(3) assessment data for the site indicate concentrations of chemicals of concern are below the risk-based screening levels or site-specific target levels, as appropriate, but the samples are determined to not be representative; therefore, further assessment is needed.

i. The Department or owner or operator may re-evaluate the priority of a release upon receipt of additional information. However, the Department shall make the final decision as to priority classification.

2. The following risk-based corrective action procedures shall be used for releases from USTs upon Department approval. Risk evaluations shall be performed in accordance with this regulation and applicable Department performance standards and criteria.

a. The information necessary for a Tier 1 evaluation includes, but is not limited to, the following:

(1) A review of historical records of site activities and past releases;

(2) Quantification of the concentrations of the chemicals of concern;

(3) Parameters necessary to utilize soil leachability models, if appropriate;

(4) Location of source(s) of chemicals of concern;

(5) Location of maximum concentrations of chemicals of concern in soil and ground water:

(6) Determination of regional or site-specific hydrogeologic conditions such as depth to ground water, ground-water flow direction, hydraulic gradient, ground-water flow velocity;

(7) Determination if the chemicals of concern in the soil will leach to ground water in excess of risk-based screening levels;

(8) Location of current and reasonable future receptors;

(9) Identification of potential significant transport and exposure pathways.

(10) Determination of current and reasonably anticipated future use of the property, ground water, surface water, and sensitive habitats where the release has occurred and the surrounding property.

(11) If an exposure is identified, concentrations of chemicals of concern measured at point(s) of exposure.

b. The UST owner or operator shall use the data collected as described in (a) to evaluate the risk presented by the release using the following Tier 1 evaluation method:

(1) Develop a site conceptual exposure model to identify all exposure pathways.

(a) Information about the facilities operations, the source of chemicals of concern, current and expected site conditions and/or land use, proximity to receptors, current and expected use of ground water, and human receptors is necessary to develop the model.

(b) Potential exposure pathways to be considered for evaluation based on the site conceptual model shall include: air inhalation, ground water ingestion, surficial soil ingestion, dermal contact, and subsurface soil leaching to ground water.

(c) A summary of all complete exposure pathways at a site shall be completed for current conditions and for reasonably anticipated future use if different from the current use.

(2) Use the site conceptual exposure model developed in (1) to identify the data required to quantify the exposure by estimating the dose for all complete pathways. In Tier 1, risk-based

screening levels for dermal contact, soil ingestion, and vapor inhalation pathways are based on a Carcinogenic Risk Limit of 10^6 and a Hazard Index of ≥ 1 for non-carcinogens unless a different risk level for a specific chemical of concern has been established by the Department. Risk-based screening levels for the soil leaching to ground water pathway shall be based on leaching models approved by the Department. Risk-based screening levels for ground water ingestion shall be based on maximum contaminant levels or other health based criteria for chemicals of concern without established maximum contaminant levels. For complete pathways other than the soil leaching to ground water and ground-water ingestion, risk-based screening levels shall be calculated based on the carcinogenic risk limit and the hazard quotient values stated in (2) above, published toxicity data and published reasonable maximum exposure values. The exposure factors used in the calculations shall be based on reasonable maximum exposure.

(3) Calculate the exposure for all identified complete pathways. The risk-based screening levels established by the Department for the chemicals of concern must be met at the exposure point(s). In Tier 1, the exposure point(s) and point(s) of compliance shall be located within the source area of the release or the area containing the highest concentrations of the chemicals of concern.

c. Representative concentrations of chemicals of concern in affected media are determined by the following:

(1) For ground water: the maximum concentrations of chemical of concerns obtained from last sampling event.

(2) For soil: the maximum concentrations of chemicals of concern obtained in the last sampling event for the ingestion, inhalation, and dermal contact pathway; and the average chemical of concern concentrations in the source area for the soil leaching to ground water pathway. To determine representative chemical of concern concentrations in the soil to be used in a leachability model, for each chemical of concern, the three soil samples with the highest non-zero concentration of chemicals of concern shall be averaged.

(3) For vapor: the maximum concentrations of chemicals of concern obtained in last sampling event.

d. If the concentrations of the chemical of concern at representative sample locations are below the Risk-Based Screening Levels, further assessment or cleanup may not be necessary, upon Department approval.

e. If the representative concentrations of chemical(s) of concern in the affected media are above the risk-based screening levels, the UST owner or operator shall conduct one or more of the following: interim remedial action; remedial action using the risk-based screening levels as target levels, as approved by the Department; other Department approved actions necessary to reduce risk; or further Tier evaluation. Further tier evaluation is warranted if: the site-specific target levels developed under further tier evaluation will be significantly different than the Tier 1 risk-based screening levels, the cost of remedial action to risk-based screening levels will likely be greater than further tier evaluation and subsequent remedial action, or the approach or assumptions, used to derive the current tier's goals are not appropriate for conditions at the site.

f. If a Tier 2 assessment is warranted, the UST owner or operator shall perform a Tier 2 assessment in accordance with this regulation and applicable Department criteria. Additional site assessment for a Tier 2 evaluation may include, but is not limited to: determination of site-specific hydrogeologic conditions; determination of horizontal and vertical extent of chemicals of concern relative to the Risk-Based Screening Levels, as appropriate; determination of changes in concentrations of chemicals of concern over time; determination of concentrations of chemicals of concern measured at exposure points; and, fate and transport evaluation to predict the attenuation of the chemicals of concern away from the source area.

g. The UST owner or operator shall use the data collected as described in (f) to evaluate the risk presented by the release using the following Tier 2 evaluation:

(1) Establish the exposure point. The most likely point of exposure closest to the source area shall be established as the exposure point for each complete pathway identified.

(2) For the ground-water ingestion pathway, the exposure point shall be established based on the current and reasonably anticipated future use of the ground water.

(a) If the ground water at a site is a current source of drinking water, or is reasonably anticipated to be utilized, the exposure point shall be established in the source area of the release or the area with the highest concentrations of chemicals of concern.

(b) If the ground water at a site is not currently used as a source of drinking water, or is not reasonably anticipated to be utilized, the exposure point shall be located hydraulically upgradient of the nearest receptor or the first ground water hydraulically downgradient of the site reasonably anticipated to be utilized.

(c) If the site is located within a designated Wellhead Protection Area, the exposure point(s) shall be established to prevent concentrations of chemical(s) of concern from exceeding maximum contaminant levels in the drinking water well.

(3) Establish a site-specific target level for each chemical of concern identified at the site which exceeds it's risk-based screening level. A site-specific target level shall be established for each complete pathway identified that calculates an acceptable source area concentration so that risk-based screening levels are not exceeded at the point(s) of exposure.

(a) For the ground-water exposure pathway, the reduction of chemicals of concern in the saturated zone shall be estimated using either empirical data or models approved by the Department and implemented with site-specific data. Empirical data can be used to estimate the overall concentration reduction factor of the chemicals of concern in the relevant media from the source to the exposure point. Models can also be used to estimate the fate and transport of the chemicals of concern away from the source area.

(b) For the soil leaching to ground water pathway, the site-specific target level for each chemical of concern in soil shall be calculated using leachability models approved by the Department.

(c) Site-specific target levels for the dermal contact, soil ingestion, and vapor inhalation pathways shall be based on a Carcinogenic Risk Limit of 10^{6} and a Hazard Index of ≥ 1 for non-carcinogens to be applied at the exposure point unless a different risk level for a specific chemical of concern has been established by the Department. Department approved less conservative exposure factors may be used in the calculations for commercial and industrial scenarios. Site-specific exposure factors or most likely or average exposure factors may be used, as appropriate.

(4) Establish the point(s) of compliance. The point(s) of compliance shall be established hydraulically downgradient of the source area and hydraulically upgradient of an exposure point. At least one point of compliance must be located directly downgradient of the source area between the source area and the exposure point for each complete pathway. A minimum of one year travel time for the chemicals of concern from the point of compliance to the exposure point shall be established where possible. Additional point(s) of compliance are necessary where complex hydrogeologic conditions exist that may control chemical of concern migration.

h. If the concentrations of the chemicals of concern are below their site-specific target levels, the UST owner or operator shall submit a corrective action plan proposing a monitoring program to verify intrinsic remediation.

i. If representative concentrations of chemical(s) of concern in the affected media are above the site-specific target levels, the UST owner or operator shall conduct one or more of the following: interim remedial action; remedial action using the site-specific target levels, as approved by the Department; other Department approved actions necessary to reduce risk; or further Tier evaluation. Further tier evaluation is warranted if: the site-specific target levels developed under further tier evaluation will be significantly different than the Tier 2 site-specific target levels; the cost of remedial action to site-specific target levels will likely be greater than further tier evaluation and subsequent remedial action; or the approach or assumptions, used to derive the current tier's goals are not appropriate for conditions at the site.

j. If further Tier evaluation is warranted, the UST owner or operator shall perform a Tier 3 assessment to collect additional appropriate site-specific data to evaluate the risk presented by the release for a Tier 3 evaluation.

k. Based on the results of the Tier 3 evaluation, the owner or operator shall perform the appropriate action as approved by the Department based on the following:

(1) If the concentrations of the chemicals of concern are below the site-specific target levels, the UST owner or operator shall develop a corrective action plan proposing a monitoring program to verify intrinsic remediation.

(2) If the concentrations of the chemicals of concern are above the site-specific target levels, the UST owner or operator shall develop a corrective action plan which shall include active cleanup which may include intrinsic remediation as a component.

3. Corrective Action.

a. The UST owner or operator shall develop and implement a Department approved corrective action plan for each release to achieve risk-based screening levels or site-specific target levels established under the risk-based corrective action procedures. The corrective action plan shall include a schedule for implementation and for achieving risk-based screening levels or site-specific target levels. The corrective action plan must be developed and implemented in accordance with R.61-92 including procedures for Department approval and public notice. Any selected corrective action alternative funded by the SUPERB Account shall be a reasonable, cost-effective response for soil and/or ground-water contamination. In evaluating the cost effectiveness of proposed action, the UST owner or operator shall take into account the total short and long-term costs of such action, including the costs of operation and maintenance for the entire period during which such activities will be required.

b. The UST owner or operator and the Department shall encourage the use of innovative treatment technologies, where appropriate.

c. The Department shall require monitoring, evaluation, and reporting of corrective actions to evaluate whether the corrective action is efficient and cost effective.

d. UST owners or operators shall implement modifications to the corrective action, as required by the Department, to increase efficiency and cost effectiveness.

e. Once the Department agrees that monitoring data supports the conclusion that: the risk-based screening levels or site-specific target levels have been met; the chemicals of concern have reached equilibrium or are not moving at a significant rate; concentrations of chemicals of concern are not increasing, no unacceptable risk to human health, safety, or the environment exists, and that concentrations of chemicals of concern will not exceed risk-based screening levels at the exposure point or receptor, the Department may issue a decision that further site rehabilitation is not necessary. These shall be conditional no further action decisions based on site-specific conditions and the current or reasonably anticipated future use of the site. The assumptions and conditions shall be outlined in writing. The Department shall maintain a registry of releases having conditional no further action decisions.

f. The Department approval of a corrective action plan or issuance of a conditional decision that further site rehabilitation is not necessary shall be considered an order of the Department enforceable pursuant to the 1976 Code Section 44-2-140. The UST owner or operator shall not undertake any actions that result in an increase in risk of exposure to the chemicals of concern including modification of the current or reasonably anticipated future use of the site without Department approval. The SUPERB Account shall not be responsible for funding further site rehabilitation as a result of an increase in risk under these conditions unless a variance to this provision is granted by the Department.

g. The Underground Storage Tank Program shall coordinate, on behalf of the owner or operator, all Department permits associated with implementation of a corrective action plan.

4. Variances. The Department may issue a variance to this Section, when, in its opinion, the UST owner or operator has demonstrated that an equivalent degree of protection will be provided to human health and the environment. Any variance granted or denied by the Department shall be in writing and shall contain a brief statement of the reasons for the approval or denial.

SECTION III. SUPERB Fund Requirements.

1. Site Rehabilitation Application.

a. A UST owner or operator requesting monies from the SUPERB Fund shall submit to the Department a written application on a form provided by the Department. The written application shall include certification that:

(1) The chemicals of concern resulted from a release from a UST, including supporting documentation.

(2) Site rehabilitation is necessary.

(3) The USTs at the site have been registered in compliance with applicable UST laws and regulations.

(4) The UST registration fees have been paid.

b. The Department shall accept certification that the site is in need of rehabilitation if the certification is provided jointly by the UST owner or operator and a South Carolina registered professional geologist or engineer, and if reasonably supported by geotechnical data and information documenting the site investigation and assessment activities performed.

c. The application shall also include:

(1) a description of all abatement actions taken in response to the release pursuant to Regulation 61-92, and

(2) a notarized statement confirming the existence or absence of environmental liability insurance for the site that covers site rehabilitation activities in response to a UST release.

d. For denied applications, the Department shall provide written notice of its findings to the applicant, including detailed reasons for denial. The Department shall deny application for reasons including, but not limited to, the following:

(1) where the application is incomplete;

(2) where, in the opinion of the Department, the application is not reasonably supported by geotechnical data;

(3) where, in the opinion of the Department, the available information documents that site rehabilitation is not appropriate.

e. For approved applications, the Department shall respond in writing confirming the relative priority of the site as described in this section and provide general directives.

2. The Department shall provide access to the SUPERB Fund shall based on the priority classification system.

3. General Requirements.

a. UST owners or operators or site rehabilitation contractors may not propose or invoice costs to the SUPERB fund above reasonable, usual and customary costs.

b. Reimbursement for site rehabilitation activities shall in no event exceed the actual costs incurred by the UST owner or operator.

c. The Department shall not process incomplete invoices or invoices which are not supported by site rehabilitation reports and/or technical data.

d. The Department may withhold taking action on an application for monies during pendency of an enforcement action by the state or federal government related to the UST or a release from the UST.

e. The Department may deny or reduce payment for reported costs for failure by the UST owner or operator or site rehabilitation contractor to substantially comply with applicable statutory or regulatory requirements, including the provisions of this regulation, the SUPERB Act, or the Underground Storage Tank Control Regulations.

f. The Department may conduct an audit to assure compliance with this regulation. Audits will include, but not be limited to, determining that:

(1) funds were expended in a manner consistent with that reported to the Department;

(2) all necessary information needed to determine that costs represented were actually incurred.

g. Any funds paid to UST owner or operator or site rehabilitation contractor which are disallowed in accordance with this regulation shall be considered a debt to the fund. In addition to requiring repayment, the Department shall have the authority to offset any incorrect payment against other invoices for that or other releases for the same person. If no ability to offset exists and

a debt is not paid within ninety (90) days after demand, the State may take other actions permitted by law and this regulation.

h. Any proceeds gained from the sale or salvage of site rehabilitation equipment purchased with SUPERB funds shall be returned to the SUPERB fund.

i. The Department reserves the right to arrange to have any equipment appraised for determination of fair market or salvage value. The cost of the appraisal shall be paid from the SUPERB Account.

j. The Department shall develop criteria for the following:

(1) the minimum supporting technical and financial documentation for proposed or performed site rehabilitation activities;

(2) a maximum frequency of billing;

(3) a minimum invoice amount unless it is the final invoice for an approved site rehabilitation activity;

(4) retainer amounts;

(5) requirements for processing final invoices; and

(6) procedures for processing technical and financial changes associated with administration of the fund.

k. In developing and periodically updating the performance standards and criteria, the department shall make public notice and receive and consider public comments.

l. A UST owner or operator or site rehabilitation contractor shall provide proposed costs and documentation of incurred costs for site rehabilitation activities in accordance with applicable Department performance standards and criteria and on forms provided by the Department.

4. Site Rehabilitation Payments.

a. The Department shall establish and periodically update reasonable, usual and customary costs and activities based on the Department's experience and industry-typical costs after sufficient public notice and consideration of public comments. These may include, but not be limited to the following:

(1) costs for site rehabilitation activities as authorized in this section;

(2) personnel and equipment categories;

(3) definitions, payment rates, and duration of activities, where appropriate, for categories that are commonly used in site rehabilitation activities; and

(4) the requirements for competitive pricing for site rehabilitation activities and equipment, where necessary;

b. Reasonable, usual and customary costs, established in paragraph (a), above, are payable from the SUPERB fund for activities including, but not limited to, the following:

(1) recovery, storage, sampling, treatment, and proper disposal of released petroleum, petroleum products and/or petroleum/water mixtures;

(2) storage, sampling (to determine the method of disposal), and proper disposal of soils containing chemicals of concern;

(3) boreholes with associated soil sampling and chemical analysis as required by the Department to assess the extent of chemicals of concern in the soil;

(4) boreholes with associated ground-water sampling and chemical analyses, installation and sampling of temporary and permanent monitoring wells to assess the extent and severity of chemicals of concern in the ground-water;

(5) installation and sampling of recovery wells;

(6) hydrogeologic evaluation;

(7) preparation and submittal of assessment plans, assessment reports, corrective action plans, and mixing zone applications;

(8) routine ground-water monitoring and reporting as approved by the Department;

(9) construction, operation, and maintenance of a treatment system specifically constructed for site rehabilitation, or;

(10) treatment, associated sampling, and proper disposal of petroleum or petroleum product contaminated ground water as required;

(11) plans for termination of site rehabilitation activities.

c. Activities that are not payable from the SUPERB fund include, but are not limited to, the following:

(1) UST system replacement, UST system removal, UST system upgrade, UST system testing, UST closure and other assessments to determine if a release has occurred;

(2) actions taken to stop the UST from leaking;

(3) the investigation and cleanup of any release other than a release of petroleum or petroleum products from a UST;

(4) loss of product;

(5) payment of liability claims against the owners or operators of a UST;

(6) legal fees;

(7) loss of revenue;

(8) loss of trees, shrubs, or signs;

(9) overnight or express mail costs for plans, reports, and assorted paper documentation;

(10) costs related to unnecessary environmental permits;

(11) costs incurred to prepare and implement plans and reports that are not technically warranted or do not substantially address the Department's performance standards;

(12) costs incurred in general consultation with the Department or the UST owner or operator regarding plan or cost preparation;

(13) costs associated with the replacement of capital expense items which have been lost, stolen, or damaged by acts of vandalism and/or natural disasters;

(14) handling fees, markups, commissions, percentages or other similar considerations on any activity furnished or completed by any entity which has a familial or financial relationship and/or related interest to the property owner, UST owner or operator, or site rehabilitation contractor.

(15) costs incurred for unnecessary or inappropriate site rehabilitation activities.

5. SUPERB Eligibility Appeals. A UST owner or operator shall be granted a hearing by an independent hearing officer to appeal a denial of SUPERB eligibility, if requested in writing within 15 days of receipt of the letter denying SUPERB eligibility.

6. Invoice Review.

a. A UST owner or operator or a site rehabilitation contractor may seek a review of a staff decision by the UST Program Director regarding an invoice for which the Department denies payment. Requests for review shall be submitted to the Department within thirty (30) days of the date of receipt of Department correspondence that denies the invoice. Requests for reviews shall be in accordance with a Department established format.

b. The UST Program Director shall review all requests for review described in (a) above and provide a written determination thereto within forty-five (45) days.

7. Cost Recovery.

a. When the Department is required to perform site rehabilitation through its own personnel or contractors, the Department shall diligently seek cost recovery of any cost incurred as authorized by the SUPERB Act.

b. For sites that do not qualify for SUPERB eligibility,but for which SUPERB funds have been expended by the Department, the Department shall recover all expenditures from the owner or operator, as appropriate. This may include, but not be limited to:

(1) all materials and labor;

(2) all contractual costs; and

(3) all actual administrative costs incurred by the Department to conduct site rehabilitation activities and to secure cost recovery.

c. For sites that qualify for SUPERB monies but where the owner or operator is unable or unwilling to perform site rehabilitation, the Department may recover from the SUPERB Account. For site rehabilitation activities or costs not covered by the SUPERB Act, the Department may recover, as appropriate, from the owner or operator:

(1) all materials and labor;

(2) all contractual costs; and

(3) all actual administrative costs incurred by the Department to conduct site rehabilitation activities and to secure cost recovery.

d. Cost recovery shall be in addition to any fines imposed by the Department pursuant to the SUPERB Act.

SECTION IV. Certification of Site Rehabilitation Contractors.

A. Certification Requirements.

1. Applicability. This section applies to contractors or subcontractors who directly or indirectly participate in site rehabilitation whether or not SUPERB funding has been or will be sought.

2. Within 120 days of regulation promulgation, site rehabilitation contractors who perform on-site work as a primary contractor under the SUPERB Act must be certified under this regulation. The Department will certify those site rehabilitation contractors that demonstrate sufficient experience and knowledge in performing site rehabilitation activities related to releases of regulated substances from underground storage tanks. Site rehabilitation contractors must maintain certification to perform site rehabilitation actions. Contractors providing off-site support services (e.g., analytical laboratories) are not required to be certified under this regulation. Class I sub-contractors are also required to be certified under this regulation. The primary contractor maintains responsibility for the quality of work performed by individuals or companies sub-contracted to them.

3. Classes of Certification. Site rehabilitation contractors shall be certified in one or both of the following classes:

a. Class I. Contractors performing work involving the collection and interpretation of investigative data; the evaluation of risk; and/or the design and implementation of corrective action plans.

b. Class II. Contractors performing work involving routine investigative activities (e.g., soil or ground water sampling, well installation, aquifer testing) where said activities do not require interpretation of the data and are performed in accordance with established regulatory or industry standards.

4. Qualifications. An applicant, which may be an individual or a company, shall be certified as a site rehabilitation contractor upon satisfaction of the requirements in 4.a or 4.b, as appropriate. For a company to become certified, a full-time permanent employee of that company must satisfy the requirements in 4.a or 4.b, as appropriate.

a. Applicants for a Class I certification must satisfy the following:

(1) registration as a Professional Engineer or Geologist in South Carolina including three years applicable experience in performing site rehabilitation activities related to releases of regulated substances from underground storage tanks.

b. Applicants for a Class II certification must satisfy the following:

(1) a minimum of three years applicable experience in performing site rehabilitation activities related to releases of regulated substances from underground storage tanks; and,

(2) any necessary South Carolina certification and/or license (e.g., Well Driller).

c. Applicants for either class shall maintain liability insurance coverage of the types and in the amounts described in the table below and shall provide certification to the Department of such coverage upon meeting the requirements of 4.a and/or 4.b. of this Section, and yearly thereafter.

Type of Policy	Limits of Liability
General Liability	$500,000 per occurrence $1,000,000 aggregate
Professional Liability	$500,000 per occurrence $1,000,000 aggregate
Pollution/Property Damage	$300,000

The contractor shall be required to indemnify the property owner, underground storage tank owner/operator and the State of South Carolina from and against all claims, damages, losses and expenses arising out of or resulting from activity conducted by the contractor, its agents, employees or subcontractors.

B. Public Notice and Certificate Issuance.

1. For new applications, a list of those contractors requesting certification shall be placed on public notice in the State Register each month and shall be open for comment for a period of thirty (30) days.

2. The Department shall issue a Certificate to any applicant who has satisfactorily met all the requirements of these rules. Certificates shall show the full name of the contractor, the date of certification, give a certification number, and be signed by a Department representative.

3. The Department shall publish a roster showing the names and places of business of all certified site rehabilitation contractors. Copies of this roster shall be provided to the public on request.

4. Each applicant for, or holder of, a certificate shall notify the Department at its office within thirty (30) days of any changes of address or telephone number.

5. Each applicant for, or holder of, a certificate shall notify the Department at its office within thirty (30) days of any changes that may affect qualification pursuant to Section IV.A.4 of this regulation.

6. Within thirty (30) days of receipt of information that may affect certification of an applicant for, or holder of, a certificate, the Department shall evaluate the current qualifications of the applicant or holder and make a determination as to certification per the requirements of this regulation.

C. General Requirements.

1. All plans, reports, invoices and other documents relating to site rehabilitation activities which have been prepared or approved by a certified contractor shall be signed by the certified contractor and bear his certification number.

2. The certification of a site rehabilitation contractor shall in no way establish liability or responsibility on the part of the Department or the State of South Carolina in regards to the services provided by the contractor or circumstances which may occur as a result of such services.

3. Except as permitted by this regulation, a UST owner or operator shall not knowingly allow the initiation, implementation or completion of site rehabilitation with a decertified or suspended contractor. A UST owner or operator may rely upon the certification of a contractor that it or its affiliates are not decertified or suspended from site rehabilitation, unless it knows that the certification is erroneous.

D. Use of Owner/Operator Personnel.

1. The use of an UST owner or operator's personnel and equipment in performing site rehabilitation activities must be approved by the Department.

a. Prior to commencing any site rehabilitation activities, the owner or operator shall make a demonstration to the satisfaction of the Department with respect to the capability of the owner or operator's personnel to perform the work in a manner which shall comply with § 44-2-50 of the SUPERB Act. Particular consideration shall be given to the background and experience of the personnel who will perform the work and their knowledge of the technical considerations necessary to perform the site rehabilitation; and

b. An owner or operator or his personnel who performs site rehabilitation activities is required to comply with the provisions of Section IV.A. of this regulation.

c. An owner or operator or his personnel desiring to perform site rehabilitation activities must satisfy the liability insurance requirements of IV.A.4.c. above, including indemnification of other property owners.

2. If the Department determines that an owner or operator cannot perform site rehabilitation in compliance with Section II.A of this regulation, the Department may require the owner or operator to obtain the services of a certified site rehabilitation contractor.

SECTION V. Suspension, Decertification, and Appeals.

A. Suspension and Decertification.

1. Effect of Action. Contractors who are suspended or decertified shall be excluded from performing site rehabilitation throughout the state for the period of their suspension or decertification. No UST owner or operator shall knowingly have any suspended or decertified contractors, including affiliates, perform site rehabilitation during such period or enter any agreement that would stipulate the suspended or decertified contractor perform site rehabilitation during such periods.

2. Suspension. Summary shall be for a temporary period pending the completion of an investigation or ensuing decertification or legal proceedings. The Department may impose summary suspension in egregious cases posing imminent harm to the environment or the public.

3. Decertification.

a. The Department may decertify a contractor performing or seeking to perform site rehabilitation in South Carolina when:

(1) the contractor fails to maintain qualification pursuant to Section IV.A.4;

(2) the contractor has had administrative or civil enforcement action under the provisions of this chapter taken against him within the last three years;

(3) the contractor has demonstrated repeated noncompliance with financial criteria established by the Department, to include, but not be limited to:

(a) submitting bills to the Department that are inconsistent with regulations, established criteria and/or general accounting principles;

(b) submitting duplicate or fraudulent bills to the Department;

(c) submitting bills to the Department for work not yet performed or equipment and materials not yet delivered or received; and

(d) failure to pay cost recovery requests from the Department (including disallowed costs and overpayment), provided the debt is uncontested by the debtor or if contested provided that the debtor's legal and administrative remedies have been exhausted.

(4) where a person has demonstrated repeated inability to perform site rehabilitation in accordance with performance standards and criteria developed by the Department and accepted industry standards to include, but not be limited to:

(a) deliberate failure to perform according to the specifications or within the schedule approved by the Department;

(b) a record of failure to perform or of unsatisfactory performance according to the terms of one or more site rehabilitation work plans; provided that failure to perform or unsatisfactory performance caused by acts beyond the control of the person shall not be considered a basis for decertification;

(5) any other cause that the Department determines to be so serious and compelling as to affect the ability of a contractor or subcontractor to perform site rehabilitation activities in a satisfactory manner, including decertification or similar action by another governmental entity.

4. Investigation. Information of a cause for decertification from any source shall be promptly reported to the Department by UST owners, operators, site rehabilitation contractors, or other persons. The Department will promptly investigate, and may issue a notice of proposed decertification.

5. Notice of Proposed Decertification. A decertification notice shall be issued to the contractor advising:

a. That decertification is being considered;

b. Of the reasons for the proposed decertification in terms sufficient to put the respondent on notice of the conduct or site rehabilitation activity upon which it is based;

c. Of the potential effect of decertification.

6. Opportunity For Review of Proposed Decertification. Within fifteen (15) days after receipt of the notice of proposed decertification, the contractor may submit in writing information and argument in opposition to the proposed decertification and notify the Department if a conference is desired. If such request is made, the contractor shall be afforded an opportunity to appear with a representative, and submit documentary evidence and other appropriate information.

7. Notice of Decertification.

a. The decision shall be made within forty-five (45) days after receipt of any information and argument submitted by the respondent, unless the Department extends the period for good cause.

b. The notice of the Department's decision shall specify the reason(s) for decertification; state the period of decertification; and advise that the decertification is effective for all UST site rehabilitation activities in the State except as provided for by this section.

c. If the Department decides not to impose decertification, the contractor shall be given prompt notice of that decision. A decision not to impose decertification shall be without prejudice to a subsequent imposition of decertification by the Department.

d. When in the best interest of the State or the Department, the Department may, at any time, settle a decertification or suspension action.

8. Period of Decertification.

a. Decertification shall be for a period commensurate with the seriousness of the cause(s). If a suspension precedes a decertification, the suspension period shall be considered in determining the decertification period.

b. Decertification should generally not exceed three (3) years. Where circumstances warrant, a longer period of decertification may be imposed.

c. The Department may extend an existing decertification for an additional period, if the Department determines that an extension is necessary to protect the public interest. However, a decertification may not be extended solely on the basis of the facts and circumstances upon which the initial decertification action was based.

9. Reversal of Decertification. The Department may reverse a decertification decision for reasons including, but not limited to:

a. newly discovered material evidence;

b. reversal of the conviction or civil judgement upon which the decertification was based;

c. bona fide change in ownership or management;

d. elimination of other causes for which the decertification was imposed; or

e. other reasons the Department deems appropriate.

10. Exceptions.

a. The Department may grant an exception permitting a decertified or suspended contractor to participate in a particular site rehabilitation activity upon prior notice and subsequent to a written determination by the Department stating the reason(s) for deviating from the requirements of this regulation. Exceptions shall be granted on a case by case basis.

b. UST owners or operators shall not renew or extend agreements to allow decertified or suspended contractors from continuing with site rehabilitation, except as provided in (a) above.

11. Failure to Adhere to Restrictions. Except as permitted by this regulation, a UST owner or operator shall not knowingly allow the initiation, implementation or completion of site rehabilitation with a decertified or suspended contractor. A UST owner or operator may rely upon the certification

of a contractor that it or its affiliates are not decertified or suspended from site rehabilitation, unless it knows that the certification is erroneous.

B. Appeals.

1. Any person that has been suspended or decertified shall have the right to appeal in accordance with the Administrative Procedures Act. Appeals shall be heard by an independent hearing officer.

61–101. Water Quality Certification.

A. GENERAL

1. This regulation establishes procedures and policies for implementing State water quality certification requirements of Section 401 of the Clean Water Act, 33 U.S.C. Section 1341.

2. Any applicant for a Federal license or permit to conduct any activity which during construction or operation may result in any discharge to navigable waters is required by Federal law to first obtain a certification from the Department. Potential applicants are encouraged to contact the Department prior to submitting an application. Federal law provides that no Federal license or permit is to be granted until such certification is obtained. Federal permits or licenses for which certification is required as determined by the Federal agency include but are not necessarily limited to:

(a) individual or general Federal permits issued pursuant to Section 404 of the Clean Water Act, 33 U.S.C. Section 1344.

(b) Federal permits issued pursuant to Sections 9 and 10 of the Federal River and Harbor Act, 33 U.S.C. Sections 401 and 403.

(c) permits or licenses issued by the Federal Energy Regulatory Commission, 16 U.S.C. Section 1791, et seq.

3. The Department may issue, deny, or revoke general certifications for categories of activities or for activities specified in Federal nationwide or general dredge and fill permits pursuant to Federal law or regulations. Such general certifications are subject to the same process as individual certifications.

4. Any certification issued by the Department shall specify where appropriate that any such discharge will comply with applicable provisions of Sections 301, 302, 303, 306, and 307 of the Federal Clean Water Act. If there is not an applicable effluent limit or standard under such sections,the Department will so certify. The Department shall also certify that there is reasonable assurance that the activity will be conducted in a manner which will not violate applicable water quality standards regulations. No certification will be issued if such assurance is not provided.

5. Any certification issued by the Department shall also set forth any limitations, conditions, or monitoring requirements necessary to assure maintenance of classified or existing water uses and standards and compliance with other requirements of these regulations or other appropriate requirements of State law.

6. The Department is required by Federal law to issue, deny, or waive certification for Federal licenses or permits within one (1) year of acceptance of a completed application unless processing of the application is suspended. If the Federal permitting or licensing agency suspends processing of the application on request by the applicant or the Department or of its own volition, suspension of processing of application for certification will also occur, unless specified otherwise in writing by the Department. Unless otherwise suspended or specified in this regulation, the Department shall issue a proposed decision on all applications within 180 days of acceptance or an application.

7. For Federal permits that require both a water quality certification and a coastal zone consistency certification, the coastal zone consistency certification determination shall be issued as a component of, and concurrently with, the water quality certification, according to the administrative procedures set forth in this regulation, and in accordance with the management policies of the S.C. Coastal Management Program and applicable laws and regulations. In these instances, the water quality certification will serve also as the coastal zone consistency certification.

8. The Department will not issue a separate 401 water quality certification for an activity which requires a direct permit for alteration of the critical area of the coastal zone pursuant to applicable

regulations governing issuance of permits for alteration of the critical area of the coastal zone. The Department will process permit applications pursuant to applicable regulations governing issuance of permits for alteration of the critical area of the coastal zone with coordination and input from appropriate staff regarding water quality impacts. The direct permit will serve as the 401 water quality certification for an associated Federal permit.

9. If an activity also requires a permit for construction in State navigable waters pursuant to applicable laws and regulations, the review for the water quality certification will consider issues of that permit and the Department will not issue a separate permit for construction in State navigable waters. The certification will serve as the permit.

B. DEFINITIONS

Other than those terms defined below, any term used in this regulation shall be the same as defined in Section 48-1-10 or Regulation 61-68 of the Code of Laws, 1976.

1. "Board" means the Board of the Department of Health and Environmental Control.

2. "Certification" means certification as required under Section 401 of the Clean Water Act, 33 U.S.C. Section 1341.

3. "Commissioner" means the Commissioner of the Department of Health and Environmental Control.

4. "Department" means the Department of Health and Environmental Control.

C. APPLICATIONS

1. Any applicant for certification needed for a Federal license or permit must present a complete application to the Department in a manner specified by the Department. Federal application forms or forms provided by the Department will be accepted. Upon receipt of an application, the Department may require additional information to make the application complete. The Department will accept a public notice issued by the Federal permitting or licensing agency as application for certification if it contains sufficient information. Generally, the date of receipt of the public notice will be considered the date of application for certification. As a minimum the application must contain the following information:

(a) the name, address, phone numbers, principal place of business of the applicant and, if applicable, the name and address of the agent for the applicant.

(b) a complete description of the proposed permitted activity, including the location, affected waterbody(s), purpose, and intent of the project; maps, drawings, and plans sufficient for review purposes (detailed engineering plans are not required).

(c) a description of all proposed activities reasonably associated with the proposed permitted project either directly or indirectly, including planned or proposed future development that relate to water quality considerations.

(d) a description of the composition, source, and quantity of any material to be dredged or used as fill and a description of the area to be impacted, including the area of fill in acres.

(e) the method of dredging or filling and specific plans for disposal and control of dredge spoils.

(f) the names and addresses of adjacent property owners.

2. If the Department does not request additional information within ten (10) days of receipt of the application or joint public notice, the application will be deemed complete for processing; however, additional information may still be requested of the applicant within sixty (60) days of receipt of the application.

3. The Department may require the applicant to provide water quality monitoring data, water quality modelling results, or other environmental assessment related to factors in Article F.3 prior to accepting or processing the application and assessing the impacts of the proposed activity.

4. When the Department requests additional information it will specify a time for submittal of such information. If the information is not timely submitted and is necessary for reaching a certification decision, certification will be denied without prejudice or processing will be suspended upon notification to the applicant by the Department. Any subsequent resubmittal will be considered a new application.

D. PUBLIC NOTICE

1. Public notice is required of all applications for certification of Federal licenses or permits. When consistent with procedures herein and practical, joint public notice procedures with Federal or State agencies will be used to facilitate processing.

2. The public notice of application shall provide a reasonable period of time, normally thirty (30) days from the date of notice within which interested persons may submit their views and information concerning the certification application to the Department.

3. If the Department determines that an application is of a type that is routinely granted and the impacts are minor, the Department may reduce the notice period to fifteen (15) days. If the Department determines that an application involves a major activity, the notice period may be extended up to sixty (60) days from the date of the initial public notice.

4. Public notice of the application shall be by each of the following methods:

(a) by the Department's mailing a copy of the Notice of Application to:

1. the applicant.

2. any agency with jurisdiction over or interest in the activity or disposal site.

3. owners or residents of property adjoining the area of the proposed activity as identified in the application.

4. newspapers of local and statewide interest in the area.

5. any adjacent State agency of North Carolina or Georgia with jurisdiction over or interest in common waters affected by the proposed activity.

6. anyone who has specifically requested copies of public notices. The list of such person will be updated periodically and persons deleted who fail to respond to normal Department requests to identify continued interest. Nongovernmental interests out-of-state may be charged an annual fee of $25.00 for notices.

(b) by publication by the applicant of the Notice of Application in a newspaper of local or general circulation reasonably expected to cover the area affected by the activity. Such publication by the applicant shall contain sufficient information for the reader to understand the location, nature, and extent of the proposed activity and a contact for further information. The applicant shall provide the Department with an affidavit of publication from the newspaper within fifteen (15) days of publication.

(c) the Department will coordinate with other regulatory agencies and develop joint procedures for publication of notices of applications where feasible to minimize duplication.

E. PUBLIC HEARING

1. Any person may request a public informational hearing during the initial comment period discussed in Article D.2. and D.4. above. Requests shall be in writing and shall state the nature of the issues to be raised at the hearing.

2. The Department shall hold a public informational hearing whenever twenty (20) or more individual written requests are received during the public comment period and which raise water quality and classified use issues. A hearing may also be held whenever the Department staff determines that it may be useful in reaching a decision on an application. Such hearing will be conducted by Department staff personnel.

3. All public hearings shall be reported verbatim. A copy of the transcript shall be made available for public inspection.

4. The public comment period on an application will automatically be extended to fifteen (15) days past the date of the hearing. Further extensions may be granted at the discretion of the hearing officer.

5. The Department will coordinate with other regulatory agencies and conduct joint public hearings where feasible.

F. SCOPE OF REVIEW FOR APPLICATION DECISIONS

1. The Department shall prepare a written assessment on each proposed activity requiring a Federal license or permit. This assessment shall address the water quality impacts of the project and will make conclusions concerning compliance with water quality standards, protection of classified

uses, and related water quality impacts. Such assessment shall be available to the applicant and to the public upon request.

2. A certification shall be issued if the applicant has demonstrated that the project is consistent with the provisions of these regulations; the State Water Quality Standards, R. 61-68; and the Federal Clean Water Act, 33 U.S.C. 1341, and regulations promulgated thereunder by the U.S. Environmental Protection Agency.

3. In assessing the water quality impacts of the project, the Department will address and consider the following factors:

(a) whether the activity is water dependent and the intended purpose of the activity;

(b) whether there are feasible alternatives to the activity;

(c) all potential water quality impacts of the project, both direct and indirect, over the life of the project including:

(1) impact on existing and classified water uses;

(2) physical, chemical, and biological impacts, including cumulative impacts;

(3) the effect on circulation patterns and water movement;

(4) the cumulative impacts of the proposed activity and reasonably foreseeable similar activities of the applicant and others.

4. Certification of the activities listed below will be issued when there are no feasible alternatives. When issuing certification for such activities, the Department shall condition the certification upon compliance with all measures necessary to minimize adverse effects, including stormwater management. The Department shall issue proposed certification decisions on such applications within sixty (60) days of acceptance of the application unless otherwise suspended or in accordance with State permitting agency procedures. The Department will also attempt to issue general certifications for such activities.

(a) public boat ramps to enhance recreational use of waters.

(b) filling necessary for public highways or bridges.

(c) filling or disturbances to facilitate construction of electric transmission lines or other public utility crossings, including those of rural electric cooperatives.

(d) dredging and filling related to maintenance of Federal or State navigational channels and ports.

(e) activities utilizing Best Management Practices (BMP) which are part of an established ongoing farming, ranching, aquaculture, or silviculture operation.

(f) public water supplies.

5. Certification will be denied if:

(a) the proposed activity permanently alters the aquatic ecosystem in the vicinity of the project such that its functions and values are eliminated or impaired;

(b) there is a feasible alternative to the activity, which reduces adverse consequences on water quality and classified uses;

(c) the proposed activity adversely impacts waters containing State or Federally recognized rare, threatened, or endangered species;

(d) the proposed activity adversely impacts special or unique habitats, such as National Wild and Scenic Rivers, National Estuarine Research Reserves, or National Ecological Preserves, or designated State Scenic Rivers;

6. Certification will not be issued unless the Department is assured appropriate and practical steps including stormwater management will be taken to minimize adverse impacts on water quality and the aquatic ecosystem.

7. After-the-fact certifications will be reviewed under the same standards as normal applications; however, the Department may require restoration and/or other actions as a condition of certification. The applicant in such cases shall have the burden of proving the original baseline conditions, and certification may be denied in the absence of such proof.

G. NOTICE OF PROPOSED DECISIONS AND ADJUDICATORY HEARINGS FOR CERTIFICATIONS FOR FEDERAL LICENSES OR PERMITS

1. The Department shall issue a notice of proposed decision on application for certification, including any proposed conditions. Such notice shall advise of availability of the staff assessment and related file information. Such notice shall be mailed to:

(a) the applicant;

(b) agencies having jurisdiction or interest over the disposal site or activity site;

(c) owners or residents of property adjoining the area of the proposed activity; and

(d) those persons providing comment in response to the initial notice of application.

2. Persons with legal standing to contest the certification shall have rights to appeal the decision.

3. A person desiring to appeal a determination must submit a written request for an adjudicatory hearing within fifteen days of notice of the determination. The request must set forth the manner in which the person requesting the hearing would be injured by issuance of the certification. If no appeal of the proposed decision is timely received, the proposed decision of the Department shall become final.

4. Upon timely request for a hearing, the matter shall be heard as a "contested case" under the South Carolina Administrative Procedures Act, and shall be processed according to law. Determinations of whether a person has legal standing to contest a determination shall be made in the course of the contested case proceeding.

5. Appeals of a certification which include coastal zone consistency certification will be heard according to the above procedures unless the appeal is based exclusively on a coastal zone management issue. In that case the appeal will be heard according to the procedures for appeals of coastal zone consistency certifications.

6. Appeals of a certification included in the direct permit for alteration of the critical area of the coastal zone will be heard as part of that permit appeal according to the procedures for appeals of direct permits for alteration of the critical area of the coastal zone.

H. ENFORCEMENT OF CERTIFICATION DECISIONS AND CONDITIONS

1. Any certification condition is intended to become a condition of the Federal or State license or permit as specified in Federal or State law.

2. Certification conditions which are included as conditions of such license or permit are subject to enforcement mechanisms available to the Federal or State agency issuing the license or permit. Other mechanisms under State law may also be used to correct or prevent adverse water quality impacts from construction or operation of activities for which certification has been issued.

3. The Department may conduct inspections for determining compliance with certification conditions.

HISTORY: Added by State Register Volume 14, Issue No. 2, eff February 23, 1990; Amended by State Register Volume 19, Issue No. 6, eff June 23, 1995.

61–102. Standards for Licensing Birthing Centers for Deliveries by Midwives.

A. Definitions, Interpretations and Penalties

(1) Definitions:

For the purpose of these Standards, the following definitions shall apply:

(a) Administrator means the person who is delegated the responsibility for interpreting, implementing, and applying policies and programs established by the governing authority. He/she is delegated responsibility for the establishment of safe and effective administrative management, and the control and operation of the services provided.

(b) Birthing center means a facility or other place where human births are planned to occur. This does not include the usual residence of the mother or any facility which is licensed as a hospital or the private practice of a physician who attends the birth.

(c) Birthing room means a room and environment designed, equipped and arranged to provide for the care of a woman and newborn and to accommodate her support person(s) during the process of vaginal birth.

(d) Board means the South Carolina Board of Health and Environmental Control.

(e) Certified Nurse Midwife (CNM) means a person licensed by the South Carolina State Board of Nursing as a Registered Nurse with official recognition as a Certified Nurse Midwife.

(f) Clinical staff means the physicians, certified nurse midwives and lay midwives appointed by the governing authority to practice within the birthing center and governed by rules approved by the governing body.

(g) Department means the South Carolina Department of Health and Environmental Control (DHEC).

(h) Governing body means an individual or group which is legally responsible for the operation and maintenance of the birthing center.

(i) Lay Midwife means an individual so licensed by the Department.

(j) Licensing agency means DHEC.

(k) Low risk means normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health.

(*l*) Midwifery means the application of scientific principles in "with woman" care during uncomplicated pregnancy, birth, and puerperium including care of the newborn, support of the family unit, and gynecologic health care.

(m) Person means a natural individual, private or public organization, political subdivision, or other governmental agency.

(n) Personnel means individual(s) in training and/or employed by the birthing center.

(*o*) Physician means a doctor of medicine or osteopathy with training in obstetrics or midwifery and licensed by the South Carolina State Board of Medical Examiners to practice medicine.

(p) Recovery means that period or duration of time starting at birth and ending with the discharge of a client from the birthing center.

(q) Registered Nurse means a person licensed by the South Carolina State Board of Nursing as a registered nurse.

(2) Interpretations:

(a) No person shall establish, conduct or maintain a birthing center without first obtaining a license from the Department.

(b) The license shall be posted in a conspicuous place in a public lobby or waiting room. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of a facility. A license is not assignable or transferable and is subject to revocation by the Department for failure to comply with the laws and regulations of the State of South Carolina.

(c) Any birthing center which is in operation at the time of promulgation of these regulations shall be given a reasonable time, not to exceed one year from date of such promulgation, within which to comply with such regulations.

(d) Effective Date and Term of License: A license shall be effective for a 12-month period following the date of issue and shall expire one year following such date; however, a facility that has not been inspected during that year may continue to operate under its existing license until an inspection is made.

(e) Separate Licenses: Separate licenses are required for facilities not maintained on the same premises. Separate licenses may be issued for facilities maintained in separate buildings on the same premises.

(f) Licensing Fees: Each applicant shall pay an annual license fee prior to issuance of the license. The annual fee shall be $200.00.

(g) Inspections: Each facility submitting an application for licensing or re-licensing shall be inspected prior to initial licensure and at least annually by authorized representatives of the Department. All licensed and prospective licensed facilities are subject to inspection at any time. All facilities to which these requirements apply shall permit entrance to all properties and access to every area, object and records and reports by representatives of the Department.

(h) Initial License: A new facility or one that has not been continuously licensed under these Standards, shall not provide birthing center services until it has been issued an initial license. Section L sets forth the prerequisites for initial license.

(i) Noncompliance: When noncompliances with the Licensing Standards are detected, the applicant or licensee will be notified of the violations and at the same time requested to provide information as to how and when such items will be corrected. If an item of noncompliance is of a serious nature and is not promptly corrected, a penalty may be invoked or a license may be denied, suspended or revoked.

(j) Exceptions to Licensing Standards: The Department reserves the right to make exceptions to these Standards where it is determined that the health and welfare of the community requires the services of the facility and that the exception, as granted, will have no significant impact on the safety, security or welfare of the facility's occupants.

(k) Change of License: A facility shall request issuance of an amended license, by application to the Department, prior to any of the following circumstances:

(1) Change of ownership by purchase or lease.

(2) Change of facility's name or address.

(3) Addition or replacement of a birthing room or any part thereof.

(3) Penalties:

Facilities shall be subject to a penalty for violating Licensing Regulations. When the Department determines that a facility is in violation of any statutory provision, rule or regulation relating to the operation or maintenance of such facility, the following conditions shall apply:

(a) Class I violations are those which the Department determines present an imminent danger to the patients or other occupants of the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition, one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

(b) Class II violations are those, other than Class I violations, which the Department determines have a direct or immediate relationship to the health, safety or security of the facility's patients or other occupants. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

(c) Class III violations are those which are not classified as serious in these regulations or those which are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of said time shall be considered a subsequent violation.

(d) Class I and II violations are indicated by notation after each applicable section, e.g., (I) or (II). Violations of sections which are not annotated in that manner will be considered as Class III violations.

(e) The Department may deny, suspend, or revoke licenses or assess a monetary penalty for violations of provisions of law or departmental regulations. The Department shall exercise discretion in arriving at its decision to take any of these actions. The Department will consider the following factors: specific conditions and their impact or potential impact on health, safety or welfare; efforts by the facility to correct; overall conditions; history of compliance; any other pertinent conditions.

(f) If a decision is made to assess monetary penalties, the following schedule will be used as a guide to determine the dollar amount.

Frequency of violation of standard within a 24–month period	MONETARY PENALTY RANGES		
	Class I	Class II	Class III
1st	$ 200–1000	$ 100–$500	0
2nd	500–2000	200–1000	100–500
3rd	1000–5000	500–2000	200–1000
4th	5000	1000–5000	500–2000
5th	5000	5000	1000–5000
6th and more	5000	5000	5000

B. Licensing Procedures

(1) Application:

(a) Applicants for a license shall file applications under oath annually with the Department upon forms provided by the Department, and shall pay an annual license fee. The application shall set forth the following:

(1) Name, address, and telephone number of facility;

(2) Name and address of licensee;

(3) Names of all parties with at least five percent ownership;

(4) Name of governing authority;

(5) Name of chief executive officer;

(6) Numerical composition of nurse-midwives and support staff;

(7) Number of birthing rooms;

(8) Description of arrangements for emergency transportation of patients from the facility;

(9) Name of hospital(s) with which a transfer agreement has been made;

(10) Description of arrangements for obstetric and pediatric consultation and referral.

(b) The governing authority shall file application for a new facility or for the renewal of a license for an existing facility. Applications for a new facility or additional birthing rooms shall be submitted at least 30 days prior to opening.

(2) Requirements for Issuance of License:

(a) Upon receipt of an application for a license a representative of the Department shall make an inspection of that facility.

(b) When it is determined that the facility is in compliance with the requirements of these Standards, and a properly completed application and licensing fee have been received by the Department, a license shall be issued.

(c) No proposed facility shall be named nor may any existing facility have its name changed to the same or similar name as a facility licensed in the State. If it is part of a ''chain operation'' it shall then have the area in which it is located as part of its name.

(3) Termination of License: A license is not assignable or transferable and is subject to revocation at any time by the Department for failure to comply with laws and regulations of the State of South Carolina.

C. Governing Authority and Management

(1) General: Every facility shall be organized, equipped, manned and administered to provide adequate care for each person admitted.

(2) Governing Authority: The governing authority shall be the supreme authority responsible for the management control of the facility and shall develop a written set of bylaws or other appropriate policies and procedures for operation of the facility. These shall: (II)

(a) State the purpose of the facility;

(b) Specify by name the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the governing authority for holding such individual responsible;

(c) Provide for at least annual meetings of the governing authority;

(d) Provide for a policies and procedures manual which is designed to ensure professional and safe care for the patients to include but not limited to:

(1) admission criteria;

(2) extent of physician participation in the services offered;

(3) rights and responsibilities of patients;

(4) patient grievance procedures;

(5) infection control procedures;

(6) personnel training requirements;

(7) transfer of mothers who, during the course of pregnancy, labor, delivery or recovery, are determined to be ineligible for continued care;

(8) the use of IV's, food, fluids, analgesia/anesthesia, oxytocin, episiotomies, positions for delivery;

(9) provisions for the education of mother, family and others, as appropriate in birthing, newborn care, and maternal postpartum care.

(10) plans for follow-up of mother and infant after discharge from the center;

(11) plans for tests/treatments including, but not limited to, PKU, bilirubin, Rh factor, ophthalmic prophylaxis, and prophylaxis for neonatal hemorrhagic disease;

(12) plan for circumcision.

(e) Provide for annual reviews and evaluations of the facility's policies, procedures, management and operation.

(f) Provide for a facility-wide quality assurance program to evaluate the provision of patient care. The program shall be ongoing and have a written plan of implementation.

(3) Administrator: The chief administrative officer shall be selected by the governing authority and shall have charge of and be responsible for the management and administration of the facility in all its branches and departments and shall see that the bylaws and amendments thereto are complied with. Any change in the position of the chief administrative officer shall be reported immediately by the governing authority to the Department in writing. An individual shall be appointed to act in the absence of the administrator. (II)

(4) Administrative Records: The following essential documents and references shall be on file in the administrative office of the facility:

(a) appropriate documents showing control and ownership;

(b) bylaws, policies and procedures of the governing authority;

(c) minutes of the governing authority meetings if applicable;

(d) minutes of the facility's professional and administrative staff meetings;

(e) a current copy of these regulations;

(f) reports of inspections, reviews, and corrective actions taken related to licensure;

(g) contracts and agreements to which the facility is a party;

(h) a record of each accident or incident occurring in the facility.

(5) Personnel: Qualified personnel shall be employed in sufficient numbers to carry out the functions of the facility. The licensee shall obtain written applications for employment from all employees. Such applications shall contain accurate information as to education, training, experience, health and personal background of each employee. All applications for licensed personnel shall contain the South Carolina license number and/or current renewal number, if applicable. (II)

(a) All new employees who have contact with patients shall have a physical examination prior to employment, which shall include a tuberculin skin test, unless a previously positive reaction can be documented. The intradermal (Mantoux) method, using five tuberculin units of stabilized purified protein derivative (PPD) is recommended. (II)

(1) Employees with positive reactions to the pre-employment tuberculin test and those who are documented with previously positive reactions shall be given a chest x-ray to determine whether tuberculin disease is present. If tuberculosis is diagnosed, appropriate treatment should be given.

(2) Employees who complete treatment, either for disease or infection, may be exempt from further screening unless they have symptoms of tuberculosis.

(3) Positive reactors who are unable or unwilling to take preventive treatment need not receive an annual chest x-ray. These individuals shall be informed of their lifelong risk of developing and transmitting tuberculosis to individuals in the agency and in the community. They shall be informed of symptoms which may suggest the onset of tuberculosis, and of the procedure to follow in reporting suspect symptoms to a designated member of the agency staff.

(4) Employees with negative tuberculin skin tests shall have an annual tuberculin skin test.

(b) Personnel Records: A personnel record folder shall be maintained for each employee. The folder shall contain history and physicals, laboratory test results, resumes of training and experience, current job description that reflects the employee's responsibilities and work assignments, orientation and periodic evaluations. (II)

(c) Job Descriptions:

(1) Written job descriptions which adequately describe the duties of every position shall be maintained.

(2) Each job description shall include: position title, authority, specific responsibilities and minimum qualifications.

(3) Job descriptions shall be reviewed at least annually, kept current and given to each employee when assigned to the position and when revised.

(d) Orientation shall be provided to familiarize each new employee with the facility, its policies, and job responsibility.

(e) Continuing education must be provided to all non-clerical employees at least once a year. Inservice training may be provided by qualified facility staff.

(f) All professional personnel and clinical staff shall be certified in adult and neonatal American Red Cross CPR training.

(6) Emergency:

(a) All practicing and/or consulting physicians shall have admitting privileges at one or more hospitals with appropriate obstetrical services, or other arrangements approved by the Department for the transfer of emergency cases when hospitalization becomes necessary. (I)

(b) Equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital for both mother and infant. (I)

(c) The center shall enter into a signed written agreement with an ambulance service licensed in this state to ensure the immediate transfer of mothers and/or newborns in emergencies, where appropriate. (I)

(7) Client's Rights:

(a) The birthing center shall have written policies and procedures to assure the individual client the right to dignity, privacy, and safety. The policies and procedures shall be developed by the Director of Midwifery Services and the Director of Medical Affairs, if appropriate, and approved by the governing body.

(b) Each center shall display in a conspicuous place on the premises, a copy of the "Rights of Patients."

D. Professional Care

(1) Limitation of Services Offered by Birthing Center: (I)

In order to be delivered in a birthing center, the woman and/or her infant shall exhibit no evidence of:

(a) severe anemia;

(b) diabetes mellitus;

(c) symptomatic heart disease;

(d) severe hypertension or preeclampsia;

(e) renal disease;

(f) thrombophlebitis;

(g) multiple gestation;

(h) active herpes (within one week of delivery), syphilis, or HIV positive;

(i) placental abnormalities;

(j) premature labor;

(k) intrauterine growth retardation;

(*l*) fetal disease;

(m) previous caesarean delivery with classical incision;

(n) desire for transfer;

(*o*) anticipated macrosomia;

(p) breech birth;

(q) six or more (nonmiscarriage or nonabortion) pregnancies;

(r) polyhydramnios or oligohydramnios, or chorionitis;

(s) malformed fetus;

(t) any other high risk condition.

(2) Birthing Center Policies and Procedures: The facility shall formulate written policies and procedures which shall include, but not be limited to: (II)

(a) Informed consent which shall be obtained prior to the onset of labor and shall include evidence of an explanation by personnel of the birthing service offered and potential risks. Documentation of the informed consent must be filed in the patient's chart.

(b) Registration of birth and fetal death or death certificates.

(c) Infection control committee duties and responsibilities shall include the development and implementation of specific patient care and administrative policies aimed at investigating, controlling and preventing infections in the facility.

(d) Arrangements shall be made for all mothers to be screened for blood type and Rh factor. Those determined to be Rh negative shall have provision for appropriate follow-up studies both prenatally and at time of delivery in order to determine the need for Anti D Immune Globulin (Human) to prevent sensitization by the post partum mother. There shall be evidence of a plan for the appropriate use of Rh immune globulin.

(e) The physician or midwife shall, upon the birth of a child, instill or cause to be instilled in each eye of such newborn antibiotics of currently proven efficacy in preventing development of ophthalmia neonatorum. A maximum delay of one hour shall be allowed between the time of birth and the administration of an approved prophylactic agent.

(3) Pharmaceutical Services: (I)

(a) Written policies shall be established addressing the type and intended use of any drug to be used within the facility.

(b) There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration of drugs.

(c) There shall be written prescriptions or orders signed by a practitioner legally authorized to prescribe in South Carolina for all drugs administered to mother and infant within the birthing center.

(d) Drugs shall be administered by personnel or clinical staff currently licensed in South Carolina to administer drugs.

(e) Drugs, medications, and chemicals kept anywhere in the center shall be clearly labeled with drug name, strength, and expiration date.

(f) Drugs, medications, and chemicals shall be stored and secured in specifically designated cabinets, closets, drawers, or storerooms and made accessible only to authorized persons.

(g) Drugs requiring refrigeration shall be kept secure in a refrigerator under proper temperature. Each refrigerator shall be provided with a thermometer.

(4) Laboratory Services:

The center shall enter into a signed written agreement with a certified clinical laboratory to ensure accessibility to a full range of clinical laboratory testing, as may be required.

(5) Birthing Center Equipment and Supplies:

There shall be appropriate equipment and supplies maintained for the mother and the newborn to include but not limited to: (II)

(a) A bed suitable for labor, birth, and recovery;

(b) Oxygen with flow meters and masks or equivalent;

(c) Mechanical suction and bulb suction (immediately available);

(d) Resuscitation equipment to include resuscitation bags, endotracheal tubes and oral airways for the mother and newborn;

(e) Firm surfaces suitable for resuscitation;

(f) Emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn;

(g) Fetal monitoring equipment;

(h) A means of monitoring and maintaining the optimum body temperature of the newborn;

(i) A clock with a sweep second hand;

(j) Sterile suturing equipment and supplies;

(k) Adjustable examination light;

(*l*) Containers for soiled linen and waste materials which shall be closed;

(m) Refrigeration unit or units;

(n) Matching identification for the baby to the mother shall be provided.

(6) Clinical Staff:

(a) All clinical staff who practice in a facility shall be organized as a clinical staff with appropriate bylaws approved by the governing body. The clinical staff shall meet at least quarterly and minutes shall be maintained of such meetings.

(1) A physician must be on call and available to provide medical assistance at the birthing center at all times that it is serving the public. (I)

(2) A physician shall make a written determination that the planned birth is low risk. (I)

(3) The center shall enter into a signed written agreement with an obstetrician(s) and a pediatrician(s) to ensure their availability to the staff and mother at all times that it is serving the public. (I)

(b) The facility shall have an organized midwifery department under the supervision of a Director of Midwifery. (II)

(1) The Director of Midwifery shall be a certified nurse-midwife and be responsible and accountable for all midwifery service to include:

(a) delivery of midwifery services to patients;

(b) development and maintenance of midwifery service objectives, standards of midwifery practice, midwifery policy and procedure manuals (reviewed annually), written job descriptions for each type of midwifery personnel;

(c) coordination of midwifery services with other patient services;

(d) establishment of a means of assessing the midwifery care needs of patients and staffing to meet those needs;

(e) staff development.

(c) An adequate number of licensed and ancillary midwifery personnel shall be on duty to meet the total midwifery needs of patients. Midwifery personnel shall be assigned to duties consistent with their training and experience. (I)

(d) At least one member of the clinical staff or a registered nurse shall be in the facility when a patient is present; and up to at least one hour after each mother's delivery. Two members of the clinical staff or one member of the clinical staff and a registered nurse shall be present during the mother's delivery. (I)

(7) Medical Records: An accurate complete medical record shall be maintained for each patient.

(a) A legible medical record in ink shall include at least the following:

(1) admitting identification data including patient history and physical examination;

(2) signed consent;

(3) orders of physician or certified practitioner;

(4) laboratory tests;

(5) prenatal care record containing at least prenatal blood serology, Rh factor determination and obstetrical history and physical examination;

(6) labor and delivery record;

(7) records of anesthesia and analgesia and medication given in the course of labor, delivery and post partum;

(8) recovery and other progress notes;

(9) record of all medications and treatments ordered and administered;

(10) condition and referral on discharge.

(b) Records of newborn infants shall include in addition to the requirements for medical records the following information:

(1) date and hour of birth, birth weight and length, period of gestation, sex, condition of infant on delivery and APGAR rating;

(2) mother's name and patient number, and/or similar identification;

(3) record of opthalmic prophylaxis;

(4) record of administration of Rh immune globulin if any;

(5) appropriate physical examination at birth and at discharge;

(6) Test results and date specimen was collected for PKU and hypothyroid newborn screening test. (Exempt only when parents object because of religious convictions; then file copy of executed "Statement of Religious Objection Form," DHEC #1804 with newborn record.)

(c) Provisions shall be made by the facility for the storage of medical records in an environment which will prevent unauthorized access and deterioration. The records shall be treated as confidential and shall not be disposed of under 10 years. Records may be destroyed after 10 years provided that:

(1) Records of minors must be retained until after the expiration of the period of election following achievement of majority as prescribed by statute.

(2) The facility retains an index, register, or summary cards providing such basic information as dates of admission and discharge, name of responsible clinical staff, and record of diagnoses for all records so destroyed.

(d) Facilities that microfilm before 10 years have expired must film the entire record.

(e) In the event of change of ownership, all medical records shall be transferred to the new owners.

(f) Prior to the closing of a facility for any reason, the facility shall arrange for preservation of records to insure compliance with these regulations. The facility shall notify the Department, in writing, describing these arrangements.

(g) Information to be Provided to Other Health Care Providers. In order to contribute to the continuity of quality of care, procedures must be established and implemented to provide discharge summaries and/or other appropriate information to health care providers to whom patients are discharged, transferred or referred.

E. Functional Safety

(1) General:

(a) The governing authority shall develop written policies and procedures designed to enhance safety within the facility and on its grounds and to minimize hazards to patients, staff and visitors.

(b) The policies and procedures shall include: (II)

(1) safety rules and practices pertaining to personnel, equipment, gases, liquids, drugs, supplies and services;

(2) provisions for reporting and investigating accidental events regarding patients, visitors and personnel and corrective action taken;

(3) provisions for disseminating safety-related information to employees and users of the facility;

(4) provision of syringe and needle storage, handling and disposal.

(2) Maintenance:

(a) Facility Maintenance: A facility's structure, its component parts, and all equipment such as elevators, furnaces and emergency lights, shall be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. (II)

(b) Equipment Maintenance: A written preventive maintenance program for all patient monitoring equipment shall be developed and implemented. This equipment shall be checked and/or tested at such intervals to insure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before returning it to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance. (II)

(3) Disaster Preparedness:

(a) General:

(1) The facility shall have a posted plan for evacuation of patients, staff, and visitors in case of fire or other emergency. (II)

(2) A facility that participates in a community disaster plan shall establish plans, based on its capabilities, to meet its responsibilities for providing emergency care.

(b) Fire Drills: At least one drill shall be held every three months to familiarize all employees with the drill procedure. Reports of the drills shall be maintained. (II)

F. Infection Control and Sanitation

(1) General: The governing authority shall provide adequate space, equipment, and personnel to assure safe and aseptic treatment and protection of all patients and personnel against cross-infection. (II)

(2) Sterilization Procedures:

(a) Policies and procedures shall be established in writing for storage, maintenance and distribution of sterile supplies and equipment. (II)

(b) Sterile supplies and equipment shall not be mixed with unsterile supplies, and shall be stored in dust-proof and moisture-free units. They shall be properly labeled. (I)

(c) Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials. The sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be checked at

least quarterly by an approved method; periodic calibration and/or preventive maintenance shall be provided as necessary, and a log maintained. (II)

(d) The date of expiration shall be marked on all supplies sterilized in the facility. (I)

(3) Linen and Laundry:

(a) An adequate supply of clean linen or disposable materials shall be maintained. (II)

(b) Provisions for proper laundering of linen and washable goods shall be made. Soiled and clean linen shall be handled and stored separately. Storage shall be in covered containers. (II)

(c) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel can be used after each handwashing. Towels shall not be shared.

(4) Sanitation:

(a) All garbage and waste shall be collected, stored and disposed of in a manner designed to prevent the transmission of disease. Containers shall be washed and sanitized before being returned to work areas. Disposable type containers shall not be reused. (II)

(b) All contaminated dressings, pathological and/or similar waste shall be properly disposed of by incineration or other approved means. (I)

(5) Housekeeping: (II)

(a) General: A facility shall be kept neat, clean and free from odors. Accumulated waste material must be removed daily or more often if necessary. There must be frequent cleaning of floors, walls, ceilings, woodwork, and windows. The premises must be kept free from rodent and insect infestation. Bath and toilet facilities must be maintained in a clean and sanitary condition at all times.

(b) Cleaning materials and supplies shall be stored in a safe manner. All harmful agents shall be locked in a closet or cabinet used for this purpose only.

(c) Dry sweeping and dusting of walls and floors are prohibited.

(6) Refuse and Waste Disposal: (II)

(a) Containers for garbage and refuse shall be covered and stored outside and placed on an approved platform to prevent overturning by animals, the entrance of flies or the creation of a nuisance. All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect or other vermin problem.

(b) Immediately after emptying, containers for garbage shall be cleaned.

(7) Outside Areas: All outside areas, grounds and/or adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a fire hazard or as a haven for roaches, rodents and other pests. Outside stairs, walkways, ramps and porches shall be maintained free from accumulations of water, ice, snow and other impediments.

G. Dietary Services (II)

(1) General:

When the birthing center policy provides for allowing the preparation and/or storage of food, there shall be adequate means for maintaining cold foods at a temperature of 45 degrees Fahrenheit or lower; a microwave oven; and a dishwashing machine provided with hot water at a temperature of not less than 160 degrees Fahrenheit.

(2) Food Storage:

(a) Food shall not be stored together with medicines requiring refrigeration.

(b) All refrigerated food items shall be labeled and dated.

H. Design and Construction

(1) General: Every facility must be planned, designed and equipped to provide adequate facilities for the care and comfort of each patient.

(2) Local and State Codes and Standards: Facilities shall substantially comply with pertinent local and state laws, codes, ordinances and standards with reference to design and construction. Birthing Centers are a "business occupancy" as defined in the Standard Building Code. No facility will be licensed unless the Department has assurance that responsible local officials sanction the licensing of

the facility. The Department uses as its basic codes the Standard Building Code, the Standard Plumbing Code, the Standard Mechanical Code, and the National Electrical Code. Buildings designed in accordance with the above mentioned codes will be acceptable to the Department, provided, however, that the minimum requirements set forth in these standards are met. (II)

(3) Submission of Plans and Specifications:

(a) New Buildings, Additions or Major Alterations to Existing Buildings: When construction is contemplated either for new buildings, additions or major alterations to existing buildings, plans and specifications shall be submitted to the Department for review. Such plans and specifications shall be prepared by an architect registered in the State of South Carolina and shall bear his/her seal. These submissions shall be made in at least two stages: preliminary and final. All plans shall be drawn to scale with the title and date shown thereon. Construction work shall not be started until approval of the final drawings or written permission has been received from the Department. Any construction changes from the approved documents require approval by the Department. (II)

(b) Preliminary submission shall include the following:

(1) Plot plan showing size and shape of entire site; orientation and location of proposed building; location and description of any existing structures, adjacent streets, highways, sidewalks, railroads, et cetera, properly designated; size, characteristics and location of all existing public utilities, including information concerning water supply available for fire protection.

(2) Floor plans showing overall dimensions of buildings; locations, size and purpose of all rooms; location and size of doors, windows and other openings with swing of doors properly indicated; locations of smoke partitions and firewalls; locations of stairs, elevators, dumbwaiters, vertical shafts and chimneys.

(3) Outline specifications listing a general description of construction including interior finishes and mechanical systems.

(c) Final submission shall include the following: Complete working drawings and contract specifications, including layouts for plumbing, air conditioning, ventilation and electrical work and complete fire protection layout.

(d) In construction delayed for a period exceeding 12 months from the time of approval of final submission, a new evaluation and/or approval is required.

(e) One complete set of as built drawings shall be filed with DHEC.

(4) Licensure of Existing Structures: When an existing structure is contemplated for licensure as a new facility or as an expansion to an existing facility, the following submittals shall be made to the Department: (II) (All plans shall be neatly prepared and drawn to scale with the title and date shown thereon.)

(a) Plot plan in accordance with H.(3)(b)(1).

(b) Floor plan(s) in accordance with H.(3)(b)(2).

(c) Description of construction including outside walls, partitions, floor, ceiling and roof. The method of heating and cooling shall also be included.

(5) Minor Alterations in Licensed Facilities: When alterations are contemplated that may affect life safety, preliminary drawings and specifications, accompanied by a narrative completely describing the proposed work, shall be submitted to the Department for review and approval to insure that the proposed alterations comply with current safety and building standards.

(6) Location:

(a) Environment: The facility shall be located in an environment that is conducive to the type of care and services provided.

(b) Transportation: The facility must be served by roads which are passable at all times and are adequate for the volume of expected traffic.

(c) Parking: The facility shall have parking space to satisfy the minimum needs of patients, employees, staff and visitors.

(d) Communications: A telephone must be provided on each floor used by patients and additional telephones or extensions must be provided, as required, to summon help in case of fire or other emergency. Pay station telephones are not acceptable for this purpose.

(7) Physical Facilities:

(a) Birthing rooms shall have at least a gross floor space of 120 square feet with a minimum room dimension of 10 feet.

(b) Birthing rooms shall be located to provide unimpeded, rapid access to an exit of the building which will accommodate emergency transportation vehicles and equipment.

(c) Adequate fixed or portable work surface areas shall be maintained for use in each birthing room.

(d) Toilet and bathing facilities:

(1) A toilet and lavatory shall be provided in the immediate vicinity of the birthing room.

(2) A bathing facility shall be available for the mother's use.

(e) Doors providing access into the birthing center and birthing room(s) shall be at least 44 inches wide to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment. Hallways shall be at least 48 inches wide.

(f) Heating and ventilation:

(1) Lighting, heating, and ventilation systems shall comply with the local and state codes. There shall be approved equipment capable for maintaining a minimum temperature of 72 degrees Fahrenheit and a maximum temperature of 76 degrees Fahrenheit in patient areas.

(2) Mechanically operated systems shall be used to supply air to and exhaust air from soiled workrooms or soiled storage areas, janitor's closets, toilet rooms, and from spaces which are not provided with operable windows or outside doors.

(g) The entrance shall be at grade level or above, be sheltered from the weather and accommodate wheelchairs.

(h) Multipurpose room(s) shall be available for interviews, education, training, and other purposes.

(i) There shall be adequate general storage space for office, sterile supplies and other storage. There shall be a work counter for charting purposes.

(j) Sufficient janitor's closets shall be provided throughout the facility as required to maintain a clean and sanitary environment. Each shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

(k) A clean work area shall contain space for handwashing and clean storage and may include clean linen storage.

(*l*) There shall be at least two exits remote from each other.

(m) Items such as drinking fountains, machines, and portable equipment or any other items shall not be located in the required exit corridors to restrict corridor traffic.

(n) Thresholds and expansion joint covers shall be made sufficiently flush with the floor surface to accommodate wheeled service carts, wheelchairs, gurneys, etc.

(*o*) All corridor glazing materials that extend within 18 inches of the floor shall be of safety glass, plastic, wireglass, or other material that will resist breaking and will not create dangerous cutting edges when broken. Safety glass or plastic glazing materials shall be used for any shower doors or bath enclosures.

(p) Cubicle curtains and draperies shall be noncombustible or rendered flame retardant.

(q) Wall finishes shall be washable and, in the immediate area of plumbing fixtures, shall be smooth and moisture resistant.

(r) Wall bases in soiled equipment and material workrooms and other areas which are frequently subject to wet cleaning methods shall be tightly sealed and constructed without voids that can harbor insects.

(s) Floor and wall penetrations by pipes, ducts, and conduits shall be tightly sealed to minimize entry of rodents and insects. Joints of structural elements shall be similarly sealed.

(t) Interior finish materials shall comply with these flame spread limitations:

(1) Floor, walls, and ceilings in exit ways and storage rooms containing flammable storage materials and in other rooms of unusual fire hazard such as furnace rooms shall have a flame spread rating of 75 or less (ASTM Standard E84) and a smoke production rating of .45 watts or less.

(2) Building insulation materials, unless sealed on all sides and edges, shall have a flame spread rating of 25 or less and a smoke developed rating of 150 or less.

(u) A special unit or area for transitional care shall be provided for increased observation of the infant while stabilizing vital signs, i.e., respiration, temperature, and body weight, or for acute supportive care prior to transfer to referral facilities.

(v) Adequate space for the storage, handling and/or preparation of formulas.

(8) Water Supply and Plumbing:

(a) Water Supply: Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the facility and shall be adequate in volume and pressure for all purposes including fire fighting. (II)

(b) Plumbing:

(1) All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of the Standard Plumbing Code.

(2) All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies. (II)

(3) There shall be access to a sink with hot and cold running water with elbow/wrist controls.

I. Fire Protection and Prevention

(1) Fire Extinguishers, Standpipes, and Automatic Sprinklers: Fire-fighting equipment such as fire extinguishers, standpipes and automatic sprinklers shall be provided as required by the Standard Building Code. Extinguishers shall be sized, located, installed and maintained in accordance with NFPA No. 10. Suitable fire extinguishers shall also be installed in all hazardous areas. Each facility shall conform with all state and local fire and safety provisions. (II)

(2) Alarms: Where required, a manual fire alarm system in accordance with provisions of "Local Protective Signaling System," NFPA No. 72A, shall be provided. (II)

(3) Gases: Gases (flammable and nonflammable) shall be handled and stored in accordance with the provisions of applicable NFPA codes. (II)

J. Mechanical Requirements

(1) Emergency Electrical Power: The facility shall be equipped with an emergency power source. The emergency electrical power system shall be adequate to maintain the operation of lighting for egress, fire detection equipment, and alarms. (I)

(2) Lighting and Electrical Services: There shall be sufficient safe lighting for individual activities, including suitable lighting for corridors and baths. Lighting in work area shall not be less than 50 foot candles. (II)

K. General: Conditions arising which have not been covered in these regulations shall be handled in accordance with the best practices as interpreted by the Department.

L. Prerequisites for Initial Licensure. Prior to admission of patients to, and issuance of a license for new facilities or additional stations, the following actions must be accomplished and documentation furnished at the final inspection:

(1) Plans and construction must be approved by the Division of Health Facilities Construction, DHEC.

(2) The facility shall submit a completed Application for License on forms which shall be furnished by the Division of Health Licensing. The following documents shall be submitted with the application:

(a) Final construction approval of both water and wastewater systems by the appropriate District Environmental Quality Control Office of DHEC. (Includes satisfactory laboratory reports of water samples taken by the local office of Environmental Quality Control.)

(b) Approval from appropriate building official stating that all applicable local codes and ordinances have been complied with.

(1) If the facility is located within town or city limits, approval by the local fire chief stating that all applicable requirements have been met, or

(2) If the facility is located outside town or city limits, a written agreement with the nearest fire department that will provide protection and respond in case of fire at the facility.

(c) Certification and laboratory test reports, provided by the manufacturer or supplier, that all carpeting purchased by the facility has been tested under

(1) ASTM E-84 and has a flame spread rating of not more than 75, or

(2) ASTM E-648 or NFPA No. 253 with a rating of not less than .45 watts/sq. cm.

(d) Certification by the contractor that only the carpeting described in (c) above was installed in the facility.

(e) Certification by the manufacturer or supplier that all drapes and cubicle curtains purchased by the facility are flame or fire resistant or retardant.

(f) Certification by the owner or contractor that only materials described in (e) above were installed.

(g) Certification by the manufacturer or supplier that all wall covering materials purchased by the facility are fire or flame resistant or retardant.

(h) Certification by the contractor that only the materials described in (g) above were installed.

(i) Certification by the engineer that all fire alarm and smoke detection systems have been installed according to plans and specifications, have been tested and operate satisfactorily.

(j) Certification by the contractor that the automatic sprinkler system has been completed and tested in accordance with the approved plans and specifications and NFPA No. 13. Include a copy of the approval letter of the sprinkler shop drawings.

(k) Certification that all medical gas systems have been properly installed and tested.

(*l*) For corporation-owned facilities, a list of all officers and their corporate titles.

(3) Resumes for the persons in charge of the day to day operation of the facility and midwifery services.

(4) Required personnel must be employed, available, trained and capable of performing their duties.

(5) The Division of Health Licensing shall inspect the facility and require compliance with these regulations.

(6) The facility must pay the required licensing fee.

HISTORY: Added by State Register Volume 15, Issue No. 5, eff May 24, 1991. Amended by State Register Volume 34, Issue No. 6, eff June 25, 2010.

61–103. Residential Treatment Facilities for Children and Adolescents.

(Statutory Authority: 1976 Code Section 44–7–260)

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SECTION 100. DEFINITIONS AND LICENSE REQUIREMENTS

101. Definitions

For the purpose of these standards, the following definitions shall apply:

A. Abuse. Physical abuse or psychological abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing to be inflicted physical injury on a resident by an act or failure to act. Physical abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that a therapeutic procedure prescribed by a licensed physician or other legally authorized healthcare professional or that is part of a written care plan by a physician or other legally authorized healthcare professional is not considered physical abuse. Physical abuse does not include altercations or acts of assault between residents.

2. Psychological Abuse. Deliberately subjecting a resident to threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Administrator. The individual designated by the governing body or licensee who is in charge of and responsible for the administration of the facility.

C. Airborne Infection Isolation (AII). A room designed to maintain Airborne Infection Isolation (AII), formerly called a negative pressure isolation room. An Airborne Infection Isolation (AII) room is a single-occupancy resident-care room used to isolate persons with suspected or confirmed infectious tuberculosis (TB) disease. Environmental factors are controlled in Airborne Infection Isolation (AII) rooms to minimize the transmission of infectious agents that are usually spread from person-to-person by droplet nuclei associated with coughing or aerosolization of contaminated fluids. Airborne Infection Isolation (AII) rooms may provide negative pressure in the room (so that air flows under the door gap into the room), an air flow rate of six to twelve (6 to 12) air changes per hour (ACH), and direct exhaust of air from the room to the outside of the building or recirculation of air through a high efficiency particulate air (HEPA) filter.

D. Annual. A time period that required an activity to be performed at least every twelve (12) months.

E. Assessment. A procedure for determining the nature and extent of the problem(s) and needs of a resident or prospective resident to ascertain if the facility can adequately address those problems, meet those needs, and to secure information for use in the development of the treatment plan. Included in the process is an evaluation of the physical, psychiatric, psychological, developmental, social, nursing, educational, vocational, recreational, and legal status and/or needs of a resident or prospective resident. Consideration of each resident's needs, strengths, and weaknesses shall be included in the assessment.

F. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific treatments, care, or services to residents, such as an advanced practice registered nurse or physician assistant.

G. Blood Assay for *Mycobacterium tuberculosis* (BAMT). A general term to refer to *in vitro* diagnostic tests that assess for the presence of tuberculosis (TB) infection with *M. tuberculosis*. This term includes, but is not limited to, IFN-*y* release assays (IGRA).

H. Child, Adolescent, or Young Adult. An individual who is at least one (1) year of age but under twenty-one (21) years of age.

I. Consultation. A visit by Department representative(s) who will provide information to the licensee with the goal of facilitating compliance with these regulations.

J. Contact Investigation. Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent TB Infection (LTBI) or TB disease, and treatment of these persons, as indicated.

K. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, or V of the Federal Controlled Substances Act and the South Carolina Controlled Substances Act.

L. Department. The South Carolina Department of Health and Environmental Control (DHEC).

M. Designee. A staff member designated by the administrator to act on his or her behalf.

N. Dietitian. A person who is registered by or meets the requirements of the American Dietetic Association and has at least one (1) year of experience in clinical nutrition.

O. Direct Care Staff Member. The individual(s) who provide assistance to residents.

P. Discharge. The point at which residence in a facility is terminated and the facility no longer maintains active responsibility for the care of the resident.

Q. Dispensing Medication. The transfer or possession of one (1) or more doses of a medication or device by a licensed pharmacist or individual as permitted by law, to the ultimate consumer or his or her agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a resident.

R. Exploitation. 1) Causing or requiring a resident to engage in an activity or labor that is improper, unlawful, or against the reasonable and rational wishes of a resident. Exploitation does not include requiring a resident to participate in an activity or labor that is a part of a written care plan or prescribed or authorized by the resident's attending physician; 2) an improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a resident by an individual for the profit or advantage of that individual or another individual; or 3) causing a resident to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the resident through cunning arts or devices that delude the resident and cause him or her to lose money or other property.

S. Facility. A Residential Treatment Facility for Children and Adolescents licensed by the Department.

T. Health Assessment. An evaluation of the health status of a staff member by a physician, other authorized healthcare provider, or registered nurse, pursuant to written standing orders and/or protocol approved by a physician's signature. The standing orders or protocol shall be reviewed annually by the physician, with a copy maintained at the facility.

U. Incident. An unusual unexpected adverse event resulting in harm, injury, or death of staff or residents, accidents, such as medication errors, adverse medication reactions, or elopement of a resident.

V. Individual Treatment Plan (ITP). A documented regimen of appropriate care and/or services or written action plan prepared by the facility for each resident based on the resident's assessment, needs and preferences and which is to be implemented for the benefit of the resident.

W. Inspection. Specific scrutiny of a facility or prospective facility by a Department representative(s) for the purpose of determining compliance with this regulation. Inspections include, but are not limited to, plan reviews, construction inspections, and licensing inspections.

X. Investigation. A visit by a Department representative(s) to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

Y. Latent TB Infection (LTBI). Infection with *M. tuberculosis*. Persons with Latent TB Infection carry the organism that causes TB but do not have TB disease, are asymptomatic, and are noninfectious. Such persons usually have a positive reaction to the tuberculin skin test and/or positive BAMT.

Z. Legend Drug.

1. A drug when, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only"; or

2. A drug which is required by any applicable federal or state law to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only;

3. Any drug products considered to be a public health threat, after notice and public hearing as designated by the South Carolina Board of Pharmacy; or

4. Any prescribed compounded prescription drug within the meaning of the Pharmacy Act.

AA. License. The authorization to operate a facility as defined in this regulation and as evidence by a current certificate issued by the Department to a facility.

BB. Licensed Nurse. A person to whom the South Carolina Board of Nursing has issued a license as a registered nurse or licensed practical nurse or an individual licensed as a registered nurse or licensed practical nurse who resides in another state that has been granted multistate licensing privileges by the South Carolina Board of Nursing may practice nursing in any facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.

CC. Licensee. The individual, corporation, organization, or public entity that has been issued a license to provide care, treatment, and services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

DD. Local Transportation. The maximum travel distance the facility shall undertake, as addressed by the resident written agreement, to secure or provide healthcare for the resident. Local transportation shall be based on a reasonable assessment of the proximity of customary healthcare resources in the region, such as the nearest hospitals, physicians, or other healthcare providers, and appropriate consideration of resident preferences.

EE. Medication. A substance that has therapeutic effects, including, but not limited to, legend, nonlegend, herbal products, over-the-counter, nonprescription, vitamins, and nutritional supplements.

FF. Neglect. The failure or omission of a staff member to provide the care, goods, or services necessary to maintain the health or safety of a resident including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Failure to provide adequate supervision resulting in harm to residents, including altercations or acts of assault between residents, may constitute neglect. Neglect may be repeated conduct or a single incident that has produced or could result in physical or psychological harm or substantial risk of death. Noncompliance with regulatory standards alone does not constitute neglect.

GG. Nonlegend Drug. A drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws of this state and the federal government.

HH. Physical Examination. An examination of a resident by a physician or other authorized healthcare provider which addresses those issues identified in Section 1100 of this regulation.

II. Physician. An individual currently licensed to practice medicine by the South Carolina Board of Medical Examiners.

JJ. Physician Assistant. An individual currently licensed as such by the South Carolina Board of Medical Examiners.

KK. Quarterly. A time period that requires an activity to be performed at least four (4) times a year within intervals ranging from eighty-one to ninety-nine (81 to 99) days.

LL. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a thirty-six (36) month period. The time period determinant of repeat violation status is applicable in instances when there are ownership changes.

MM. Resident. Any individual who has been admitted for treatment in a residential treatment facility.

NN. Resident Room. An area enclosed by four (4) ceiling high walls that can house one (1) or more residents of the facility.

OO. Residential Treatment Facility for Children and Adolescents. A facility operated for the assessment, diagnosis, treatment, and care of two (2) or more children and/or adolescents in need of mental health treatment which provides:

1. An education program, including a program for students with disabilities, that meets all applicable federal and state requirements, as defined by the South Carolina Department of Education (SCDE). The education program may be provided at the facility, if appropriate space is available to provide a free appropriate public education in the least restrictive environment, or an alternate location;

2. Recreational facilities with an organized youth development program; and

3. Residential treatment for a child or adolescent in need of mental health treatment.

PP. Responsible Party. A person who is authorized by law to make decisions on behalf of a resident, to include, but not be limited to, a court-appointed guardian (or legal guardian as referred to in the Resident's Bill of Rights) or conservator, or healthcare or other durable power of attorney.

QQ. Restraint. Any means by which movement of a resident is inhibited, for example, physical, mechanical, or chemical. In addition, devices shall be considered a restraint if a resident is unable to easily release from the device.

RR. Revocation of License. An action by the Department to cancel or annul a facility license by recalling, withdrawing, or rescinding its authority to operate.

SS. Risk Assessment. An initial and ongoing evaluation of the risk for transmission of *M. tuberculosis* in a particular healthcare setting. To perform a risk assessment, the following factors shall be considered: the community rate of TB, number of TB residents encountered in the setting, and the speed with which residents with TB disease are suspected, isolated, and evaluated. The TB risk assessment determines the types of administrative and environmental controls and respiratory protection needed for a setting.

TT. Sponsor. The public agency or individual involved in one (1) or more of the following: protective custody authorized by law, placement, providing ongoing services, or assisting in providing services to a resident(s) consistent with the wishes of the resident or responsible party or specific administrative or court order.

UU. Staff Member. An adult, to include the administrator, who is a compensated employee or contract employee of the facility on either a full- or part-time basis.

VV. Suspension of License. An action by the Department requiring a facility to cease operations for a period of time or to require a facility to cease admitting residents, until such time as the Department rescinds that restriction.

WW. Volunteer. An adult who performs tasks at the facility at the direction of the administrator without compensation.

102. License Requirements (II)

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself by advertising or marketing, as a Residential Treatment Facility for Children and Adolescents in South Carolina without first obtaining a license from the Department. The facility shall not admit residents prior to the effective date of the license. When it has been determined by the Department that room, board, and a degree of personal care to two (2) or more children or adolescents unrelated to the owner is being provided at a location, and the owner has not been issued a license from the Department to provide such care, the owner shall cease operation immediately and ensure the safety, health, and well-being of the occupants. Current and/or previous violations of state law and/or Department regulations may jeopardize the issuance of a license for the facility or the licensing of any other facility, or addition to an existing facility which is owned and/or operated by the licensee. The facility shall provide only the care and services it is licensed to provide pursuant to the definition in Section 101.OO of this regulation. (I)

B. Compliance. An initial license shall not be issued to a proposed facility that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility or activity licensed by the Department makes application for another facility or increase in licensed bed capacity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or amended license to the existing facility. A copy of the

licensing standards shall be maintained at the facility and accessible to all staff members. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations.

C. Compliance with Structural Standards. Facilities licensed at the time of promulgation of these regulations shall be allowed to continue utilizing the previously-licensed structure without modification.

D. Licensed Bed Capacity. No facility that has been authorized to provide a set number of licensed beds, as identified on the face of the license, shall exceed the bed capacity. No facility shall establish new care or services or occupy additional beds or renovated space without first obtaining authorization from the Department. (I)

E. Persons Received in Excess of Licensed Bed Capacity. No facility shall receive for care or services persons in excess of the licensed bed capacity, except in cased of justified emergencies. (I)

EXCEPTION: In the event that the facility temporarily provides shelter for evacuees who have been displaced due to a disaster, then for the duration of that emergency, provided the health, safety, and well-being of all residents are not compromised, it is permissible to temporarily exceed the licensed capacity for the facility in order to accommodate these individuals (See Section 606).

F. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, services, personal safety, fire safety, or the well-being of any resident or occupant of a facility.

3. A license is not assignable or transferrable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this state.

4. A license shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but are not located on the same adjoining or contiguous property shall be separately licensed. Road or local streets, except limited access, such as interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property. Facilities owned by the same entity, separate licenses are not required for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

6. Multiple types of facilities on the same premises shall be licensed separately even if owned by the same entity.

G. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in South Carolina. The Department shall determine if names are similar. If the facility is part of a "chain operation," it shall have the geographic area in which it is located as part of its name.

H. Application. Applicants for license shall submit to the Department a complete and accurate application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application shall include both the applicant's oath assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; or in the case of a corporation, by two (2) of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction over it. The application shall set forth the full name and address of the facility for which the license is sought and of the owner(s) in the event his or her address is different from that of the facility, and the names of persons in control thereof. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or limited partnerships, limited liability companies, or any other organized business entity must be registered with the South Carolina Office of the Secretary of State if required to do so by state law.

I. Licensing Fees. The annual license fee shall be ten dollars ($10.00) per licensed bed or seventy-five dollars ($75.00), whichever is greater. Such fee shall be made payable by check or credit card to the Department and is not refundable. Fees for additional beds shall be prorated based upon the remaining months of the licensure years.

J. Late Fee. Failure to submit a renewal application or fee by the license expiration date may result in a late fee of seventy-five dollars ($75.00) or twenty-five percent (25%) of the licensing fee amount, whichever is greater, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time period specified by the Department may result in an enforcement action.

K. License Renewal. For a license to be renewed, applicants shall file an application with the Department, pay a license fee, and shall not be undergoing enforcement actions by the Department. If the license renewal is delayed due to enforcement actions, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department, or when the adjudicatory process is completed, whichever is applicable.

L. Change of License.

1. A facility shall request issuance of an amended license, by application to the Department, prior to any of the following circumstances:

a. Change of ownership by purchase or lease;

b. Change of licensed bed capacity; or

c. Change of facility location from one geographic site to another.

2. Changes in facility name or address, as notified by the post office, shall be accomplished by application or by letter from the licensee.

M. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where the Department determines the health, safety, and well-being of the residents are not compromised, and provided the standard is not specifically required by statute.

SECTION 200. ENFORCEMENT OF REGULATIONS

201. General

The Department shall utilize inspections, investigations, consultations, or other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

202. Inspections and Investigations

A. Inspections shall be conducted prior to initial licensing of a facility. The Department, at its own determination, may also conduct subsequent inspections. (I)

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the South Carolina Code of Laws. When staff members and/or residents are absent, the facility shall provide information to those seeking legitimate access to the facility, including visitors, as to the expected return of the staff members and/or residents. (I)

C. Individuals authorized by South Carolina law shall be allowed to enter the facility for the purpose of inspection and/or investigation and granted access to all properties and areas, objects, and records in a timely manner, and have the authority to require the facility to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or affect upon residents as determined by the inspector. (I)

D. A facility found noncompliant with the standards of this regulation or governing statute shall submit an acceptable written plan of correction to the Department that shall be signed by the Administrator and returned by the date specified by the Department. The written plan of correction shall describe: (II)

1. The actions taken to correct each cite deficiency;

2. The actions taken to prevent recurrences (actual and similar); and

3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the facility response, shall be provided to the public upon written request with the redaction of the names of those individuals in the reports as provided by S.C. Code Sections 44–7–310 and 44–7–315.

F. In accordance with S.C. Code Section 44–7–260, the Department may charge a fee for inspections. The fee for initial and biennial routine inspections shall be three hundred fifty dollars ($350.00) plus eight dollars ($8.00) per licensed bed. The fee for follow-up inspections shall be two hundred dollars ($200.00) plus eight dollars ($8.00) per licensed bed.

203. Consultations

Consultations shall be provided by the Department as requested by the facility or as deemed appropriate by the Department.

SECTION 300. ENFORCEMENT ACTIONS

301. General

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of a facility, the Department, upon proper notice to the licensee, may impose a monetary penalty, and deny, suspend, or revoke its license.

302. Violation Classifications

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health and safety of the persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition, one or more practices, means, methods, or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of persons in the facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, as "(I)" or "(II)." Sections not annotated in that manner denote Class III violations. A classification at the beginning of a section and/or subsection applies to all subsections following, unless otherwise indicated.

E. In arriving at a decision to take enforcement action, the Department will consider the following factors:

1. Specific conditions and their impact or potential impact on the health, safety, or well-being of the residents including, but not limited to: deficiencies in medication management, such as evidence that residents are not routinely receiving their prescribed medications; serious waste water problems, such as toilets not operating or open sewage covering the grounds; housekeeping, maintenance, or fire and life safety related problems that pose a health threat to the residents; power, water, gas, or other utility and/or service outages; residents exposed to air temperature extremes that jeopardize their health; unsafe condition of the building or structure, such as a roof in danger of collapse; indictment of an administrator for malfeasance or a felony, which by its nature, such as dealing drugs, indicates a threat to the residents; direct evidence of abuse, neglect, or exploitation; lack of food or evidence that the residents are not being fed properly; no staff available at the facility with residents present; unsafe procedures or treatment being practiced by staff; (I)

2. Repeated failure of the licensee or facility to pay assessed charges for utilities and/or services resulting in repeated or ongoing threats to terminate the contracted utilities and/or services; (II)

3. Efforts by the facility to correct cited violations;

4. Overall conditions of the facility;

5. History of compliance; and

6. Any other pertinent conditions that may be applicable to current statutes and regulations.

F. When a decision is made to impose monetary penalties, the Department may utilize the following schedule as a guide to determine the dollar amount:

Frequency of violation of standard within a thirty-six (36) month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$500–1500	$300–800	$100–300
2nd	1000–3000	500–1500	300–800
3rd	2000–5000	1000–3000	500–1500
4th	5000	2000–5000	1000–3000
5th	5000	5000	2000–5000
6th and more	5000	5000	5000

SECTION 400. POLICIES AND PROCEDURES (II)

A. Written policies and procedures addressing each section of this regulation regarding resident care, rights, and the operation of the facility shall be developed and implemented, and revised as required in order to accurately reflect actual facility operation. Each facility shall have a clear written statement of its purpose and objectives. This policy shall include a specifically delineated description of the services the facility offers, in order to provide a frame of reference for judging the various aspects of the program. The policy shall also include:

1. The population to be served, age groups, and other limitations;
2. The initial screening process;
3. Intake and/or admission process;
4. Methods for involving family members or significant others in assessment, treatment, and follow-up plans;
5. An organizational chart with a description of each unit or department and its services, goals, policies and procedures, staffing patterns and its relationship to other services and departments and how these are to contribute to the priorities and goals of the facility; and
6. Plan for cooperation with other public and private entities to ensure that each resident will receive comprehensive treatment, to include any working arrangement contracts and any regularly scheduled conferences.

B. Facilities shall review of all policies and procedures, at a minimum of every two (2) years, and such reviews shall be documented. These policies and procedures shall be accessible and available to staff at all times, and shall be available to residents and/or their responsible parties upon their request for review.

SECTION 500. STAFF AND TRAINING

501. Governing Authority

The governing board, or the owner, or the person or persons designated by the owner as the governing authority shall be the supreme authority responsible for the management control of the facility and is ultimately accountable for the safety of residents and staff and the quality of care, treatment, and services provided.

502. Administrator (II)

A. The facility administrator shall be designated by the governing body or licensee and is in charge of and responsible for the administration of the facility.

B. An administrator appointed subsequent to the promulgation of these regulations shall have a baccalaureate or associate degree with at least two (2) years of experience in a health-related field within the past five (5) years.

C. The administrator shall demonstrate adequate knowledge of these regulations.

D. A staff member shall be designated in writing to act in the absence of the administrator, for example, a listing of the lines of authority by position title, including the names of the persons filling these positions.

503. Personnel (II)

A. Prior to being employed or contracted as a staff member by a licensed facility, an individual shall undergo a criminal background check pursuant to S.C. Code Section 44–7–2910. Documentation of the results of the background check shall be maintained by the facility. Staff members of the facility shall not have a prior conviction or pled no contest (nolo contendere) to abuse, neglect, or exploitation of a child or a vulnerable adult.

B. No facility shall knowingly employ or retain an individual who has been convicted of having committed a crime of violence, an offense against morality and decency or contributed to the delinquency of a minor. Violent crimes include, but are not limited to, such offenses as simple assault committed within the last three (3) years; assault and battery; assault and battery of a high and aggravated nature; assault with a deadly weapon; assault with intent to kill; pointing and presenting a firearm; criminal sexual conduct in the first, second, or third degree (rape); all forms of homicide, such as murder and manslaughter; kidnapping; and arson. Offenses against morality and decency include, but are not limited to, committing or attempting lewd acts upon a child under fourteen (14); knowingly distributing obscene material to a minor under sixteen (16); knowingly employing or using a minor under sixteen (16) to disseminate or promote obscene matter; photographing of a minor for an obscene film or photograph; dissemination of sexually oriented material to minors. Conviction includes the results of a jury trial, guilty plea, plea of no contest, or forfeiture of bond in cases of a misdemeanor. (I)

C. Staff members shall be provided the necessary training to perform the duties for which they are responsible in an effective manner. (I)

D. Staff members shall have at least the following qualifications: (I)

1. Capable of rendering care and services to residents;

2. Sufficient education to be able to perform their duties, and to speak, read, and write English; and

3. Demonstrate a working knowledge of applicable regulations.

E. There shall be accurate and current information maintained regarding all staff members of the facility, to include at least address, phone number, and personal, work, and training background.

F. All staff members shall be assigned certain duties and responsibilities which shall be in writing and in accordance with the individual's capability.

G. When a facility engages a source other than the facility to provide services normally provided by the facility, such as staffing, training, recreation, food service, professional consultant, maintenance, or transportation, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to resident care, services, and rights.

504. Staff (I)

A. There shall be a direct care staff member actively on duty and present in the facility at all times that the facility is occupied by residents and to whom the residents can immediately report injuries, symptoms of illness, or emergencies. This staff member shall recognize and report significant changes in the physical, mental, or behavioral condition of each resident and shall ensure that appropriate action is taken.

B. The number and qualifications of staff members shall be determined by the number and condition of the residents. There shall be sufficient staff members to provide supervision, direct care, and basic services for all residents.

C. The facility shall maintain documentation to ensure the facility meets the requirements of Section 505.

505. Direct Resident Care Staffing

A. There shall be a physician or authorized healthcare provider on-call twenty-four (24) hours a day, and his or her name and where he or she can be reached shall be clearly posted in accessible places for all staff. (I)

B. At least one (1) registered nurse shall be immediately accessible by phone and available in the facility within thirty (30) minutes. Additional onsite coverage by licensed nurses shall be required if needed depending upon the size of the facility and needs of the residents served. Nursing personnel shall be assigned to duties consistent with their training and experience. (I)

C. An adequate number of licensed and direct care staff shall be on duty to meet the total needs of the residents. (I)

506. Inservice Training (I)

A. Documentation of all inservice training shall be signed and dated by both the individual providing the training and the individual receiving the training. The following training shall be provided by appropriate resources, such as licensed, registered, or certified persons, books, or electronic media, to all staff members in the context of their job duties and responsibilities, prior to resident contact and at a frequency determined by the facility, but at least annually unless otherwise specified by certificate, such as cardiopulmonary resuscitation (CPR):

1. Basic first-aid to include emergency procedures as well as procedures to manage and/or care for minor accidents or injuries;

2. Management and care of persons with contagious and/or communicable disease, such as hepatitis, tuberculosis, or HIV infection;

3. Medication management including storage, administration, receiving orders, securing medications, interactions, and adverse reactions;

4. Depending on the type of residents, care of persons specific to the physical or mental condition being care for in the facility, such as cognitive disability, mental illness, or aggressive, violent, and/or inappropriate behavioral symptoms, to include understanding and coping with behaviors, safety, and activities;

5. Use of restraint techniques;

6. Crisis management;

7. OSHA standards regarding blood-borne pathogens;

8. Cardiopulmonary resuscitation (CPR) for designated staff members to ensure that there is a certified staff member present whenever residents are in the facility;

9. Confidentiality of resident information and records;

10. Resident Rights;

11. Fire response training within twenty-four (24) hours of their first day on the job in the facility (See Section 1502);

12. Emergency procedures and disaster preparedness within twenty-four (24) hours of their first day on the job in the facility (See Section 1401); and

13. Activity training (for designated staff only).

B. All new staff members shall have documented orientation to the organization and environment of the facility, specific duties and responsibilities of staff members and residents' needs within twenty-four (24) hours of their first day on the job in the facility.

507. Health Status (I)

All staff members who have contact with residents, including food service staff members, shall have a health assessment within twelve (12) months prior to initial resident contact. The health assessment shall include tuberculin skin testing in accordance with Section 1702.

SECTION 600. REPORTING

601. Accidents and/or Incidents

A. A facility shall maintain a record of each accident and/or incident, including usage of mechanical and/or physical restraints, involving residents, staff members, or visitors, occurring in the facility or on the facility grounds. A facility's record of each accident and/or incident shall be documented, reviewed,

investigated, and if necessary, evaluated in accordance with facility policies and procedures, and retained by the facility for six (6) years after the resident stops receiving services.

B. The licensee shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin or party responsible for each affected individual at the earliest practicable hour, not to exceed twenty-four (24) hours. The licensee shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email, or facsimile. The licensee shall submit a report of the licensee's investigation of the accident and/or incident to the Department within five (5) days. Accidents and/or incidents requiring reporting include, but are not limited to:

1. Crime(s) against resident;
2. Confirmed or suspected cases of abuse, neglect, or exploitation;
3. Medication error with adverse reaction;
4. Hospitalization as a result of the accident and/or incident;
5. Severe hematoma, laceration, or burn requiring medical attention or hospitalization;
6. Fracture of bone or joint;
7. Severe injury involving the use of restraints;
8. Attempted suicide;
9. Fire; and
10. Resident left without notification or elopement.

C. A facility shall immediately report every serious accident and/or incident to the attending physician, next of kin or responsible party, and local law enforcement when applicable, for example, abuse and suspected abuse, neglect, or exploitation of resident, crime against resident, or elopement. The Department shall be notified via telephone, email, or facsimile within twenty-four (24) hours of the serious accident and/or incident.

D. A facility shall submit a written report of its investigation of every serious accident and/or incident to the Department within five (5) calendar days of the serious accident and/or incident. A facility's written report to the Department shall provide at a minimum:

1. Facility name;
2. License number;
3. Type of accident and/or incident;
4. Date accident and/or incident occurred;
5. Number of residents directly injured or affected;
6. Resident record number or last four (4) digits of Social Security Number;
7. Resident age and sex;
8. Number of staff directly injured or affected;
9. Number of visitors directly injured or affected;
10. Name(s) of witness(es);
11. Identified cause of accident and/or incident;
12. Internal investigation results if cause unknown; and
13. Brief description of the accident and/or incident including the location of occurrence and treatment of injuries.

E. A facility shall retain a report of every serious accident and/or incident with all of the information provided to the Department and the names, injuries, and treatments associated with each resident, staff, and/or visitor involved.

F. The administrator or his or her designee shall report abuse and suspected abuse, neglect, or exploitation of residents to the appropriate agency and/or law enforcement, such as the Department of Social Services and the South Carolina Law Enforcement Division.

602. Fire and Disasters (II)

A. The administrator or his or her designee shall immediately notify the Department via telephone or email of any fire in the facility and submit to the Department a complete written report including fire department reports, if any, within seventy-two (72) hours of the occurrence of the fire.

B. The administrator or his or her designee shall report any natural disaster or fire requiring displacement of the residents or jeopardizing or potentially jeopardizing the safety of the residents to the Department via telephone or email immediately, with a complete written report including the fire department or other applicable reporting authority submitted within seventy-two (72) hours.

603. Communicable Diseases and Animal Bites (I)

All cases of diseases and animal bites which are required to be reported to the appropriate county health department shall be accomplished in accordance with Regulation 61–20, Communicable Diseases.

604. Administrator Change

The licensee shall notify the Department in writing within seventy-two (72) hours of any change in administrator status. The licensee shall provide the Department in writing within ten (10) days the name of the newly-appointed administrator, the effective date of the appointment, and the hours each day the individual will be working as the administrator of the facility.

605. Accounting of Controlled Substances (II)

Any facility registered with the Department's Bureau of Drug Control and the United States Drug Enforcement Agency shall report any theft or loss of controlled substances to local law enforcement and to the Department's Bureau of Drug Control upon discovery of the loss or theft.

606. Emergency Placement Notification

In instances where evacuees have been relocated, the Department shall be notified by the relocating facility in writing no later than the following workday, the names of the individuals relocated and the name, address, and phone number of the Department-approved temporary sheltering facility(ies) to which the residents have been relocated. Relocation to the receiving facility shall not exceed five (5) days. Prior to the fifth (5th) day, if the facility determines an extension of time is needed, the facility shall request approval from the Department.

607. Facility Closure

A. Prior to the permanent closure of a facility, the licensee shall notify the Department in writing of the intent to close and the effective closure date. Within ten (10) days of closure, the facility shall notify the Department of the provisions for the maintenance of the records, the identification of those residents displaced, the relocated site, and the dates and amounts of resident refunds. On the date of closure the license shall be returned to the Department.

B. In instances where a facility temporarily closes, the licensee shall notify the Department in writing within fifteen (15) days prior to temporary closure. In the event of temporary closure due to an emergency, the facility shall notify the Department within twenty-four (24) hours of the closure via telephone, email, or facsimile. At a minimum, this notification shall include, but not be limited to: the reason for the temporary closure, the location where the residents have or will be transferred, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards of the facility prior to its reopening. If the facility is closed for a period longer than one (1) year, and there is a desire to reopen, the facility shall reapply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

608. Zero Census

In instances when there have been no residents in a facility for any reason for a period of ninety (90) days or more, the facility shall notify the Department in writing that there have been no admissions, no later than the one hundredth (100th) day following the date of departure of the last active resident. At the time of this notification, the Department shall consider, upon appropriate review of the situation, the necessity of inspecting the facility prior to any new and/or readmissions to the facility. The facility shall still submit an application and pay the licensing fee to keep the license active, even though the facility is at zero census or temporarily closed. If the facility has no residents for a period longer than one (1) year, and there is a desire to admit a resident, the facility shall reapply to the Department for

licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

SECTION 700. RESIDENT RECORDS

701. Content (II)

A. The facility shall initiate and maintain onsite an organized record for each resident. The record shall contain sufficient documented information to identify the resident and the agency and/or person responsible for each resident; support the diagnosis, secure the appropriate care and/or services as needed; justify the care and/or services provided to include the course of action taken and results; the symptoms or other indications of sickness or injury; changes in physical, mental, and/or behavioral condition; the response or reaction to care, medication, and diet provided; and promote continuity of care among providers, consistent with acceptable standards of practice. All entries shall be written legibly in ink, typed or electronic media, and signed and dated.

B. Specific entries and/or documentation shall include at a minimum:

1. Personal data sheet to include the following information, when obtainable: resident name; address including county; occupation; date of birth; sex; marital status; race; religion; county of birth; father's name; mother's maiden name; husband's or wife's name; health insurance number; provisional diagnosis; case number; days of care; Social Security number; name of the person providing information; name, address, and telephone number of person(s) to be notified in the event of an emergency; name and address of referral source; name of attending physician; and date and hour of admission;

2. Consultations by physicians or other authorized healthcare providers;

3. Orders and recommendations for all medication, care, services, procedures, and diet from physicians or other authorized healthcare providers, which shall be completed prior to, or within forty-eight (48) hours after admission, and thereafter as warranted. Verbal orders received shall be documented and include the date and time of receipt of the order, description of the order, and identification of the individual receiving the order;

4. Medication Administration Record (MAR) or similar document for recording of medications, treatments, and other pertinent data and procedures followed if an error is made;

5. Special examinations, if any, for example, consultations, clinical laboratory, x-ray and other examinations;

6. Notes of observation. In instances that involve significant changes in a resident's medical and/or mental condition and/or the occurrence of a serious incident, notes of observation shall be documented at least daily until the condition is stabilized and/or the incident is resolved. In all other instances, notes of observation for residents shall be documented;

7. Progress notes from all treatment services;

8. Time, circumstances, final diagnosis and condition of discharge, transfer, or death. In case of death, cause and autopsy findings, if an autopsy is performed;

9. Provisions for routine and emergency medical care, to include the name and telephone number of the resident's physician, plan for payment, and plan for securing medications;

10. Special information, such as proof of legal guardianship status, allergies, power of attorney, or responsible party;

11. Photograph of resident. Resident photographs shall be at a minimum two and one half inches by three and one half inches (2.5″ by 3.5″) in size, dated no more than twelve (12) months old, unless significant changes in appearance have occurred necessitating a more recent photograph;

12. Psychological testing;

13. Childhood development history;

14. Immunization history;

15. Psychosocial assessment, care plan;

16. Preadmission identification of current legal status, such as proof of custody;

17. Educational testing and prior educational records, when available upon request;

18. Treatment plan;

19. Activities assessment, care plan; and

20. Comprehensive treatment plan formulated by interdisciplinary team.

702. Initial Assessment and Treatment Planning

A. A written initial assessment of the resident shall be conducted and dated and signed by all participants to ensure appropriateness of placement prior to admission, but no later than seventy-two (72) hours after admission.

B. An initial treatment plan shall be formulated, written, and interpreted to the staff and resident within seventy-two (72) hours of admission.

703. Comprehensive Assessment

A. The facility shall describe the treatment modalities it provides, including content, methods, equipment, and personnel involved. Each treatment program shall conform to the stated purpose and objectives of the agency. (II)

B. Assessment. The facility is responsible for a comprehensive assessment of the resident by reliable professionals acceptable to the facility's staff. The complete assessment shall be signed and dated by all participants and shall include, but is not limited to, the following:

1. Psychiatric. The assessment includes direct evaluation and behavioral appraisal, evaluation of sensory, motor functioning, a mental status examination appropriate to the age of the resident and a psychodynamic appraisal. A history of any previous treatment for mental, emotional, or behavioral disturbances shall be obtained, including the nature, duration, and results of the treatment, and the reason for termination.

2. Psychological. The psychological assessment includes appropriate testing.

3. Developmental and Social.

a. The developmental assessment of the resident includes the prenatal period and from birth until present, the rate of progress, developmental milestones, developmental problems, and past experiences that may have affected the development. The assessment shall include an evaluation of the resident's strengths as well as problems. Consideration shall be given to the healthy developmental aspects of the resident, as well as to the pathological aspects, and the effects that each has on the other. There shall be an assessment of the resident's current age-appropriate developmental needs, which shall include a detailed appraisal of his peer and group relationships and activities.

b. The social assessment includes evaluation of the resident's relationships within the structure of the family and with the community at large, and evaluation of the characteristics of the social, peer group, and institutional settings from which the resident comes. Consideration shall be given to the resident's family circumstances, including the constellation of the family group, their current living situation, and all social, religious, ethnic, cultural, financial, emotional, and health factors. Other factors that shall be considered are past events and current problems that have affected the resident and family; potentialities of the family members meeting the resident's needs; and their accessibility to help in the treatment and rehabilitation of the resident. The expectations of the family regarding the resident's treatment, the degree to which they expect to be involved, and their expectations as to the length of time and type of treatment required shall be assessed.

4. Nursing. The nursing screening includes, but is not limited to, the evaluation of:

a. Self-care capabilities including bathing, sleeping, and eating;

b. Hygienic practices, such as routine dental and physical care and establishment of healthy toilet habits;

c. Nutritional habits including a balanced diet and appropriate fluid and caloric intake;

d. Responses to physical diseases, such as acceptance by the resident of a chronic illness as manifested by his compliance with prescribed treatment;

e. Responses to physical disabilities, such as the use of prosthesis or coping patterns used by the visually impaired; and

f. Responses to medications, such as allergies or dependence.

5. Educational and/or Vocational. Residents shall be evaluated using appropriate educational and vocational assessments.

6. Recreational. The resident's work and play experiences, activities, interests, and skills shall be evaluated in relation to planning appropriate recreational activities.

704. Individual Treatment Plan (II)

A. Using the written assessment, the facility shall develop, within fourteen (14) days of admission, an Individual Treatment Plan (ITP) with participation of the resident, administrator or designee, and/or the sponsor or responsible party when appropriate, as evidenced by their signatures and date. The ITP shall be reviewed and/or revised as changes in resident needs occur, but not less than semi-annually with the administrator or designee, and/or the sponsor or responsible party as evidenced by their signatures and date.

B. The comprehensive treatment plan shall be formulated for each resident by a multidiscipline staff, written and placed in his or her records within fourteen (14) days of admission. This plan must be reviewed at least every ninety (90) days, or more frequently if the objectives of the program indicate. Review shall be noted in the record. A psychiatrist as well as multidisciplinary professional staff shall participate in the preparation of the plan and any major revisions.

C. The ITP shall describe the following:

1. Requirements and arrangements for visits by or to physicians or other authorized healthcare providers;

2. Recreational and social activities which are suitable, desirable, and important to the well-being of the resident; and

3. Nutritional needs.

D. The ITP shall delineate the responsibilities of the sponsor and of the facility in meeting the needs of the resident, including provisions for the sponsor to monitor the care and the effectiveness of the facility in meeting those needs. Included shall be specific goal-related objectives based on the needs of the resident as identified during the assessment phase, including adjunct support service needs, other special needs, and the methods for achieving objectives and meeting needs in measurable terms with expected achievement dates.

705. Record Maintenance

A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection and storage of resident records.

B. When a resident is transferred from one facility to another, a transfer summary to include, at a minimum, copies of the most recent physical examination, the two-step tuberculosis test, the ITP and medication administration record (MAR), shall be forwarded to the receiving facility at the time of transfer or immediately after the transfer if the transfer is of an emergency nature. The transfer summary shall include the date sent and the signature of the transferring facility staff member. (I)

C. The resident record is confidential and shall be made available only to individuals authorized by the facility and/or the South Carolina Code of Laws. (II)

D. Records generated by organizations and/or individuals contracted by the facility for care or services shall be maintained by the facility that has admitted the resident.

E. The facility shall determine the medium in which information is stored.

F. Upon discharge of a resident, the record shall be completed within thirty (30) days, and filed in an inactive or closed file maintained by the licensee. Prior to the closing of a facility for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations. The licensee shall notify the Department, in writing, describing these arrangements and the location of the records.

G. Records of residents shall be maintained for at least six (6) years following the discharge of the resident. Other regulation-required documents, for example, fire drills and activity schedules, shall be retained at least twelve (12) months or since the most recent Department general inspection, whichever is the longer period.

H. Records of minors shall be retained until after the expiration of the period of election following achievement of majority as prescribed by statute.

I. Records of current residents are the property of the facility and shall be maintained at the facility and shall not be removed without court order.

EXCEPTION: When a resident moves from one licensed facility to another within the same provider network, meaning the same licensee, the original record may follow the resident; the sending facility shall maintain documentation of the resident's transfer or discharge date and identification information. In the event of change of ownership of the facility, all active resident records or copies of active resident records shall be transferred to the new owner(s).

SECTION 800. ADMISSION AND RETENTION

A. Admission shall be in keeping with stated policies of the facility and shall be limited to those persons for whom the facility is qualified by staff, program, and equipment to give adequate care. (II)

B. The admission procedure shall include documentation concerning: (II)

1. Consent for admission and treatment;
2. Proof of legal guardianship status;
3. Consent for medical, surgical, and dental care and treatment;
4. Guidelines for appropriate family participation in the program, communications, contact, and visits when indicated;
5. Guidelines for appropriate clothing, allowances, and gifts;
6. Guidelines for the resident's leaving the facility with medical or multidisciplinary clinical staff's consent; and
7. Financial responsibility.

C. Acceptance of a child or adolescent for continuing residential treatment shall be based on a documented assessment which shall be clearly explained to the resident and the family as evidenced by their signatures. Whether the family and/or guardian voluntarily requested services or the resident was referred by the court or other agency, the facility shall involve the family's participation to the fullest extent possible. (II)

D. Acceptance of the child or adolescent for treatment shall be based on the determination by a licensed physician, preferably psychiatrist, that the child or adolescent does not need acute psychiatric hospitalization, but does need treatment of a comprehensive and intensive nature and is likely to benefit from the programs the facility has to offer. This determination shall be documented and reviewed by the physician and treatment team at least monthly. (II)

E. Staff members who will be working with the resident, but who did not participate in the initial assessment, shall be oriented regarding the resident prior to meeting the resident. The orientation shall be documented. When the resident is to be assigned to a group, the other residents in the group shall be prepared for the arrival of the new member. There shall be a staff member(s) assigned to the new resident to observe the resident and help the resident with the unit orientation period. The staff member(s) assigned to the new resident shall be documented. (II)

SECTION 900. RESIDENT CARE AND SERVICES

901. General

A. Prior to admission, there shall be a written agreement between the resident, and/or his or her responsible party, and the facility, as evidenced by their signatures. The agreement shall be revised upon any changes and shall include at least the following:

1. An explanation of the specific care, services, and/or equipment provided by the facility, such as administration of medication or provision of special diet as necessary;
2. Disclosure of fees for all care, services, and/or equipment provided;
3. The facility shall ensure that each resident has a primary physician and a psychiatrist who maintain familiarity with the resident's physical and mental health status. Physicians, psychiatrists, and other clinicians shall be licensed to practice in South Carolina as required by state law;
4. Advance notice requirements of not less than thirty (30) days to change fee amount for care, services, and/or equipment;
5. Refund policy to include when monies are refunded upon discharge, transfer, or relocation;

6. The amount a resident receives for his or her personal needs allowance, if applicable;

7. Transportation policy;

8. Discharge and transfer provisions to include the conditions under which the resident may be discharged and the agreement terminated; and

9. Documentation of the explanation of the Resident's Rights and the grievance procedure. (II)

B. The facility shall coordinate with residents to provide care, including diet, services, such as routine and emergency medical care, dental care, counseling, and medications, as ordered by a physician or other authorized healthcare provider. Such care shall be provided and coordinated among those responsible during the process of providing such care and services and modified as warranted based upon any changing needs of the resident. Such care and services shall be detailed in the ITP. (I)

C. The facility shall render care and services in accordance with orders from physicians or other authorized healthcare providers and take precautions for residents with special conditions. The facility shall assist in activities of daily living as needed and appropriate. Each facility is required to provide only those activities of daily living and only to the levels specifically designated in the written agreement between the resident, and/or his or her responsible party or guardian, and the facility. (I)

D. The facility shall provide necessary items and assistance, if needed, for residents to maintain their personal cleanliness. (II)

E. The provision of care and services to residents shall be guided by the recognition of and respect for cultural differences to ensure reasonable accommodations shall be made for residents with regard to differences, such as, but not limited to, religious practice and dietary preferences.

F. In the event of closure of a facility for any reason, the facility shall ensure continuity of care and services by promptly notifying the resident's attending physician or other authorized healthcare provider, and responsible party, and arranging for referral to other facilities at the direction of the physician or other authorized healthcare provider. (II)

902. Program Activities

A. The facility shall offer a variety of recreational programs to suit the interests and capabilities of the residents that choose to participate. The facility shall provide recreational activities that provide stimulation; promote or enhance physical, mental, and/or emotional health; are age-appropriate; and are based on input from the residents and/or responsible party, as well as information obtained in the initial assessment.

B. There shall be at least one (1) different structured recreational activity provided daily each week that shall accommodate residents' needs, interests, and capabilities as indicated in the ITPs.

C. The facility shall develop the recreational program, and provide and coordinate recreational activities for the residents, including maintaining recreational supplies.

D. The recreational supplies shall be adequate and shall be sufficient to accomplish the activities planned.

E. Appropriate, organized programs of recreational and social activities shall be provided for all residents for daytime, evenings, and weekends. Resident participation shall be based on the resident's therapeutic needs, and shall be documented in the clinical record. A current month's schedule shall be posted in order for residents to be made aware of activities offered. This schedule shall include activities, dates, times, and locations. Schedules of any planned activities shall be maintained.

F. Program goals of the facility shall include those activities designed to promote the growth and development of the residents, regardless of diagnosis or age level. There shall be positive relationships with community resources, and the facility staff shall enlist the support of these resources to provide opportunities for residents to participate in community activities as they are able. (II)

1. The size and composition of each living group shall be therapeutically planned and depend on age, developmental level, sex, and clinical conditions. It shall allow for appropriate staff-resident interaction, security, close observation, and support. A written description of the facility's philosophy regarding group size, group composition and staff involvement, including group management and supervision, shall be maintained in the facility.

2. Basic routines shall be delineated in a written plan which shall be available to all personnel. The daily program shall be planned to provide a consistent, well-structured, yet flexible, framework for daily living and shall be periodically reviewed and revised as the needs of the individual resident or living group change. Basic daily routine, as motivated by the therapeutic needs of the resident, shall be included in the residents' written treatment plan.

3. Opportunity shall be provided for all residents to participate in religious services and other religious activities within the framework of their individual and family interests and based on the resident's clinical status.

4. Each South Carolina resident of lawful school age, both with and without disabilities, residing in a facility shall receive educational services that meet all applicable federal and state requirements, as determined by the South Carolina Department of Education (SCDE), from the school district where the facility is located. If clinically appropriate, the facility school district, the facility, and the parent or guardian of a school age resident who is referred to or placed in a facility may consider the appropriateness of providing the student's education program virtually through enrollment in either the school district's virtual program, the South Carolina Virtual School program provided through the SCDE, or a virtual charter school authorized by the South Carolina Public Charter School District. This decision shall be made jointly with the best interest of the student and what is clinically indicated being considered.

5. The facility shall arrange for or provide vocational or prevocational training for residents in the facility for whom it is indicated.

a. If there are plans for work experience developed as part of the resident's overall treatment plan, the work shall be for payment, as appropriate, and shall not be for the purpose of the facility's financial gain.

b. Residents shall not be solely responsible for any major phase of institutional operation or maintenance, such as cooking, laundering, housekeeping, farming, yard work, or repairing. Residents shall not be considered as substitutes for employed staff.

c. Attention shall be given to state and federal employment laws, including wages and hours.

903. Transportation (I)

The facility shall secure or provide transportation for residents when a physician's services are needed. Local, as defined by the facility, transportation for medical reasons shall be provided by the facility. If a physician's services are not immediately available and the resident's condition requires immediate medical attention, the facility shall provide or secure transportation for the resident to the appropriate healthcare providers, such as, but not limited to, physicians, dentists, physical therapists, or for treatment at renal dialysis facilities.

904. Restraints and Seclusion (I)

A. The facility shall have current written policies and procedures for using seclusion or any form of restraint. Seclusion or other forms of restraint shall not be used for staff convenience or as a substitute for treatment.

B. Periodic or continuous mechanical, physical, or chemical restraints or seclusion during routine care of a resident shall not be used, nor shall residents be restrained for staff convenience or as a substitute for care and/or services. However, in cases of extreme emergencies when a resident is a danger to him or herself or others, mechanical and/or physical restraints may be used as ordered by a physician or other authorized healthcare provider, and until appropriate medical care can be secured. All forms of restraint or seclusion shall be documented when used.

C. Only those devices specifically designed as restraints may be used. Makeshift restraints shall not be used under any circumstance.

D. Emergency restraint or seclusion orders shall specify the reason for the use of the restraint, the type of restraint to be used, the maximum time the seclusion or restraint may be used, and instructions for observing the resident while restrained, if different from the facility's written procedures. Residents certified by a physician or other authorized healthcare provider as requiring restraint for more than twenty-four (24) hours shall be transferred to an appropriate facility.

E. During emergency restraint or seclusion, residents shall be monitored at least every fifteen (15) minutes, and provided an opportunity for motion and exercise at least every thirty (30) minutes.

Prescribed medications and treatments shall be administered as ordered, and residents shall be offered nourishment and fluids and given bathroom privileges.

F. The use of mechanical restraints or seclusion shall be documented in the resident's record. Documentation shall include the date and time implemented, length of time restrained or secluded, specific behaviors necessitating restraint or seclusion, pertinent observations while resident is restrained or secluded, checking of the resident for adequate circulation and comfortable position, and the offering, provision, or refusal of range of motion, bathroom privileges, fluids, and nourishment.

G. The use of mechanical restraints or seclusion shall be evaluated as part of the next treatment plan review. Program staff shall consider alternative strategies to handle the behavior that necessitated the use of mechanical restraint or seclusion. Consideration shall be documented in the resident's record. If mechanical restraints or seclusion are needed more than twenty-four (24) hours, the resident shall be transferred to a facility capable of providing proper care.

H. A room used for seclusion shall have at least forty (40) square feet of floor space and be free of safety hazards, adequately ventilated during warm weather, adequately heated during cold weather, and appropriately lighted. All parts of the room shall be clearly visible from the outside.

I. All items or articles that a resident might use to injure him or herself shall be removed from the room used for seclusion.

J. At least a mat and bedding shall be provided in the seclusion room except when a physician's orders are to the contrary.

905. Discharge and Transfer

A. Discharge planning begins at the time of admission. A discharge date shall be projected in the treatment plan. Discharge orders shall be signed by a physician. A discharge summary shall be included in the resident's record. Discharge planning shall include input from the multidiscipline staff. (II)

B. Prior to discharge, the resident, his or her appropriate family member, and the sponsor, if any, shall be consulted.

C. There shall be a written plan for follow-up services, either by the facility or another agency. (II)

D. Arrangements for alternative and more appropriate placement shall be made prior to the twenty-first (21st) birthday of any resident who needs continued treatment. (II)

E. Upon transfer or discharge of a resident, resident information shall be released in a manner that promotes continuity in the care that serves the best interests of the resident.

F. Upon transfer or discharge, the facility shall ensure that medications, as appropriate, personal possessions and funds are released to the responsible party and/or the receiving facility in a manner that ensures continuity of care and services and maximum convenience of the resident. (II)

SECTION 1000. RIGHTS AND ASSURANCES

1001. General

A. The facility shall develop and post in a conspicuous place in a public area of the facility a grievance and complaint procedure to be exercised on behalf of the residents that includes the address and phone number of the Department and a provision prohibiting retaliation should the grievance right be exercised.

B. Care, services, and items provided by the facility, the charges, and those services that are the responsibility of the resident shall be delineated in writing. The resident shall be made aware of such charges and/or services and changes to charges and/or services as verified by the signature of the resident or responsible party.

C. The facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, such as Title VII, Section 601 of the Civil Rights Act of 1964, and ensure that there is no discrimination with regard to source of payment in the recruitment, location of resident, acceptance or provision of goods and services to residents or potential residents.

D. Residents shall not be requested or required to perform any type of care and/or service in the facility that would normally be the duty of a staff member.

E. Adequate safeguards shall be provided for protection and storage of residents' personal belongings.

F. Provisions shall be made for safeguarding money and valuables for those residents who request this assistance.

1002. Statement of Rights of Residents

A. Each resident shall be afforded the following rights: (II)

1. The right to be treated with consideration, respect, and dignity, including privacy in treatment and in care for personal needs;

2. The right to be cared for in an atmosphere of sincere interest and concern in which needed support and services are provided;

3. The right to a safe, secure, and clean environment;

4. The right to confidentiality;

5. The right to voice grievances without discrimination or reprisal;

6. The right to be free from harm, including isolation, excessive medication if applicable, abuse, or neglect;

7. The right to be fully informed, at the time of acceptance into the program, of services and activities available and related charges;

8. The right to communicate with others and be understood by them to the extent of the resident's capability;

9. The right to visitation of the resident's family and significant others unless clinically contraindicated and documented in the resident's records. Appropriate areas for visitation shall be provided;

10. The right to conduct private telephone conversations with family and friends and to send and receive mail. When restrictions are necessary because of therapeutic or practical reasons, these reasons shall be documented, explained to the resident and family and reevaluated at least monthly; and

11. The right to be fully informed, as evidences by the resident's written acknowledgement of these rights, of all rules and regulations regarding resident conduct and responsibilities.

B. The Statement of Rights of Residents shall be posted in a conspicuous place in the facility.

SECTION 1100. RESIDENT PHYSICAL EXAMINATION

A. A physical examination shall be completed by a physician or other authorized healthcare provider for residents within thirty (30) days prior to admission or within forty-eight (48) hours of admission and at least annually thereafter. Physical examinations conducted by physicians or other authorized healthcare providers licensed in other states are permitted for new admissions under the condition that the resident undergoes a second physical examination by a South Carolina licensed physician or other authorized healthcare provider within thirty (30) days of admission to the facility. The physical examination shall be updated to include new medical information if the resident's condition has changed since the last physical examination was completed. The physical examination shall address:

1. Complete medical history;

2. Neurological screening;

3. Motor development and functioning;

4. Dental screening upon admission and at least every six (6) months thereafter;

5. Speech, hearing, and language screening;

6. Vision screening;

7. Review of immunization status and completion;

8. Laboratory work-up, including routine blood work and urinalysis; and

9. Two-step tuberculosis skin test, in accordance with Section 1702.D, unless there is a documented previous positive reaction.

B. If any of the physical health assessments in Section 1100.A indicate the need for further testing or definitive treatment, arrangements shall be made to carry out or obtain the necessary evaluations and/or treatment by appropriately qualified and/or trained clinicians, and plans for these treatments shall be coordinated with the resident's overall treatment plan.

C. If a resident or potential resident has a communicable disease, the administrator shall seek advice from a physician or other authorized healthcare provider in order to:

1. Ensure the facility has the capability to provide adequate care and prevent the spread of that condition, and that the staff members are adequately trained; and

2. Transfer the resident to an appropriate facility, if necessary.

SECTION 1200. MEDICATION MANAGEMENT

1201. General (I)

A. Medications, including controlled substances, medical supplies, and those items necessary for the rendering of first aid shall be available and properly managed in accordance with local, state, and federal laws and regulations. Such management shall address the securing, storing, and administering of medications, medical supplies, first aid supplies, and biologicals, their disposal when discontinued or outdated, and their disposition at discharge, death, or transfer of a resident.

B. There shall be an adequate number of first aid kits stored with appropriate safeguards but accessible to staff in appropriate locations such as living units, recreation and special purpose areas, buses, and otherwise. A first aid kit shall be equipped with at least an antiseptic solution, adhesive bandages, rolled bandages, gauze pads, medical adhesive tape, cotton-tip applications, and scissors.

C. Applicable reference materials published within the previous three (3) years shall be available at the facility in order to provide staff members administering medication with adequate information concerning medications.

1202. Medication and Treatment Orders (I)

A. Medications and treatments shall be administered to residents only upon orders, to include standing orders, of a physician or other authorized healthcare provider. Medications accompanying residents at admission may be administered to residents provided the medication is in the original labeled container and the order is subsequently obtained as part of the admission physical examination. Should there be concerns regarding the appropriateness of administering medications due to the condition or state of the medication, for example, expired, makeshift or illegible labels, or the condition or state of health of the newly-admitted resident, staff members shall consult with or make arrangements to have the resident examined by a physician or other authorized healthcare provider, or at the local hospital emergency room prior to administering any medications.

B. All orders, including verbal orders, shall be received only by legally authorized staff members and shall be signed and dated by a physician or other authorized healthcare provider no later than seventy-two (72) hours after the order is given.

C. Medications and medical supplies ordered for a specific resident shall not be provided or administered to any other resident.

1203. Administering Medication and Treatments (I)

A. Doses of medication shall be administered by the same staff member who prepared them for administration. Preparation shall occur no earlier than one (1) hour prior to administering. Preparation of doses for more than one (1) scheduled administration shall not be permitted. Each physician-ordered treatment or medication dose administered or supervised shall be properly recorded by initialing on the resident's medication administration record (MAR) as the medication is administered or treatment record as treatment is rendered. Recording medication administration shall include medication name, dosage, mode of administration, date, time, and the signature of the individual administering or supervising the taking of the medication. If the ordered dosage is to be given on a varying schedule, such as, "take two tablets the first day and one tablet every other day by mouth with noon meal," the number of tablets shall also be recorded. The treatment record shall document the type of treatment, date and time of treatment, and signature of the individual administering treatment.

B. Medications shall be administered only by staff members legally authorized to administer the medication(s). (II)

C. When residents leave the facility for an extended period of time, the proper amount of medications, along with dosage, mode, date, and time of administration, shall be given to a responsible person who will be in charge of the resident during his or her absence from the facility; these details shall be properly documented in the MAR. In these instances, the amount of medication needed for the designated period of time may be transferred to a prescription vial or bottle that is properly labeled.

D. At each shift change, there shall be a documented review of the MARs by outgoing staff members with incoming staff members that shall include verification by outgoing staff members that they have properly administered medications in accordance with orders by a physician or other authorized healthcare provider, and have documented the administrations. Errors and/or omissions indicated on the MARs shall be addressed and corrective action taken at that time.

1204. Pharmacy Services (I)

A. Any pharmacy within the facility shall be provided by or under the direction of a pharmacist in accordance with accepted principles and appropriate local, state, and federal laws and regulations.

B. Facilities which maintain stocks of legend drugs and biologicals for dispensing to residents shall obtain and maintain a valid, current pharmacy permit from the South Carolina Board of Pharmacy.

C. Labeling of medications dispensed to residents shall be in compliance with local, state, and federal laws and regulations, to include expiration date.

D. A consulting pharmacist shall assist in developing policies and procedures for the administration of medication. The consulting pharmacist shall conduct monthly reviews of medication and medication records in all locations where medications are stored and shall submit at least monthly reports to the facility administrator and make recommendations for improvements concerning the handling, storage, and labeling of medications at the facility.

E. Provisions shall be made for emergency pharmaceutical service. (II)

1205. Medication Containers (I)

A. Medications for residents shall be obtained from a permitted pharmacy or prescriber on an individual prescription basis. These medications shall bear a label affixed to the container which reflects at least the following: name of pharmacy, name of resident, name of the prescribing physician or other authorized healthcare provider, date and prescription number, directions for use, and the name and dosage unit of the medication. The label shall be brought into accord with the directions of the physician or other authorized healthcare provider each time the prescription is refilled. Medication containers having soiled, damaged, incomplete, illegible, or makeshift labels shall be returned to the pharmacy for relabeling or disposal. Residents may obtain their over-the-counter (OTC) medication from a pharmacy other than a pharmacy contracted with the facility.

B. If a physician or other authorized healthcare provider changes the dosage of a medication, a label, which does not obscure the original label, shall be attached to the container which indicates the new dosage, date, and prescriber's name. In lieu of this procedure, it is acceptable to attach a label to the container that states, "Directions changes; refer to MAR and physician or other authorized healthcare provider orders for current administration instructions." The new directions shall be communicated to the pharmacist upon receipt of the order.

1206. Medication Storage (I)

A. Medications shall be properly stored and safeguarded in a locked medicine preparation room (See Section 2603) or locked in a cabinet at or near the staff work area to prevent access by unauthorized individuals. If medication carts are utilized for storage, they shall be locked when not in use. When the medication cart is in use, it shall be supervised by staff legally authorized to administer medications. Expired or discontinued medications shall not be stored with current medications. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life.

B. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U.S. Pharmacopeia, thirty-six to forty-six (36–46) degrees Fahrenheit, and recommended by the medication manufacturer. Medications requiring refrigeration shall be kept in a secured refrigerator, at or near the staff work area, used exclusively for medications, or in a secured manner in which medications are separated from other items in the refrigerator, such as a lock box. Food and

drinks shall not be stored in the same refrigerator. All refrigerators storing medications shall have accurate thermometers, within plus or minus three (3) degrees Fahrenheit.

C. Medications shall be stored:

1. Separately from poisonous substances or body fluids; and

2. In a manner which provides for separation between topical and oral medications, and which provides for separation of each individual resident's medication.

D. A facility shall maintain records of receipt, administration, and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation including:

1. Separate control sheets on any controlled substances. This record shall contain the following information: date, time administered, name of resident, dose, signature of individual administering, name of physician or other legally authorized healthcare provider ordering the medication; and

2. At each shift change, a documented review of the control sheets by outgoing staff members with incoming staff members including verification by outgoing staff members indicating they have properly administered medications in accordance with orders by a physician or other authorized healthcare provider, and have documented the administrations. Errors and/or omissions indicated on the control sheets shall be addressed and corrective action taken at that time.

E. Unless the facility has a permitted pharmacy, legend medications shall not be stored except those specifically prescribed for individual residents. Nonlegend medications that can be obtained without a prescription may be retained and labeled as stock in the facility for administration as ordered by a physician or other authorized healthcare provider.

1207. Disposition of Medications (I)

A. Upon discharge of a resident, the facility shall release unused medications to the resident's family member or responsible party, in accordance with applicable law, and shall document the release with the signature of the person receiving the unused medications unless specifically prohibited by the attending physician or other authorized healthcare provider.

B. Residents' medications shall be destroyed by the facility administrator or his or her designee when:

1. Medication has deteriorated or exceeded its expiration date; or

2. Unused portions remain due to death or discharge of the resident, or discontinuance of the medication. Medication that has been discontinued by order may be stored for a period not to exceed thirty (30) days provided they are stored separately from current medications.

C. The destruction of medication shall be witnessed by the administrator or his or her designee, the mode of destruction indicated, and these steps documented. Destruction records shall be retained by the facility for a period of two (2) years.

D. The destruction of controlled substances shall be accomplished only by the administrator or his or her designee and witnessed by the administrator or his or her designee licensed to administer medications.

SECTION 1300. MEAL SERVICE

1301. General (II)

A. All facilities that prepare food onsite shall be approved by the Department, and shall be regulated, inspected, and permitted pursuant to Regulation 61–25, Retail Food Establishments. Facilities preparing food onsite and licensed subsequent to the promulgation of these regulations shall have kitchen equipment which meets the requirements of R.61–25. If food is prepared at a central kitchen and delivered to separate facilities or separate buildings and/or floors of the same facility, Department approved provisions shall be made for the proper maintenance of food temperatures and a sanitary mode of transportation.

B. When meals are catered to a facility, such meals shall be obtained from a food service establishment permitted by the Department, pursuant to R.61–25, and there shall be a written executed contract with the food service establishment. All food to be served to residents shall be transported, stored, and handled in accordance with R.61–25. Food temperatures shall be maintained in accordance with R.61–25.

C. Liquid or powder soap dispensers and sanitary paper towels shall be available and used at each food service handwash lavatory. Alcohol-based waterless hand sanitizers shall not be used in lieu of liquid or powder soap.

1302. Food and Food Storage

For facilities preparing food onsite, at least a one (1) week supply of staple foods and a two (2) day supply of perishable foods shall be maintained on the premises. Supplies shall be appropriate to meet the requirements of the menu and special or therapeutic diets. (II)

1303. Meals and Services

A. All facilities shall provide dietary services to meet the daily nutritional needs of the residents in accordance with the USDA guidelines and the Recommended Dietary Allowance of the National Research Council for children and adolescents. (I)

B. A minimum of three (3) nutritionally-adequate meals, in accordance with Section 1303.A above, in each twenty-four (24) hour period, shall be provided for each resident unless otherwise directed by the resident's physician or other authorized healthcare provider. Not more than fourteen (14) hours shall elapse between the serving of the evening meal and breakfast the following day. (II)

C. Special attention shall be given to preparation and prompt serving in order to maintain correct food temperatures for serving at the table or resident room. (II)

D. The same foods shall not be repetitively served during each seven (7) day period except to honor specific, individual resident requests.

E. Specific times for serving meals shall be established, documented on a posted menu, and followed.

F. Suitable food and snacks shall be available and offered between meals. (II)

G. Residents shall be encouraged to eat in the dining room at mealtime. Tray service shall be permitted when the resident is medically unable to access the dining area for meals, in which case it may be provided on an occasional basis unless otherwise indicated in the facility's policies and procedures. Under no circumstances may staff members utilize tray service for their own convenience. (II)

1304. Meal Service Personnel (II)

A. Sufficient staff members shall be available to serve food and to provide individual attention and assistance, if needed.

B. Dietary services shall be organized with established lines of accountability and clearly defined job assignments for those engaged in food preparation and serving. There shall be trained staff members to supervise the preparation and serving of the proper diet to the residents including having sufficient knowledge of food values in order to make appropriate substitutions when necessary. The facility shall not permit residents to engage in food preparation.

1305. Diets

A. If the facility accepts or retains residents in need of medically-prescribed special diets, the menus for such diets shall be planned by a professionally-qualified dietitian or shall be reviewed and approved by a physician or other authorized healthcare provider. The facility shall maintain staff capable of the preparation and serving of any special diet, such as a diabetic diet. The preparation of any resident's special diet shall follow the written guidance provided by a registered dietitian, physician, or other authorized healthcare provider authorizing the resident's special diet. For each resident receiving a special diet, this written guidance shall be documented in the resident's record. (I)

B. If special diets are required, the necessary equipment for preparation of those diets shall be available and utilized.

C. A dietitian shall be employed on a consultative basis. Responsibilities of the dietitian shall be:

1. To observe the operation of the Food Service Program and to provide suggestions for improvement based on those observations;

2. To develop and/or approve menus which meet acceptable nutrition standards;

3. To assist with the development and implementation of dietary policies and procedures;

4. To prepare specialized menus for residents who have orders from a physician regarding a special diet and provide instruction for the dietary staff regarding how to prepare any special food items;

5. To review resident charts and counsel with a resident and family regarding special dietary needs;

6. To provide inservice for staff as indicated;

7. To develop food service documentation procedures and review records of the documentation; and

8. To prepare quarterly quality assurance reports for review of Food Services.

D. A diet manual published within the previous five (5) years shall be available and shall address at a minimum:

1. Food sources and food quality;

2. Food protection storage, preparation, and service;

3. Meal service personnel health and cleanliness;

4. Recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences food serving recommendations;

5. General menu planning; and

6. Menu planning appropriate to special needs or other appropriate diets.

1306. Menus

A. Menus shall be planned and written a minimum of one (1) week in advance and dated as served. The current week's menu, including routine and special diets and any substitutions or changes made, shall be readily available and posted in one (1) or more conspicuous places in a public area. All substitutions made on the master menu shall be recorded in writing. Cycled menus shall be rotated so that the same weekly menu is not duplicated for at least a period of three (3) weeks.

B. Records of menus as served shall be maintained for at least thirty (30) days.

1307. Ice and Drinking Water (II)

A. Ice from a water system that is in compliance with Regulation 61–58, State Primary Drinking Water Regulations, shall be available and precautions taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside of the ice container.

B. Potable drinking water shall be available and accessible to residents at all times.

C. The usage of common cups shall be prohibited.

D. Ice delivered to resident areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

SECTION 1400. EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1401. Disaster Preparedness (II)

A. All facilities shall develop, by contact and consultation with their county emergency preparedness agency, a suitable written plan for actions to be taken in the event of a disaster and/or emergency evacuation and implement the written plan for actions at the time of need. Prior to initial licensing of a facility, the completed plan shall be submitted to the Department for review. Additionally, in instances where there are applications for increases in licensed bed capacity, the emergency and disaster evacuation plan shall be updated to reflect the proposed new total licensed bed capacity. All staff members shall be made familiar with this plan and instructed as to any required actions. A copy of the emergency and disaster evacuation plan shall be available for inspection by the resident and/or responsible party upon request. The emergency and disaster evacuation plan shall be reviewed and updated annually, as appropriate. Staff members shall rehearse the emergency and disaster evacuation plan at least annually and shall not require resident participation.

B. The emergency and disaster evacuation plan shall include, but not be limited to,:

1. A sheltering plan to include:

a. The licensed bed capacity and average occupancy rate;

b. Name, address, and phone number of the sheltering facility(ies) to which the residents will be relocated during a disaster;

c. A letter of agreement signed by an authorized healthcare representative of each sheltering facility which shall include: the number of relocated residents that can be accommodated; sleeping, feeding, and medication plans for the relocated residents; and provisions for accommodating relocated staff members. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Horry, Jasper, and Georgetown counties, at least one (1) sheltering facility shall be located in a county other than these counties; and

d. Maximum duration of time the sheltering facility will be used for a single emergency or disaster incident.

2. A transportation plan, to include agreements with entities for relocating residents, which addresses:

a. Number and type of vehicles required;

b. How and when the vehicles are to be obtained;

c. Who, by name or organization, will provide drivers;

d. Procedures for providing appropriate medical support, food, water, and medications during transportation and relocation based on the needs and number of the residents;

e. Estimated time to accomplish the relocation; and

f. Primary and secondary routes to be taken to the sheltering facility.

3. A staffing plan for the relocated residents, to include:

a. How care will be provided to the relocated residents, including the number and type of staff members that will accompany residents who are relocated;

b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility; and

c. Cosigned statement by an authorized representative of the sheltering facility if staffing is to be provided by the sheltering facility.

1402. Emergency Call Numbers

Emergency call data shall be posted in a conspicuous place and shall include at least the telephone numbers of local fire and police departments, ambulance service, and the poison control center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

1403. Continuity of Essential Services (II)

There shall be a written plan to be implemented to ensure the continuation of essential resident support services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.

SECTION 1500. FIRE PREVENTION AND PROTECTION

1501. Arrangements for Fire Department Response and Protection (I)

A. A facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, a suitable written plan for actions to be taken in the event of fire and other emergencies. All employees shall be made familiar with these plans and instructed as to required action.

B. A facility shall meet all of the requirements prescribed by the South Carolina State Fire Marshal.

C. Where a facility is located outside of a service area or range of a public fire department, a facility shall make arrangements to have the nearest fire department respond in case of fire. A facility shall keep a copy of the agreement on file in the facility.

1502. Fire Response Training (I)

A. Each employee of the facility shall receive within twenty-four (24) hours of initial resident contact and annually thereafter instructions covering:

1. The fire plan;
2. The fire evacuation plan, including routes and procedures;
3. How to report a fire;
4. How to use the fire alarm system;
5. Location and use of fire-fighting equipment;
6. Methods of containing a fire; and
7. Specific responsibilities of the individual.

B. A facility shall maintain records of training including the date, names of participating individuals, and a description of the training.

1503. Fire Drills (I)

A. A facility shall conduct a fire drill for each shift at least once every three (3) months.

B. A facility shall maintain records of drills including the date, time, shift, and names of individuals participating, description of the drill, and evaluation.

C. Fire drills shall be designed and conducted to:

1. Ensure that all personnel are capable of performing assigned tasks or duties;
2. Ensure that all personnel know the location, use, and operation of fire-fighting equipment;
3. Ensure that all personnel are thoroughly familiar with the fire plan; and
4. Evaluate the effectiveness of plans and personnel.

SECTION 1600. PREVENTATIVE MAINTENANCE

A facility shall keep all equipment and building components, such as doors, windows, lighting fixtures, and plumbing fixtures, in good repair and operating condition. A facility shall document all preventative maintenance. A facility shall comply with the provisions of the codes applicable to residential treatment facilities referenced in Section 1902.

SECTION 1700. INFECTION CONTROL AND ENVIRONMENT

1701. Staff Practices (I)

Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable regulations and guidelines of the Occupational Safety and Health Administration, for example, the Bloodborne Pathogens Standard; the Centers for Disease Control and Prevention, for example, Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee; Regulation 61–105; and other applicable state, federal and local laws and regulations.

1702. Tuberculin Skin Testing (I)

A. All facilities shall conduct an annual tuberculosis risk assessment in accordance with CDC guidelines to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, such as low risk or medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and residents and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, such as, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, resident population, job type, or location within the setting, may have separate risk classifications.

C. Staff Tuberculin Skin Testing.

1. Tuberculosis Status. Prior to date of hire or initial resident contact, the tuberculosis status of direct care staff shall be determined in the following manner in accordance with the applicable risk classification:

2. Low Risk:

a. Baseline two-step Tuberculin Skin Test (TST) or a single Blood Assay for *Mycobacterium tuberculosis* (BAMT): All staff, within three (3) months prior to contact with residents, unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline.

b. Periodic TST or BAMT is not required.

c. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to twelve (8 to 12) weeks after that exposure to *M. tuberculosis* ended.

3. Medium Risk:

a. Baseline two-step TST or a single BAMT: All staff, within three (3) months prior to contact with residents, unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST, or the single BAMT, can be administered to serve as the baseline.

b. Periodic testing (with TST or BAMT): Annually, of all staff who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff about symptoms of TB disease, including the staff responses, documenting the questioning of the staff about the presence of symptoms of TB disease, and instructing the staff to report any such symptoms immediately to the Administrator. Treatment for latent TB infection (LTBI) shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

c. Post-exposure TST or a BAMT for staff upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to twelve (8 to 12) weeks after that exposure to *M. tuberculosis* ended.

4. Baseline Positive or Newly Positive Test Result:

a. Staff with a baseline positive or newly positive test result for *M. tuberculosis* infection, such as TST or BAMT, or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, such as, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease, or evaluate an interpretable copy taken within the previous three (3) months. These staff members shall be evaluated for the need for treatment of TB disease or latent TB infection (LTBI) and shall be encouraged to follow the recommendations made by a physician with TB expertise, such as the Department's TB Control program.

b. Staff with positive TST results, regardless of when that conversion was first documented, shall document that conversion, document a subsequent negative chest radiograph, and receive a negative assessment for signs and symptoms of TB before they may be hired or admitted, as appropriate.

c. Staff who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician, and permitted to return to work only with approval by the Department TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician.

D. Resident Tuberculosis Screening Procedures.

1. Residents shall have evidence of a two-step tuberculin (TST) skin test. If the resident has a documented negative tuberculin skin test (at least single-step) within the previous twelve (12) months, the resident shall have only one (1) tuberculin skin test to establish a baseline status.

2. Residents shall have at least the first step within thirty (30) days prior to admission and no later than forty-eight (48) hours after admission pursuant to the physical examination as specified in Section 1100.

3. Residents with Positive Tuberculosis Results.

a. Residents with a baseline positive or newly positive test result for *M. tuberculosis* infection, such as a TST or blood assay for *Mycobacterium tuberculosis* (BAMT), or documentation of treatment for latent TB infection (LTBI) or TB disease or signs or symptoms of tuberculosis, for example, cough, weight loss, night sweats, or fever, shall have a chest radiograph performed immediately to exclude TB disease, or evaluate an interpretable copy taken within the previous three (3) months. Routine repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician. These residents shall be evaluated for the need for treatment of TB disease or LTBI and shall be encouraged to follow the recommendations made by a physician with TB expertise, such as the Department's TB Control program.

b. Residents known or suspected to have TB disease shall be transferred from the facility if the facility does not have an Airborne Infection Isolation room in accordance with Section 101.C, required to undergo evaluation by a physician, and permitted to return to the facility only upon consultation with the Department's TB Control program.

1703. Housekeeping (II)

A. Effective measures shall be taken to protect against the entrance of vermin into the facility and the breeding or presence of vermin on the premises.

B. Interior housekeeping shall, at a minimum, include:

1. Cleaning each specific area of the facility;

2. Cleaning and disinfection, as needed, of equipment use and/or maintained in each area appropriate to the area and the equipment's purpose or use;

3. Cleaning and disinfection to prevent offensive odors; and

4. Safe storage of chemicals indicated as harmful on the product label, cleaning materials, and supplies in locked cabinets, or well-lighted closets and/or rooms, inaccessible to residents. If cleaning carts are utilized for storage, they shall be locked when not in use. When the cleaning cart is in use, it shall be supervised by authorized staff.

C. Exterior housekeeping shall, at a minimum, include:

1. Cleaning of all exterior areas, such as porches and ramps, and removal of safety impediments, such as snow and ice;

2. Keeping facility grounds free of weeds, rubbish, clutter, overgrown landscaping, and other potential breeding sources for vermin;

3. Storage areas for chemicals indicated as harmful on the product label, equipment, and supplies, shall be locked and inaccessible to residents. When in use, chemicals indicated as harmful on the product label, equipment, and supplies shall be supervised by authorized staff; and

4. Refuse storage and disposal shall be in accordance with R.61–25.

1704. Infectious Waste (I)

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in a manner compliant with OSHA Blood-borne Pathogens Standard, and Regulation 61–105, Infectious Waste Management.

1705. Clean and Soiled Linen and Clothing (II)

A. Clean Linen and Clothing. An adequate supply of clean, sanitary linen and clothing shall be available at all times. In order to prevent the contamination of clean linen and/or clothing by dust or other airborne particles or organisms, clean linen and clothing shall be stored and transported in a sanitary manner, such as enclosed and covered. Linen and clothing storage rooms shall be used only for the storage of linen and clothing. Clean linen and clothing shall be separated from storage of other purposes.

B. Soiled Linen and Clothing.

1. Soiled linen and clothing shall neither be sorted, rinsed, nor washed outside of the laundry service area;

2. Provisions shall be made for collecting, transporting, and storing soiled linen and clothing;

3. Soiled linen and clothing shall be kept in enclosed and/or covered containers.

SECTION 1800. QUALITY IMPROVEMENT PROGRAM

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care and services provided by the facility.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively accomplished;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Analyze the appropriateness of the ITPs and the necessity of care and services rendered;

5. Analyze all accidents and incidents, to include all medication errors and resident deaths;

6. Analyze any infection, epidemic outbreaks, or other unusual occurrences which threaten the health, safety, or well-being of the residents; and

7. Establish a systematic method of obtaining feedback from residents and other interested persons, such as, family members and peer organizations, as expressed by the level of satisfaction with care and/or services received.

SECTION 1900. DESIGN AND CONSTRUCTION

1901. General (II)

A. A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each resident. A facility shall meet the requirements of an institutional healthcare facility and shall not be considered dormitory use. Spaces within or associated with the facility provided educational program, whether dedicated solely to education or shared with other activities, shall meet the requirements of the most recent edition of the South Carolina School Facilities Planning and Construction Guide.

B. A facility shall have a fire protection sprinkler system.

1902. Codes and Standards (II)

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council, the South Carolina State Fire Marshal, and the South Carolina Department of Education Office of School Facilities applicable to residential treatment and educational facilities. No facility shall be licensed unless the Department has assurance that responsible state and local officials, zoning and building, have approved the facility for code compliance.

B. Unless specifically required otherwise by the Department, all facilities shall comply with the construction codes and regulations applicable at the time its license was issued.

1903. Submission of Plans (II)

A. Plans and specifications shall be submitted to the Department for review and approval for new construction, additions or alterations to existing buildings, replacement of major equipment, buildings being licensed for the first time, buildings changing license type, and for facilities increasing occupant load or licensed capacity. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. Unless directed otherwise by the Department, a facility shall submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission, and date indicated thereon. Any construction changes from the approved documents shall be approved by the Department. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written

notification, review, and re-approval from the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction the owner shall employ a registered architect and/or engineer for observation and inspections unless other arrangements are approved by the Department. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for new construction and for a project that has an effect on:

1. The function of a space;
2. The accessibility to or of an area;
3. The structural integrity of the facility;
4. The active and/or passive fire safety systems, including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood;
5. Doors;
6. Walls;
7. Ceiling system assemblies;
8. Exit corridors;
9. Life safety systems; or
10. Increases to the occupant load or licensed capacity of the facility.

C. All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, or other, that are required to have a flame-spread rating or other safety criteria shall be documented with copies of the documentation and certifications kept on file at the facility and made available to the Department.

E. Any construction work which violates codes or standards shall be required to be brought into compliance.

F. If construction is delayed for a period exceeding twelve (12) months from the time of approval of final submission, a new evaluation and/or approval shall be required.

G. Any building which is being licensed for the first time shall be considered new construction and shall be in compliance with the codes and standards of Section 1902.

H. If the facility will provide space for the educational program, plans and specifications shall be submitted to the South Carolina Department of Education (SCDE) Office of School Facilities for approval. Submittal and other requirements listed in Section 1900 for the Department shall be required for the SCDE Office of School Facilities.

SECTION 2000. FIRE PROTECTION EQUIPMENT AND SYSTEMS

2001. Fire Alarms and Sprinklers (I)

A. A facility with five (5) or fewer licensed beds shall have interconnected smoke alarms in the facility and in all sleeping rooms.

B. A facility with six (6) or more licensed beds shall have a partial, manual, automatic, and supervised fire alarm system. The facility shall arrange the system to transmit an alarm automatically to a third party. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculation systems and outside air units that serve the area(s) of alarm origination at a minimum.

C. All fire, smoke, heat, sprinkler flow, and manual fire alarming devices shall be connected to and activate the main fire alarm system when activated.

2002. Smoke Detection System (I)

If an approved automatic smoke detection system is required, it shall be installed in all corridors and sleeping rooms. Such systems shall be installed in accordance with the applicable codes and standards of Section 1902.

SECTION 2100. EQUIPMENT AND SYSTEMS

2101. Gases (I)

A. Gases, both flammable and nonflammable, and flammable liquids shall be handled and stored in accordance with the applicable codes in Section 1902.

B. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, and/or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place.

C. Smoking shall be allowed only in designated areas in accordance with the facility smoking policy. No smoking shall be permitted in resident rooms or staff bedrooms or bath or restrooms.

2102. Furnishings and Equipment (I)

A. A facility shall maintain the physical plant free of fire hazards or impediments to fire prevention.

B. A facility shall not permit portable electric or unvented fuel heaters.

C. Fireplaces and fossil-fuel stoves, or wood-burning, shall have partitions or screens or other means to prevent burns. Fireplaces shall be vented to the outside. A facility shall not use unvented gas logs. Gas fireplaces shall have a remote gas shutoff within the room and not inside the fireplace.

D. A facility shall require all wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows to be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant.

SECTION 2200. EXITS (I)

A. There shall be more than one (1) exit leading to the outside of the building on each floor.

B. Exits shall be placed so that the entrance door of every private room and semi-private room shall be not more than one hundred (100) feet along the line of travel to the nearest exit.

C. Exits shall be remote from each other.

D. Exits shall be arranged so that there are not corridor pockets or dead-ends in excess of twenty (20) linear feet.

E. Each resident room shall communicate directly with an approved exit access corridor without passage through another occupied space or shall have an approved exit directly to the outside at grade level, to a public space free of encumbrances. Maximum travel distance from any point in the room to an exit access corridor shall not exceed fifty (50) feet.

SECTION 2300. WATER SUPPLY, HYGIENE, AND TEMPERATURE CONTROL

2301. General (II)

A. Plumbing fixtures that require hot water and which are accessible to residents shall be supplied with water that is thermostatically controlled to a temperature of at least one hundred (100) degrees Fahrenheit and not to exceed one hundred twenty-five (125) degrees Fahrenheit at the fixture.

B. The water heater or combination of heaters shall be sized to provide at least six (6) gallons per hour per licensed bed at the temperature range indicated in Section 2301.A.

C. Hot water supplied to the kitchen equipment and utensil washing sink shall be supplied as required by R.61–25.

D. Hot water provided for washing linen and clothing shall not be less than one hundred sixty (160) degrees Fahrenheit. Should chlorine additives or other chemicals which contribute to the margin of safety in disinfecting linen be a part of the washing cycle, the minimum hot water temperature shall not be less than one hundred ten (110) degrees Fahrenheit, provided hot air drying is used.

2302. Cross-Connections (I)

There shall be no cross-connections in plumbing between safe and potentially unsafe water supplies. Water shall be delivered at least two (2) delivery pipe diameters above the rim or points of overflow to each fixture, equipment, or service unless protected against back-siphonage by approved vacuum breakers or other approved backflow preventers. A faucet or fixture to which a hose may be attached shall have an approved vacuum breaker or other approved backflow preventer.

SECTION 2400. ELECTRICAL

2401. General (I)

A facility shall maintain all electrical installations and equipment in a safe, operable condition in accordance with the applicable codes in Section 1902 and shall be inspected at least annually by a licensed electrician, registered engineer, or certified electrical inspector.

2402. Panelboards (II)

A facility shall label the panelboard directory to conform to the room numbers and/or designations.

2403. Ground Fault Interrupting Receptacles

Electrical circuits to fixed or portable equipment in hydrotherapy units or other wet areas shall be provided with five (5) milliampere ground fault interrupter (GFI) circuits or receptacles. GFI receptacles shall be used on all outside receptacles and in garages and bathrooms.

2404. Emergency Generator Service (I)

An emergency generator complying with the applicable codes and standards of Section 1902 shall be provided to deliver emergency electrical services during interruption of the normal electrical service to the distribution system as follows:

A. Exit lights;

B. Exit access corridor lighting;

C. Fire alarm;

D. Essential communication systems; and

E. Heating system.

SECTION 2500. HEATING, VENTILATION, AND AIR CONDITIONING (HVAC) (II)

A. The HVAC system shall be inspected at least once every year by a certified and/or licensed technician.

B. The facility shall maintain a temperature of between seventy-two (72) and seventy-eight (78) degrees Fahrenheit in resident areas.

C. A facility shall not install a HVAC supply or return grille within three (3) feet of a smoke detector. (I)

D. A facility shall not install HVAC grilles in floors.

E. Return air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in a manner that would be an irritant to residents, staff, or visitors.

F. A facility shall have each shower, bath, and restroom with either operable windows or have approved mechanical ventilation.

G. An exhaust fan and Type I hood of proper size shall be installed over the cook stoves and ranges vented to the outside.

H. Hoods, vents, ducts, and removable filters shall be maintained clean and free of grease accumulations.

SECTION 2600. PHYSICAL PLANT

2601. Facility Accommodations (II)

A. There shall be sufficient living arrangements providing for residents' quiet reading, study, relaxation, entertainment, or recreation, to include living, dining, and recreational areas available for residents' use.

B. Minimum square footage requirements shall be:

1. Twenty (20) square feet per licensed bed of living and recreational areas combined, excluding bedrooms, halls, kitchens, dining rooms, bathrooms, and rooms not available to the residents;

2. Fifteen (15) square feet of floor space in the dining area per licensed bed.

C. Methods for ensuring visual and auditory privacy between residents and staff and visitors shall be provided as necessary.

2602. Resident Rooms

A. Each resident room shall be equipped with the following at a minimum for each resident:

1. A comfortable single bed having a mattress with moisture-proof cover, sheets, blankets, bedspread, pillow, and pillowcases. Roll-away type beds, cots, bunkbeds, and folding beds shall not be used. Beds shall be at least thirty-six (36) inches wide and seventy-two (72) inches in length. It is permissible to utilize a recliner in lieu of a bed or remove a resident bed and place the mattress on a platform or pallet provided the physician or other authorized healthcare provider has approved it and the decision is documented in the resident's ITP. Damaged mattresses shall be replaced. (II)

2. Adequate storage to accommodate each resident's personal clothing, belongings, and toilet articles. Built-in storage is permitted.

EXCEPTION: In existing facilities, if square footage is limited, residents may share these storage areas. However, specific spaces within these storage areas shall be provided by the facility particular to each resident.

3. A comfortable chair shall be available for each resident occupying the room. In facilities licensed prior to the promulgation of this regulation, if the available square footage of the resident room will not accommodate a chair for each resident or if the provision of multiple chairs impedes resident ability to freely and safely move about within their room, the facility shall provide at least one (1) chair and have additional chairs available for temporary use in the resident's room by visitors.

4. A bedside table or desk and adequate lighting for each resident, which is conducive for studying, if the resident is of school age.

B. The resident room floor area is the usable floor area and does not include wardrobes, closets, or entry alcoves to the room. The following is the minimum floor space allowed: (II)

1. Private rooms for one (1) resident only shall be at least one hundred (100) square feet.

2. Rooms for more than one (1) resident shall be at least eighty (80) square feet per licensed bed.

C. No facility shall have set up or in use at any time more beds than the number stated on the face of the license.

D. If hospital-type beds are used, there shall be at least two (2) lockable casters on each bed, located either diagonally or on the same side of the bed.

E. Beds shall not be placed in corridors, solaria, or other locations not designated as resident room areas. (I)

F. No resident room shall contain more than four (4) licensed beds. (II)

G. Beds shall be placed at least three (3) feet apart.

H. No resident room shall be located in a basement.

I. No resident may share a bedroom with a resident of the opposite sex.

J. Access to a resident room shall not be by way of another resident room, toilet, bathroom, or kitchen.

K. In semi-private rooms, when personal care is being provided, arrangements shall be made to ensure privacy, such as portable partitions or cubicle curtains when needed or requested by a resident.

L. Consideration shall be given to resident compatibility in the assignment of rooms for which there is multiple occupancy.

M. A facility shall provide at least one (1) private room for assistance in addressing resident compatibility issues, resident preferences, and accommodations for residents with communicable disease.

2603. Work Stations

A. A work station shall be provided and shall not serve more than forty-four (44) beds.

B. A separate medicine preparation room with cabinet space for storage and work space for the preparation of medicine and a sink shall be provided at or near each work station.

C. The work station shall contain at least a telephone, bulletin board, and adequate space for keeping residents' charts and space for charting and record notation.

D. A toilet with handwashing fixtures shall be provided near each work station.

E. Each work station shall contain separate spaces for the storage of clean linen, wheelchairs, and general supplies and equipment.

2604. Bathrooms and Restrooms (II)

A. Separate bathroom facilities shall be provided for staff members, general public, and/or family.

B. Toilets shall be provided in ample number to serve the needs of staff members and general public. The minimum number of bathrooms for residents shall be one (1) toilet for each six (6) licensed beds or a fraction thereof.

C. There shall be at least one (1) handwash lavatory adjacent to each toilet. Liquid soap shall be provided in public restrooms and bathrooms used by more than one (1) resident. Communal use of bar soap is prohibited. A sanitary individualized method of drying hands shall be available at each lavatory.

D. There shall be one (1) bathtub or shower for each eight (8) licensed beds or a fraction thereof.

E. All bathtubs, toilets, and showers used by residents shall have approved grab bars securely fastened in a usable fashion.

F. Privacy shall be provided at toilets, urinals, bathtubs, and showers.

G. Toilet facilities shall be at or adjacent to the kitchen for kitchen employees.

H. Facilities for handicapped persons shall be provided whether or not any of the residents are classified as handicapped.

I. All bathroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surface to the highest level of splash.

J. An adequate supply of toilet tissue shall be maintained in each bathroom.

K. Easily cleanable receptacles shall be provided for waste materials. Such receptacles in toilet rooms for women shall be covered.

L. Soap, bath towels, and washcloths shall be provided to each resident as needed. Bath linens assigned to specific residents shall not be stored in centrally located bathrooms. Provisions shall be made for each resident to properly keep their bath linens in their room, such as on a towel bar or hook designated for each resident occupying that room, or bath linens to meet resident needs shall be distributed as needed, and collected after each use and stored properly.

2605. Doors (II)

Doors providing access into the facility and resident room(s) shall be in accordance with the applicable codes of Section 1902.

2606. Ramps (II)

A. At least one (1) exterior ramp, accessible by all residents, staff, and visitors shall be installed from the first floor to grade.

B. The ramp shall serve all portions of the facility where residents are located.

C. The surface of the ramp shall be of nonskid materials.

D. Ramps shall discharge onto a surface that is firm and negotiable by a wheelchair in all weather conditions and to a location accessible for loading into a vehicle.

2607. Handrails and Guardrails (II)

A. A facility shall provide handrails on at least one (1) side of each corridor or hallway.

B. A facility shall provide guardrails on all porches, walkways, and recreational areas, such as decks and the like, in accordance with the applicable codes of Section 1902.

2608. Janitor's Closet (II)

A. There shall be a lockable janitor's closet in all facilities. Each closet shall be equipped with a mop sink or receptor and space for the storage of supplies and equipment.

B. All janitor's closets and equipment shall be cleaned daily. Frequent inspections shall be made by a responsible person for compliance. Cleaning materials and supplies shall be stored in a safe manner in a well-lighted closet. All harmful agents and equipment shall be in a locked cabinet or closet.

2609. Storage Areas

A. The facility shall provide adequate general storage areas for resident and staff belongings, equipment, and supplies.

B. Supplies and equipment shall not be stored directly on the floor. Supplies and equipment susceptible to water damage or contamination shall not be stored under sinks or in areas with a propensity for water leakage. (II)

2610. Living, Recreation, and Dining Areas

A. A facility shall provide indoor areas where residents can go for quiet, reading, study, relaxation, entertainment, or recreation.

B. The living and recreational areas together shall provide a minimum of fifteen (15) square feet per resident, not including bedrooms, halls, kitchens, dining rooms, bathrooms, and any rooms not available to residents.

C. The dining area shall provide a minimum of fifteen (15) square feet per resident.

D. Where a central dining room is used to serve more than one facility, it shall be readily accessible to all residents of each facility and residents must be able to access the dining room through a heated corridor.

2611. Facility Grounds

A. There shall be sufficient outdoor recreational play area available as determined by the number and ages of the residents.

B. The outdoor area shall be free of unprotected physical hazards.

C. Playground equipment, such as a climbing apparatus, slide, and swing, shall be firmly anchored.

D. The facility and outside area shall be maintained in good condition and shall be clean at all times, free from accumulated dirt, trash, and rodent infestation. Garbage and outdoor trash containers shall be covered. Outdoor containers shall be emptied at least weekly.

E. Outdoor areas deemed by the Department to be unsafe, such as steep grades, cliffs, open pits, high voltage electrical equipment, high speed roads, or swimming pools, shall be enclosed by a fence or have natural barriers to protect the residents. Entrances and exits to fenced hazardous areas shall be locked when not in use.

F. Fenced areas which are part of a fire exit from the building shall have a gate which is unlockable in case of emergency on the side of the area opposite the building.

G. Machinery and equipment rooms shall be kept locked.

2612. Location

A. Transportation. A facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. A facility shall have a parking area to reasonably satisfy the needs of residents, staff members, and visitors.

C. Access to firefighting equipment. A facility shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

SECTION 2700. SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2800. GENERAL

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Added by State Register Volume 15, Issue No. 4, eff April 26, 1991. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4596, eff June 24, 2016.

61–104. Hazardous Waste Management Location Standards.

(Statutory Authority: 1976 Code § 44–56–30 et. seq.)

I. Purpose and Scope:

A. This regulation creates State requirements for the location of hazardous waste treatment, storage, and disposal (TSD) facilities. Because the location of hazardous waste TSD facilities should be limited to those areas where there will be minimal impact on human health and the environment, all operating TSD facilities must demonstrate to the Department that their location complies with this regulation.

B. The scope of the regulation is limited to issues of public health and protection of the environment. The authority to institute land use planning and zoning is an option to be instituted by local governments in South Carolina. Although the S.C. Department of Health and Environmental Control is often requested to deny permits to industries which propose activities near residential or other areas, such requests can only be considered by the Department when public health and the environment are at risk. Aesthetic considerations, nuisances such as incidental odors, noises, and lights, or competing economic interest are mainly regulated through zoning by local governments and are not addressed in this regulation.

II. Applicability:

A. This regulation shall apply to all applicants for permits as required by R.61-79 to treat, store, or dispose of hazardous waste; provided, however, it shall not apply to those applicants for permits for post-closure activities only. For those units permitted prior to the effective date of this regulation, demonstration of compliance with these location standards shall be deemed a condition of the permit. permitted until the applicant demonstrates compliance with these location standards. For units permitted prior to the effective date of this regulation, failure to submit a demonstration of compliance with these location standards within one hundred and eighty days of the effective date of this regulation shall be deemed to be a failure to meet the conditions of the permit.

B. [Blank]

C. Demonstration of compliance with this regulation must accompany the permit application required by R.61-79.270.10 unless the application is for a permit reissuance.

III. Definitions:

A. "Adjacent" to a wetland means bordering, contiguous, neighboring, or hydrologically interconnected via surface water or groundwater. Adjacent wetlands include, but are not limited to, those areas that are separated from other waters of the State by man-made dikes, berms, or barriers, natural river berms, and beach dunes. Areas hydrologically interconnected are considered to be those where a realistic potential exists for migration of a release or spill to an adjacent wetlands via surface water or groundwater.

B. "Appurtenance" means any ancillary equipment that is stationary to the unit and contains or transports hazardous waste.

C. "Areas of complex hydrogeology" typically include, but are not limited to, karst terrane; fractured rock formations (joints and faults; excludes healed fractures) irregularly stratified geologic deposits (e.g., certain fluvial, deltaic and barrier island deposits); mixed hydrogeologic regimes (e.g., sedimentary deposits overlying fractured crystalline bedrock); folded areas where flow paths may be contorted, and recharge zones where background water quality cannot be determined.

D. "Areas susceptible to mass movement" means those areas of influence (i.e., areas characterized as having an active or substantial possibility of mass movement) where the movement of earth material at, beneath, adjacent, or in the immediate area of the unit, because of natural or man-made events, results in the downslope transport of soil and rock material by means of gravitational influence. Areas of mass movement include, but are not limited to, landslides, avalanches, debris slides and flows, creep, solifluction, liquefaction, block sliding, rock fall, and slump.

E. "Braided" means a river system characterized by an intricate network of dividing and reuniting channels (frequently more than one) around a network of predominantly sand and gravel bars and islands, causing the river channels to follow a sinuous rather than straight course.

F. "Cave" means a naturally occurring cavity, recess, chamber, or series of chambers and galleries beneath the surface of the earth.

G. "Class GA groundwater" is defined in R.61-68 as those groundwaters that are characterized by either of the following factors: the groundwater is irreplaceable because no reasonable alternative source of drinking water is available to substantial populations, or the groundwater is ecologically vital because it provides the base flow for a particularly sensitive ecological system that, if polluted, would destroy a unique habitat.

H. "Coastal marine floodplain" means the area along any coast that has historically been inundated during times of flooding, but is otherwise above water, except for standing water such as in a marsh or pond.

I. "Displacement" means the relative movement of any two sides of a fault measured in any direction.

J. "Ephemeral" means a short-lived or transitory river or portion of a river that flows only in direct response to precipitation.

K. "Existing unit" means a unit which has received a hazardous waste permit by the effective date of this regulation or has met the requirements for interim status under R.61-79.270.70.

L. "Expansion or Expanding unit" means any increase in the capacity of an existing unit, as defined above, any change in the types of waste received by an existing unit, any increase in the quantities of waste received by an existing unit on a periodic basis, or the addition of a unit or units for the same activity as the existing unit.

M. "Fault" means a fracture or zone of fracturing in any material along which there has been an observable amount of displacement of the sides relative to one another and parallel to the fracture.

N. "Flow net" is a graph of flow lines and equipotential lines used in the study of groundwater flow that represents two-dimensional movement through porous media. Equivalent hydrogeologic models may be used in place of a flow net, subject to the approval of the Department.

O. "Fluvial floodplain" means the area along any river or stream that has historically been inundated during times of flooding, but is otherwise above water, except for standing water such as in a marsh, pond, or oxbow lake.

P. "Hazardous waste" means a hazardous waste as defined in R.61-79.261 of the South Carolina Hazardous Waste Management Regulations (SCHWMR).

Q. "Historical migration zone" means the area within which erosion of coastal marine, lacustrine or fluvial floodplains is predicted to occur within the next 25 years. The historical migration zone includes the following landforms: coastal marine, lacustrine, and braided or meandering fluvial systems; including ephemeral systems and local segments of other fluvial floodplains, such as canaliform systems that are locally braided, locally meandering, or ephemeral.

R. "Holocene" means the most recent geologic epoch within the Quaternary Period, from the end of the Pleistocene epoch to the present.

S. "Horizontal ground acceleration" is the change in velocity over time relative to horizontal movement of the earth's surface as measured at a particular point during an earthquake.

T. "Karst terrane" means areas where distinctive topography having characteristic surface and subterranean features is developed because of liquefaction of overburden or the dissolution of limestone, dolomite, or other soluble rock. Characteristic physiographic features present in karst terrane include but are not limited to sinkholes, closed depressions, sinking streams, caves, and blind valleys. Characteristic subsurface solution features may be evidenced by drilling rod drops and fluid loss during well drilling.

U. "Lacustrine floodplain" means the area along any lakeshore that has historically been inundated during times of flooding, but is otherwise above water, except for standing water such as in a marsh or pond.

V. "Land-based unit" means a unit which is used for the treatment, storage, or disposal of a hazardous waste and is subject to Section R.61-79.264 Subpart F including surface impoundments, landfills, waste piles, land treatment units. Units exempt from the Subpart F requirements under

264.90(b) and covered indoor waste piles in compliance with Section 264.250(c) shall be considered as non-land-based units.

W. "Locally" means a particular segment or the reach of a river which is characterized by the distance that encompasses several river bends or wave lengths, each being a minimum of eight or more channel widths.

X. "Meandering" means a sinuous river system characterized by a single main channel that is regionally characterized by a series of irregular "S" shaped curves.

Y. "Navigable waters" means those waters which are now navigable, or have been navigable at any time, or are capable of being rendered navigable by the removal of accidental obstructions, by rafts of lumber or timber or by small pleasure or sport fishing boats.

Z. "New unit" means a unit, other than an existing or expanding unit, as defined above, for which a permit decision will be made after the effective date of this regulation.

AA. "Non-land-based unit" means an incinerator, tank and its associated piping and underlying containment system, or container storage area, and other units which are used for the treatment, storage, or disposal of a hazardous waste and are not subject to Section R.61-79.264 Subpart F.

BB. "One hundred-year flood" means a flood discharge that has a one-percent chance of being equaled or exceeded in any given year.

CC. "One hundred-year floodplain" means any land area which is subject to a one percent or greater chance of flooding in any given year from any source.

DD. "Poor foundation conditions" means those areas where features exist which indicate that a natural or man-induced event may result in inadequate foundation support for the structural components of a unit.

EE. "Post-closure activities" means those regulated activities performed at a TSD unit after closure has been completed and approved by the Department.

FF. "Public drinking water supply" means water, whether bottled or piped, provided to the public for human consumption; provided that the public drinking water supply shall not include a drinking water system serving only a single private residence or dwelling (R.61-58).

GG. "Recharge area" for a particular saturated geologic unit is defined as areas where water enters the geologic unit through downward migration. Principal examples include: outcrop areas of a particular geologic unit where the potentiometric head within the unit decreases with depth; and, in the subsurface, where the potentiometric head relationship and leakage factors across any confining unit allow for downward flow into a particular geologic unit.

HH. "Release" means any spilling, leaking, pouring, emitting, emptying, discharging, injecting, pumping, escaping, leaching, dumping, or disposing of hazardous waste or hazardous constituents into the environment including the abandonment or discarding of containers, barrels, and other closed or open receptacles containing hazardous waste or hazardous constituents.

II. "Risk Assessment" means a study consisting of Hazard Identification, Dose-Response Assessment, Exposure Assessment and Risk Characterization. The study must conform at least to the EPA Guidance:"Superfund Public Health Evaluation Manual" EPA #540/1-86/06 October 1986 or more stringent guidelines as established by the Department.

JJ. "Sole source aquifer" is defined as specified in the Federal Safe Drinking Water Act.

KK. "Structural integrity" means the ability of a unit to withstand physical forces exerted upon designed components, appurtenances, and containment structures (e.g., liners, dikes) of the unit.

LL. "Underground mine" means any subterranean excavation for minerals or ores having a roof of undisturbed rock (as opposed to open-pit excavations).

MM. "Washout" means the movement of hazardous waste from the unit as a result of a flood event.

NN. "Wetland(s)" means those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support and under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands must possess three essential characteristics: (1) hydrophytic vegetation, (2) hydric soils, and (3) wetland hydrology.

IV. Location Criteria:

A. Adverse geologic and hydrologic settings:

1. Seismic considerations:

a. New and expanding land-based and non-land-based units shall not be located within a minimum of two hundred feet of a fault where displacement during the Holocene Epoch within the Quaternary Period has occurred. The setback distance or the time period for displacement may be expanded by the Department as necessary to protect human health and the environment.

b. Owners or operators of new and expanding land-based and non-land-based units must demonstrate to the satisfaction of the Department that the structural integrity of the unit will allow it to maintain confinement of the hazardous waste or hazardous waste constituents such that no adverse environmental or health impacts will occur during and after any ground movement, liquefaction, or seismic wave motion equal to the maximum horizontal acceleration predicted with a ten percent probability of occurrence at the site in two hundred and fifty years.

c. Owners or operators of existing land-based and non-land-based units must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR's unless the owners or operators can demonstrate to the satisfaction of the Department that the requirements specified in paragraphs 1.a. and 1.b. of this section are met for the existing units.

2. Floodplains

a. New and expanding land-based units and appurtenances shall not be located in a one hundred-year floodplain or in the historical migration zone of coastal marine, lacustrine, or braided or meandering fluvial system.

b. New and expanding non-land-based units and appurtenances shall not be located in a one hundred-year floodplain or the historical migration zone of a coastal marine, lacustrine, or braided or meandering fluvial system, unless the owner or operator demonstrates to the satisfaction of the Department that the unit and appurtenances are designed, constructed, operated, and maintained to prevent the washout of any hazardous waste by a one-hundred-year flood, and to enable the unit to withstand the effects of erosion during its active life.

c. Owners or operators of existing land-based and non-land-based units and appurtenances located in a one hundred-year floodplain, but outside the historical migration zone of a coastal marine, lacustrine, and braided or meandering fluvial system, must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR unless the owner or operator can demonstrate to the satisfaction of the Department that such units and appurtenances are designed, operated, and maintained to prevent washout of any hazardous waste by a one hundred-year flood, and that such units and appurtenances can withstand the effects of erosion during their active life.

d. Owners or operators of existing land-based units and appurtenances located inside the historical migration zone of a coastal marine, lacustrine, braided or meandering fluvial system must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR.

e. Owners or operators of existing non-land-based units and appurtenances located inside the historical migration zone of a coastal marine, lacustrine, or braided or meandering fluvial system must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR unless the owner or operator can demonstrate to the satisfaction of the Department that the unit and appurtenances are designed, constructed, operated, and maintained to withstand the effects of erosion during its active life.

f. The historical migration zone, as outlined under paragraphs 2.a. through 2.e., shall be determined by the owner or operator through a geomorphic study as approved by the Department.

3. Underground mines and caves; the placement of any hazardous waste in any underground mine or cave is prohibited.

B. Unstable terrains

1. Karst

a. New and expanding land-based and non-land-based units shall not be located in karst terrane unless the owner or operator demonstrates to the satisfaction of the Department that:

(1) A geotechnical and hydrogeologic investigation of the site shows that the site is historically stable and subsidence into or collapse of subsurface solution cavities as a consequence of instability caused by liquefaction of overburden or by the dissolution of soluble rocks will not occur; or

(2) Where the requirement of paragraph 1.a.(1) cannot be met, that appropriate engineered measures are applied to ensure the unit's structural integrity and to contain or eliminate any adverse effects to human health and the environment that may occur as a result of karst terrane.

b. Owners or operators of existing land-based or non-land-based units located in karst terrane must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR's, unless the appropriate demonstration specified in paragraphs 1.a. of this section is made to the satisfaction of the Department.

2. Poor foundation conditions

a. New and expanding land-based and non-land based units shall not be located in regions where poor foundation conditions may exist unless the owner or operator demonstrates to the satisfaction of the Department the following:

(1) The absence of poor foundation conditions at, beneath, adjacent, or in the immediate area of the unit; or,

(2) If poor foundation conditions exist, the problem conditions are corrected.

b. Owners or operators of existing land-based and non-land-based units located in regions where poor foundation conditions may exist must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR, unless the owner or operator demonstrates to the satisfaction of the Department:

(1) The absence of poor foundation conditions, at, beneath, and adjacent to the unit, or in the immediate area of the unit, or

(2) If poor foundation conditions exist, the problem conditions can and will be corrected by modifying subsurface soil conditions, unit location, or design and operation of the unit.

3. Areas susceptible to mass movement.

a. New and expanding land-based and non-land-based units shall not be located in regions where mass movement may occur unless the owner or operator demonstrates to the satisfaction of the Department the following:

(1) That the unit is not in an area susceptible to mass movement, or

(2) If evidence of mass movement exists, appropriate engineered measures are applied to ensure unit structural integrity and to eliminate the threats posed to human health and the environment by mass movement.

b. Owners or operators of existing land-based and non-land-based units located in regions where mass movement may occur must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR, unless the owner or operator demonstrates to the satisfaction of the Department the following:

(1) The unit is not in an area susceptible to mass movement, or

(2) If evidence of mass movement exists, appropriate engineered measures can and will be applied to ensure unit structural integrity and to eliminate the threats posed to human health and the environment by mass movement.

C. Media-specific requirements

1. Groundwater

a. Groundwater vulnerability.

(1) New land-based units and expansions of existing land-based units are prohibited in areas where the owner or operator cannot demonstrate to the satisfaction of the Department:

(a) That the unit is underlain by a protective clay or silty clay unit. The thickness of this unit must be greater than five feet. The hydraulic conductivity of this unit must not exceed 1E-06 centimeters per second. This unit must be composed of materials with a protective high ion exchange capacity and it should have a high organic content. The continuity of this protective unit must be such that it exceeds a minimum of two hundred feet in the hydraulically upgradient direction and a minimum of five hundred feet in the hydraulically sidegradient directions, and it is continuous from below the site to the point where shallow groundwater is discharging to the nearest surface water body; and

(b) That the site is not located in an area where the hydrogeologic conditions allow the migration of groundwater in shallow geologic units, having little potential as an underground source of drinking water, into deeper units. Specific detail concerning this requirement are as follows. At all locations across the site, the potentiometric head in the shallow saturated geologic material overlying the confining unit described in paragraph (a) of this section must be lower than the potentiometric surface of the geologic material below the confining unit (i.e., an upward hydraulic gradient must exist). If the material above the confining unit is not permanently saturated under natural conditions, then the potentiometric head in the geologic units underlying the confining unit must be at an elevation higher than the top of the confining unit; and

(c) That a minimum ten foot separation can be maintained between the base of the waste management unit and the high water table as it exists naturally, or through long-term, permanent and maintenance-free methods; and

(d) That a minimum fifteen foot vertical separation of naturally occurring or engineered material can be maintained between the base of the constructed liner and bedrock. The nature of the material making up this interval is subject to Department approval; and

(e) That the unit is not located over an area where a stratum of limestone exhibiting secondary permeability with an average thickness of greater than five feet lies within fifty feet of the base of the unit.

(f) That a unit can be located such that if a leak should occur, the resulting groundwater discharge to the receiving surface water body shall not contravene standards set by the State Water Classifications and Standards (R.61-68).

(2) Owners or operators of existing land-based units which cannot meet the requirements of paragraph (1) of this section shall submit to the Department an amended closure plan and close the unit in accordance with the requirements in R.61-79.264 or 265 Subpart G of the SCHWMR's, unless, except in the case (1)(e) of this section, appropriate engineered measures are applied to ensure the unit's structural integrity and to contain or eliminate any adverse effects to human health and the environment that may occur as a result of a release from the unit.

(3) New and expanding non-land-based units are prohibited in areas where the owner or operator cannot demonstrate to the satisfaction of the Department that the requirements of paragraph (1) of this section are met or that appropriate engineered measures are applied to ensure the unit's structural integrity and to contain or eliminate any adverse effects to human health and the environment that may occur as a result of a release from the unit.

(4) Owners or operators of existing non-land-based units which cannot meet the requirements of paragraph (1) of this section shall submit to the Department an amended closure plan and close the unit in accordance with the requirements in R.61-79.264 or 265 Subpart G of the SCHWMR's unless appropriate engineered measures are applied to ensure the unit's structural integrity and to contain, or eliminate any adverse effects to human health and the environment that may occur as a result of a release from the unit.

b. Complex hydrogeology.

(1) New land-based units and expansions of existing land-based units are prohibited in areas where the owner or operator cannot demonstrate to the satisfaction of the Department:

(a) That the hydrogeologic properties of the site can be adequately characterized. The characterization shall include a detailed description of the geologic units below the site (including mineralogy, sedimentary structures, thickness, continuity, and structure), the

hydraulic properties of each geologic unit (including secondary porosity and a discussion of variations noted across the site), and direction and rate of groundwater flow within the uppermost aquifer and all interconnected aquifers and confining units using a groundwater flow net. In addition, the relationship between the units below the site to locally and regionally recognized geologic and hydrogeologic units must be described; and

(b) Compliance with the groundwater monitoring requirements under R.61-79.264 Subpart F of the SCHWMR's and

(c) The feasibility of a corrective action program at the site. The demonstration shall show how a corrective action response will be effectively implemented to prevent a release to groundwater from migrating beyond the facility property boundary. The corrective action feasibility demonstration shall illustrate all the factors that are necessary to be in compliance with the corrective action requirements under R.61-79.264 Subpart F of the SCHWMR's.

(2) Owners or operators of existing land-based units in areas which cannot meet the requirements of paragraph (1) of this section shall submit to the Department an amended closure plan and close the unit in accordance with the requirements in R.61-79.264 or 265 Subpart G of the SCHWMR's.

(3) New and expanding non-land-based units are prohibited where the owner or operator cannot demonstrate to the satisfaction of the Department that the requirements of paragraph (1) of this section are met or that appropriate engineered measures are applied to ensure the unit's structural integrity and to contain or eliminate any adverse effects to human health and the environment that may occur as a result of a release from the unit.

(4) Owners or operators of existing non-land-based units which cannot meet the requirements of paragraph (1) of this section shall submit to the Department an amended closure plan and close the unit in accordance with the requirements in R.61-79.264 or 265 Subpart G of the SCHWMR's unless appropriate engineered measures are applied to ensure the unit's structural integrity and to contain or eliminate any adverse effects to human health and the environment that may occur as a result of a release from the unit.

c. Groundwater resource value.

(1) New land-based units and expansions of existing land-based units shall not be located over Class GA groundwater or over the recharge area for Class GA groundwater as designated by the Department, over a sole source aquifer, or over the recharge area for a sole source aquifer as designated by the Department.

(2) Owners or operators of existing land-based units which cannot meet the requirements of paragraph (1) of this section shall submit to the Department an amended closure plan and close the unit in accordance with the requirements in R.61-79.264 or 265 Subpart G of the SCHWMR's.

(3) New and expanding non-land-based units are prohibited in areas where the owner or operator cannot demonstrate to the satisfaction of the Department that the requirements of paragraph (1) of this section are met, or that appropriate engineered measures are applied to ensure the unit's structural integrity and to contain or eliminate any adverse effects to human health and the environment that may occur as a result of a release from the unit.

(4) Owners or operators of existing non-land-based units which cannot meet the requirements of paragraph (1) of this section shall submit to the Department an amended closure plan and close the unit in accordance with the requirements in R.61-79.264 or 265 Subpart G of the SCHWMR's unless appropriate engineered measures are applied to ensure the unit's structural integrity and to contain or eliminate any adverse effects to human health and the environment that may occur as a result of a release from the unit.

2. Surface water

a. New and expanding land-based and non-land-based units shall be prohibited in the following areas:

(1) Within a minimum of one thousand feet of any navigable waters.

(2) Within that portion of the drainage basin included in a one-half mile radius, at a minimum, on the upstream side of a public drinking water supply intake from a river or stream;

(3) Within that portion of the drainage basin which is within one-half mile, at a minimum, of a lake, pond, or reservoir used as a source of public drinking water supply.

b. The owner or operator of existing land-based and non-land-based units located within the prohibited areas listed in 2.a. above must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR's unless the owner or operator demonstrates to the satisfaction of the Department the following:

(1) The capability of the unit and the area within the prohibited areas listed in 2.a. above to control and/or contain run-off from the maximum rainfall in twenty four hours from the twenty five-year storm and the capability to divert run-on from land adjoining this area and the unit during such a storm unless sufficient capacity is included in the run-off system to control and/or contain run-on.

(2) The result of any release of hazardous waste to the receiving surface water body will not contravene standards set by the State Water Classifications and Standards (R.61-68).

c. No new and expanding unit shall be located within a minimum of one-half mile of a federally designated wild and scenic river or a state designated scenic river.

3. Air

a. New and expanding hazardous waste units shall not be located in an EPA designated non-attainment area unless the owner or operator demonstrates, prior to operation, that the unit will be in compliance with the Department's Air Pollution Control Requirements for non-attainment areas.

b. The owner or operator of new, expanding and existing hazardous waste units must describe air quality problems which may result from the maximum operations of hazardous waste units. To provide information on the facility's impact on air quality, the owner or operator must prepare an assessment of the air quality impacts which may occur based on historical or estimated meteorological conditions and to what extent such respective problems and conditions will affect neighboring communities including potential damage to wildlife, crops, vegetation and physical structures, public health and the environment.

c. The owner or operator of new, expanding and existing hazardous waste units must prepare a plan for operations when an Air Stagnation Advisory (ASA) is issued for the area in which the hazardous waste unit is located. An ASA is issued by the national Weather Service to local media and is broadcast on the National Oceanic and Atmospheric Association (NOAA) radio network. The facility must describe what actions will be taken to minimize emissions for the duration of the ASA. In addition, the facility must describe what actions will be taken in the event that any stage of an air pollution episode (as described in SC Air Pollution Control Regulation No. 61-62.3) is declared for that area. These actions must, at a minimum, meet the requirements set forth in Section II of SC Air Pollution Control Regulation No. 61-62.3 for those operations directly related to the facility's hazardous waste unit.

D. Ecological resources:

1. Wetlands

a. New land-based and non-land-based units shall be prohibited in or adjacent to wetlands.

b. Expansions of existing land-based and non-land-based units shall be prohibited in wetlands.

c. Expansions of existing land-based and non-land-based units shall be prohibited adjacent to wetlands unless the following requirements are met by the owner or operator:

(1) All expansion will be a minimum of five hundred feet from a wetlands.

(2) The owner or operator must demonstrate to the satisfaction of the Department long-term integrity of the unit so as to prevent migration of hazardous waste or hazardous constituents into the wetland and to ensure protection of human health and the environment. Such a demonstration shall include adequate design elements and operating procedures to address the following factors:

(a) Erosion, stability, and migration potential of native wetland soils, muds, and deposits used to support the unit or ancillary structures,

(b) Erosion, stability, and migration potential of dredged and fill materials used to support the unit or ancillary structures,

(c) Pathways for movement of hazardous waste or constituents and the migration potential of these materials in the event of a release from the unit,

(d) Ease and ability of characterizing groundwater and surface water flow rates and directions and the effectiveness of groundwater and surface water monitoring in the presence of tidal and other hydrogeologic influences, and

(e) Any additional factors, as necessary, to demonstrate that the integrity of the unit in or adjacent to the wetland is sufficiently protective of human health and the environment.

(3) The owner or operator must demonstrate to the satisfaction of the Department that the unit will be designed and operated so as to provide adequate protection of the ecological resources of the wetland from migration of hazardous waste or hazardous constituents. The demonstration shall include, but not be limited to, consideration of the following factors:

(a) The nature and chemical characteristics of the waste and constituents managed in the unit including its persistence, toxicity, mobility, and propensity to bioaccumulate,

(b) Impacts on fish, wildlife, and other marine resources and their habitat from releases of hazardous wastes or hazardous constituents that may result as a consequence of a unit expansion,

(c) The potential effects of catastrophic hazardous waste or constituent releases to the wetland and the resultant impacts on the environment, and

(d) Any additional factors, as necessary, to demonstrate that ecological resources in or adjacent to the wetland are sufficiently protected.

(4) The owner or operator shall offset unavoidable wetland impacts through wetlands restoration or creation.

(5) The owner or operator must comply with other Federal requirements, as applicable, including Section 10 of the Rivers and Harbors Act of 1899, Executive Order 11990 (Protection of Wetlands), and Executive Order 11988 (Floodplain Management).

(6) Where the proposed expansion involves the discharge of dredged or fill material in a wetland or other waters of the United States, the owner or operator must apply for a permit by the U. S. Army Corps of Engineers as required under Section 404 of the Clean Water Act.

d. Owner or operators of existing land-based or non-land-based units located in or adjacent to a wetland, including wetlands within the facility property, shall close the unit unless the requirements under paragraphs 1.c.(1)-(6) of this section are met.

2. Other environmentally sensitive areas

a. New and expanding land-based and non-land-based units shall be prohibited in the following areas:

(1) On prime farmland as designated by the United States Soil Conservation Service;

(2) Within an area that will adversely impact an archeological site as determined by the State Historic Preservation Officer and the State Archaeologist or a historic site as determined by the State Historic Preservation Officer;

(3) Within a minimum of one-half mile of national or state parks, national wildlife refuges, major water impoundments of one hundred acres or larger, state heritage preserves as defined in Section 51-17-10 of the South Carolina Code of Laws, designated wilderness areas of a national forest, and areas of special national or regional natural, recreational, scenic, or historic value, or other significant environmentally sensitive areas.

b. The owner or operator of existing land-based and non-land-based units located within the prohibited areas listed in 2.a. above must submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR's, unless the owner or operator demonstrates to the satisfaction of the Department that the environmentally sensitive area is adequately protected and will not be adversely affected by the hazardous waste activity at the unit.

E. Buffer zones and setbacks:

1. Buffer zones

a. Owners or operators of new, expanding, and existing land-based units shall establish a dedicated buffer zone of at least but not necessarily limited to two hundred feet, between the unit and the facility property boundary. The required distance will include the minimum of two hundred feet, and any additional distance determined appropriate to adequately ensure that groundwater time-of-travel measured along a one-hundred foot flow line originating at the base of the unit, allows adequate time to implement the corrective action response necessary to remedy a hazardous waste release to groundwater and to contain or eliminate the release within the facility property boundary. Calculation of the groundwater time-of-travel shall be made as specified under EPA Document (530-SW-86-0228) entitled Criteria for Identifying Areas of Vulnerable Hydrogeology under the Resource Conservation and Recovery Act.

b. New and expanding land-based units that cannot establish a dedicated buffer zone to fulfill the requirements under paragraph 1.a. of this section are prohibited.

c. Owners or operators of existing land-based units that cannot establish a dedicated buffer zone to fulfill the requirements under paragraph 1.a. of this section shall submit to the Department an amended closure plan and close the unit in accordance with the requirements in R.61-79.264 or 265 Subpart G of the SCHWMR's, unless plans are submitted to the Department for appropriate additional measures to ensure an equivalent level of protection to human health and environment, which may include, but not necessarily be limited to:

(1) Groundwater Monitoring;

(2) Installation of recovery wells; and

(3) Development of a contingent corrective action plan.

d. A dedicated buffer zone as required under paragraph 1.a. of this section shall meet the following criteria:

(1) Shall consist of an area of land between the unit and the facility property boundary, that is owned by the owner or operator and serves as a separation distance between the unit and the facility property boundary and must remain accessible for corrective action as necessary. The buffer zone shall not be used for the treatment, storage or disposal of hazardous waste;

(2) Shall serve as a buffer zone for as long as hazardous constituents remain in the unit; and

(3) Shall be recorded as a notation on the facility property deed as a dedicated portion of the facility property for the sole purpose for which it is intended as specified under paragraphs d.(1) and d.(2) of this section.

2. Setbacks

a. For new and expanding units, the owner or operator shall meet the following setback distances at the time of permit application to the Department.

(1) No land-based or non-land-based unit shall be located within a minimum of two thousand feet of any existing church, school, hospital, or any other structure which is routinely occupied by the same person or persons more than twelve hours per day or by the same person or persons under the age of eighteen for more than two hours per day, except those owned by the applicant.

(2) A land-based unit must not be located within a minimum of one thousand feet in the downgradient direction, a minimum of fifteen hundred feet in the sidegradient direction and at any distance upgradient of any well used as a source of water for human or animal consumption and/or bathing or irrigation that is in a hydrologic unit, potentially impacted by the unit. When evaluating this criteria, consideration must be given to the existing and potential use of groundwater. Exceptions to this requirement may be granted if the petitioner can demonstrate to the satisfaction of the Department that the hydrogeologic conditions below the site provide protection to the aquifer in use.

b. Existing land-based and non-land-based units that cannot meet a required setback distance under paragraph a. of this section shall submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR,

unless they perform a risk assessment, as approved by the Department, that demonstrates public health and the environment will be adequately protected.

F. Transportation and preparedness:

1. Transportation; new and expanding land-based and non-land-based units shall be prohibited and existing land-based and non-land-based units shall submit to the Department an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR's unless the transportation corridors will minimize the potential for and effects of hazardous spills and accidents in populated communities by demonstrating the following:

a. Access to sites by surface and water transportation modes shall be by roads, rails and water ways with the capacity to accept the demands created by the facility.

b. The facility must be located such that when conveyed on roadways, hazardous waste will be transported on interstate, state, or county highways or other roads which are well maintained, well constructed, free of obstructions and with a high degree of visibility. No hazardous waste shall be transported on roads where weight restrictions for the road or any bridge on the road will be exceeded in the selected route of travel.

c. The facility must be located such that an existing and acceptable alternate route is available if access by the primary transportation corridor is blocked.

2. Preparedness

a. No unit shall be located at a facility where the owner or operator cannot reach an agreement with the Local Emergency Planning Committee (LEPC) for appropriate emergency services unless the owner or operator: (1) documents the refusal of the LEPC to enter into such agreements; and (2) makes appropriate arrangements with the local emergency service authorities such as fire, police, hospitals, and local contractors.

b. The Department reserves the right to require more than minimum requirements for the purpose of protecting public health and the environment, and reserves the right to deny siting approval if adequate emergency preparedness requirements are not provided either through agreements or by the applicant.

c. Owners or operators of existing units which cannot demonstrate to the satisfaction of the Department compliance with paragraphs a. and b. of this section must submit an amended closure plan and close in accordance with the procedures specified in R.61-79.264 Subpart G of the SCHWMR's.

V. Certification; the information submitted in compliance with this regulation shall be prepared by or under the direct supervision of a professional engineer or geologist as required in the 1976 Code of Laws of South Carolina as amended, Title 40. Chapters 21 and 77.

VI. Severability; should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Added by State Register Volume 15, Issue No. 2, eff February 22, 1991.

61–105. Infectious Waste Management Regulations.

(Statutory Authority: S.C. Code §§ 44–93–10 et seq.; 44–93–100 (Act 351, July 20, 2002))

A. Purpose and Scope.

(1) The purpose of this regulation is to establish a program to carry out the provisions of the South Carolina Infectious Waste Management Act, Act Number 134 of 1989, Chapter 93 of Title 44 of the 1976 Code of Laws, as amended.

(2) This regulation shall apply to infectious waste management as defined in 44-93-20 of the Act and as further defined herein, that is generated, stored, contained, transferred, transported, treated, destroyed, disposed, or otherwise managed within South Carolina.

(3) Generators, transporters, owners/operators of intermediate handling facilities and treatment facilities, or any other persons who generate, store, contain, transport, transfer, treat, destroy, dispose, or otherwise manage infectious waste in South Carolina shall comply with this regulation.

(4) In addition to the requirements of this regulation, all other applicable requirements of the Department of Health and Environmental Control shall be met.

(5) In addition to the requirements of this regulation, generators, transporters, owners/operators of intermediate handling facilities and treatment facilities, or any other person shall comply with applicable Federal, State, county, and local rules, regulations, and ordinances.

B. Severability.

If any section, subsection, phrase, clause, or portion of this regulation, or the applicability to any person, is adjudged to be unconstitutional or invalid for any reason by a court of competent jurisdiction, the remaining portions of this regulation shall not be affected.

C. Use of Number and Gender.

As used in this regulation:

(1) Words in the masculine gender also include the feminine and neuter genders; and

(2) Words in the singular include the plural; and

(3) Words in the plural include the singular.

(4) Words have common dictionary meaning unless otherwise specified.

D. Definitions.

(1) Definitions carry common dictionary meanings unless otherwise specified. When used in this regulation the following words have the meaning given below:

(a) "Act" means the S. C. Infectious Waste Management Act, Act Number 134 of 1989, Chapter 93 of Title 44 of the Code of Laws of 1976, as amended.

(b) "Board" means the South Carolina Board of Health and Environmental Control which is charged with the responsibility for implementation of the Infectious Waste Management Act.

(c) "Certification" means a statement of professional opinion based upon knowledge and belief.

(d) "CFR" means the Code of Federal Regulations.

(e) "Closure" means the point in time at which facility owners or operators discontinue operation by ceasing to accept, treat, store, or dispose of infectious waste.

(f) "Commissioner" means the Commissioner of the Department or his authorized agent.

(g) "Container" means any portable device in which a material is stored, transported, treated, disposed of, or otherwise managed.

(h) "Containment" means the packaging of infectious waste or the containers in which infectious waste is placed.

(i) "Contingency Plan" means a document setting out an organized, planned and coordinated course of action to be followed in case of a fire, explosion, or release of infectious waste or infectious waste constituents , or interruption of normal procedures of infectious waste management.

(j) "Department" means the South Carolina Department of Health and Environmental Control, including personnel of the Department authorized by the Board to act on behalf of the Department or Board.

(k) "Destination facility" means an infectious waste treatment facility which has received a permit from the Department in accordance with this regulation or an appropriate out-of-state facility and which is the facility designated by the generator to which waste is to be transported.

(*l*) "Discharge" or "infectious waste discharge" means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of infectious waste into or onto any land or waters of the State, including groundwater.

(m) "Dispose" means to discharge, deposit, inject, dump, spill, leak, or place any waste into or on any land or water, including groundwater, so that the substance may enter the environment or be emitted into the air or discharged into any waters, including groundwater.

(n) "EPA" means the U. S. Environmental Protection Agency.

(*o*) "EPA identification number" means the EPA assigned Medical Waste Identification Number.

(p) ''Existing facility'' means a facility which was in operation under permits issued by the Department on June 8, 1989.

(q) ''Expand'' means an increase in the capacity of the facility or an increase in the quantity of infectious waste received by a facility that exceeds a permit condition.

(r) ''Facility'' means a location or site within which infectious waste is treated, stored, and/or disposed of.

(s) ''Final closure'' means the closure of all infectious waste management units at the facility in accordance with all applicable closure requirements so that infectious waste management activities are no longer conducted at the facility.

(t) ''Free liquids'' means liquids which separate readily from the portion of a waste under ambient temperature and pressure.

(u) ''Generator'' means the person producing infectious waste except waste produced in a private residence.

(v) ''Generator facility'' means a facility that treats infectious waste that is owned or operated by a combination or association of generators, a nonprofit professional association representing generators or a nonprofit corporation controlled by generators, nonprofit foundation of hospitals or nonprofit corporations wholly owned by hospitals, if the waste is generated in this State and treatment is provided on a nonprofit basis.

(w) ''Generator Registration Status'' means classification of a facility that generates regulated infectious waste, based on the largest amount documented by weight in any one calendar month of the last 12 (twelve) consecutive calendar months.

(x) ''Hazardous waste'' means a Resource Conservation and Recovery Act (RCRA) hazardous waste as defined in R.61–79.261.3 of the S. C. Hazardous Waste Management Regulations.

(y) ''Infectious waste'' or ''waste'' means a material as defined in Section E of this regulation.

(z) ''Infectious waste management'' means the systematic control of the collection, source separation, storage, transportation, treatment, and disposal of infectious waste.

(aa) ''Intermediate handling facility'' means any transportation related facility including loading docks, parking areas, storage areas and other similar areas where shipments of infectious waste are held and/or handled for storage during the normal course of transportation and may be off loaded and on loaded.

(bb) ''Manifest'' means the shipping document authorized and signed by the generator which contains the information required by this regulation.

(cc) ''Offsite'' means not onsite.

(dd) ''Onsite'' means the same or geographically contiguous property which may be divided by public or private right-of-way provided the entrance and exit between the properties is at a crossroads intersection and access is by crossing as opposed to going along the right-of-way.

(ee) ''Person'' means an individual, partnership, co-partnership, cooperative, firm, company, public or private corporation, political subdivision, agency of this State, county, or local government, trust, estate, joint structure company, or any other legal entity or its legal representative, agent, or assigns.

(ff) ''Products of conception'' means fetal tissues and embryonic tissues resulting from implantation in the uterus.

(gg) ''Pump Event'' means any action where treatment residue is removed from a tank holding treatment residue.

(hh) ''Radioactive material'' means any and all equipment or materials which are radioactive or have radioactive contamination and which are required pursuant to any governing laws, regulations or licenses to be disposed of or stored as radioactive material.

(ii) ''Release'' means to set free from restraint or confinement.

(jj) ''Secured area'' means an area which is fenced with a locking gate or which is regularly patrolled by security personnel which prevents access by the general public. An area which has controlled access and barriers to prevent exposure of the general public.

(kk) "Site" means contiguous land, structures, and other appurtenances and improvements on the land used for generating, treating, storing, transferring or disposing of regulated infectious waste with the same ownership.

(ll) "Small quantity generator" means any in-state generator that produces less than fifty (50) pounds of infectious waste per calendar month.

(mm) "Solid waste" means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid or contained gaseous material resulting from industrial, commercial, mining and agriculture operations, and from community activities. This term does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

(nn) "State" means the State of South Carolina.

(oo) "Storage" means the actual or intended holding of infectious wastes, either on a temporary basis or for a period of time, in a manner as not to constitute disposing of the wastes.

(pp) "Supersaturated" means the condition when any absorbent material contains enough fluid so that it freely drips that fluid or if lightly squeezed, that fluid would drip from it.

(qq) "Transfer facility" means any transportation related facility where shipments of infectious waste are held during the normal course of transportation, but are not off loaded or on loaded into fixed storage areas.

(rr) "Transport" means the movement of infectious waste from the generation site to a treatment facility or site for intermediate storage and/or disposal.

(ss) "Transporter" means a person engaged in the offsite transportation of infectious waste by air, rail, highway, or water.

(tt) "Transport vehicle" means a method used for the transportation of cargo by any mode. Each cargo-carrying body (trailer, railroad freight car, etc.) is a separate transport vehicle.

(uu) "Treatment" means a method, technique, or process designed to change the physical, chemical, or biological character or composition of infectious waste so as to sufficiently reduce or eliminate the infectious nature of the waste.

(vv) "Treatment facility" means a facility which treats infectious waste to sufficiently reduce or eliminate the infectious nature of the waste.

(ww) "Treatment residue" means the solid or liquid part that remains after infectious waste has been treated to sufficiently reduce or eliminate the infectious nature of the waste.

(xx) "Universal biohazard symbol" means the symbol design that conforms to the design shown in the Federal Occupational Safety and Health Administration (OSHA) Standards .

E. Definition of Infectious Waste.

(1) An infectious waste is any used material which is: generated in the health care community in the diagnosis, treatment, immunization, or care of human beings; generated in embalming, autopsy, or necropsy; generated in research pertaining to the production of biologicals which have been exposed to human pathogens; generated in research using human pathogens; and which is not excluded in two (2) below and which is listed in the categories below:

(a) Sharps.

Any discarded article that may cause puncture or cuts, including but not limited to: needles, syringes, Pasteur pipettes, lancets, broken glass or other broken materials, and scalpel blades.

(b) Microbiologicals.

Specimens, cultures, and stocks of human pathogenic agents, including but not limited to: waste which has been exposed to human pathogens in the production of biologicals; discarded live and attenuated vaccines; and discarded culture dishes/devices used to transfer, inoculate, and mix microbiological cultures.

(c) Blood and Blood Products.

All waste unabsorbed human blood, or blood products, or absorbed blood when the absorbent is supersaturated, including but not limited to: serum, plasma and other components of blood, and visibly bloody body fluids such as suctioned fluids, excretions, and secretions.

(d) Pathological Waste.

All tissues, organs, limbs, products of conception, and other body parts removed from the whole body, excluding tissues which have been preserved with formaldehyde or other approved preserving agents, and the body fluids which may be infectious due to bloodborne pathogens. These body fluids are: cerebrospinal fluids, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, semen, and vaginal/cervical secretions.

(e) Contaminated Animal Waste.

Animal carcasses, body parts and bedding when the animal has been intentionally exposed to human pathogens in research or the production of biologicals.

(f) Isolation Waste.

All waste generated from communicable disease isolation of the Biosafety Level 4 agents, highly communicable diseases, pursuant to the 'Guidelines for Isolation Precautions in Hospitals', published by the Centers For Disease Control.

(g) Other Waste.

Any other material designated by written generator policy as infectious, or any other material designated by a generator as infectious by placing the material into a container labeled infectious as outlined in Section J. Any solid waste which is mixed with infectious waste becomes designated as infectious and must be so managed unless expressly excluded in 2 (c) below.

(h) Infectious Waste Residues Resulting from Discharges.

Any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any infectious waste.

(2) The following are excluded from the definition of infectious waste:

(a) Hazardous waste which is to be managed pursuant to the Hazardous Waste Management Regulations, R. 61-79, as amended, et seq.

(b) Radioactive material which is managed pursuant to the Department Regulation 61–63, Radioactive Material (Title A).

(c) Mixed waste containing regulated quantities of both RCRA hazardous waste and source, special nuclear, or byproduct material subject to the Atomic Energy Act of 1954, as amended, are to be managed pursuant to all applicable regulations.

(d) Infectious wastes generated in a private residence except when determined by the Commissioner to be an imminent or substantial hazard to public health or the environment.

(e) Etiologic agents or specimens being transported for purposes other than disposal to a laboratory consistent with shipping and handling requirements of the U. S. Department of Transportation, U.S. Department of Health and Human Services, and all other applicable requirements.

(f) Human corpses, remains, products of conception, and anatomical parts that are intended to be interred, cremated, or donated for medical research. Teeth which are returned to a patient.

(g) Infectious waste samples transported offsite by the EPA or the Department for possible enforcement actions or transportation of materials from other governmental response actions.

(3) The Department will determine how individual waste fits into the definitions and/or categories.

F. Generator Requirements.

(1) All in-state generators of infectious waste shall register with the Department in writing on a Department approved form. Registration will be in a manner prescribed by the Department. Registration notices will include at a minimum:

(a) name of the business;

(b) name of the owner and responsible party if different;

(c) physical location of the site of waste generated (each site of waste generated must apply separately);

(d) mailing address of the site of generation;

(e) telephone number of the site;

(f) a contact name of the infectious waste coordinator;

(g) the categories and corresponding amount of infectious waste generated annually (estimated within plus or minus (+ or -) twenty (20) percent;

(h) the method of waste treatment and disposal; and

(i) the Employer Identification Number (EIN).

(2) When any changes occur in the information required in (1) above, the Department must be notified in writing of such changes within thirty (30) days.

(3) Renewal of registration will be every three (3) years for all generators. Registered generators will be notified of renewal requirements by the Department. Facilities that store liquid treatment residue in holding tanks must submit records showing monitoring and pump events for the previous twelve (12) consecutive calendar months.

(4) Fees for registration will be due at the time of initial registration and annually thereafter. Fees will be assessed in accordance with Section DD based on generator's registration status.

(5) Each generator must have a designated infection control committee with the authority and responsibility for infectious waste management. This committee must develop or adopt a written protocol to manage the infectious waste stream from generation until offered for transport. If the generator treats infectious waste onsite, the written protocol must include contingency plans and a Quality Assurance program to monitor these onsite treatment procedures. Small quantity generators are not required to have an infection control committee or a written protocol.

(6) Each generator must:

(a) segregate infectious waste from other waste at the point of generation;

(b) assure proper packaging and labeling of waste to be transported offsite as required in Section I and J. respectively, of this regulation;

(c) ensure a manifest is initiated if waste is to be transported offsite as outlined in Section M of this regulation;

(d) prevent infectious waste containing radioactive material which is distinguishable from background from leaving the site of generation when the material is under the jurisdiction of the United States Nuclear Regulatory Commission or an Agreement State;

(e) maintain records as required by this regulation in Section AA.

(f) store waste as outlined in Section K of this regulation;

(g) manage infectious waste in a manner which prevents exposure to the public or release to the environment; and

(h) treat infectious waste onsite or transport offsite for treatment at a permitted treatment facility.

(i) offer infectious waste for offsite transport only to a transporter who maintains a current registration with the Department or the U.S. Postal Service; and

(j) Obtain and record accurate weight of waste within fifty (50) days of shipment. Unabsorbed liquid waste produced during the embalming process is exempt from this requirement.

(7) When a waste generator relocates, closes or ceases to generate infectious waste, the generator must, within thirty (30) days, dispose of all infectious waste and treatment residue in accordance with this regulation and the Department must be notified in writing.

(8) A registered generator of infectious waste may accept non-regulated infectious waste generated in a private residence, but once accepted, the generator shall assume full responsibility of generation and manage the waste according to this and all applicable regulations.

G. Small Quantity Generators.

(1) All in-state generators must comply with the provisions of Section E; Section F, Parts 1–3, 6–8; and the following:

(a) sharps, microbiological cultures, products of conception, and human blood and blood products must be managed pursuant to this regulation including but not limited to: packaging, treatment and weight generation rate requirements; and

(b) small quantity generators may dispose of all other infectious waste as solid waste after properly packaging to prevent exposure to solid waste workers and the public.

(2) Generators who qualify as small quantity generators, as defined above, may transport their own waste provided:

(a) they never transport more than fifty (50) pounds at any one time;

(b) the vehicle is identified as required in Section Q(1)(g);

(c) the waste is manifested as required in Section M;

(d) the waste is packaged and labeled as required in Section I and Section J; and

(e) the waste is not transported in the passenger compartment of the vehicle and is in a fully enclosed compartment which protects the container from weather conditions which would compromise the integrity of the container.

(3) If a small quantity generator offers infectious waste for transport offsite for treatment at a destination facility, the waste must be managed pursuant to Sections H through DD of this regulation.

(4) If, in any calendar month, fifty (50) pounds of infectious waste or more is produced, the generator must notify the Department in writing; manage infectious waste pursuant to the entire regulation; and pay the annual fee as outlined in Section DD of this regulation. A generator will be able to claim designation as a small quantity generator after submitting documentation demonstrating twelve (12) consecutive calendar months of waste production less than fifty (50) pounds, or if at the time of registration, the generator estimates that less than fifty (50) pounds a month will be generated.

H. Segregation Requirements.

Generators shall segregate infectious waste from solid waste as close to the point of generation as practical to avoid commingling of the waste. If infectious waste is put in the same container as other waste, or if solid waste is put into a container labeled as infectious waste, the entire contents of the container shall be managed as infectious waste unless hazardous and/or radioactive material regulations apply, then the most stringent regulations apply as outlined in Section E (2) (a), (b), and (c).

I. Packaging Requirements.

(1) Generators shall assure that infectious waste is packaged in accordance with the requirements of this section and to prevent any release of infectious waste from its packaging before storing, transporting, or offering for transport offsite. Absorbents may be used to aid in the prevention of releases. Waste transported by the U.S. Postal Service must meet the packaging requirements for infectious waste in the Domestic Mail Manual.

(2) All sharps shall be placed and maintained in rigid, leak resistant, and puncture resistant containers which are secured tightly to preclude loss of the contents and which are designed for the safe containment of sharps.

(3) All other types of infectious waste must be placed, stored, and maintained before and during transport in a rigid or semi-rigid, leak resistant container which is impervious to moisture.

(4) Containers must have sufficient strength to prevent bursting and tearing and withstand handling, storage, transfer, or transportation without impairing the integrity of the container.

(5) Containers must be sealed and closed tightly and securely when full by weight or volume, or when putrescent, to prevent any discharge of the contents at any time until the container enters the treatment system.

(6) Plastic bags used inside of containers shall be a red or orange color and have sufficient strength to prevent tearing.

(7) Roll-off containers, trailer bodies, or other vehicle containment areas cannot be used as rigid containment.

(8) Infectious waste must be contained in containers that are appropriate for the type and quantity of waste and must be compatible with selected storage, transportation, and treatment processes.

(9) Reusable or disposable containers are acceptable. Reusable containers must be properly disinfected after each use as outlined in Section L of this regulation.

(10) Compaction of waste by any means shall be prevented prior to entering the containment of the treatment process.

(11) Exempt or excluded waste shall not be packaged as infectious waste. Waste packaged as infectious waste must be managed as infectious waste, except as indicated in Section I(12).

(12) When infectious waste is treated by a technology which does not change the appearance of the bag or outer container, immediately after treatment it shall be clearly labeled with the word "Treated" and the date of treatment on the outside of the container to indicate that the waste was properly treated. This labeling method may be hand written, an indicator tape or chemical reaction. The labeling process shall be water-resistant and indelible.

J. Labeling of Containers.

(1) Generators and transporters must assure that once sealed, containers of infectious waste are properly labeled in English as outlined below.

(2) Containers of infectious waste offered for transport offsite must be labeled on outside surfaces so that it is readily visible with:

(a) the universal biohazard symbol sign;

(b) the Department issued number of the in-state generator;

(c) a labeling process which is water-resistant and indelible; and

(d) the date the container was placed in storage or sent offsite, if not stored.

(3) Each bag used to line the inside of an outer container shall be labeled with indelible ink or imprinted as outlined in (a) and (c)immediately above.

(4) Transporters must label each outer container at the time it is accepted as specified in Section P (2).

(5) Transporters must affix required labels so that no other required markings or labels are obscured.

(6) Abbreviations may not be used in required labeling except for the common dictionary standard abbreviations.

K. Storage of Infectious Waste.

(1) Storage shall be in a manner and location which affords protection from animals, vectors, weather conditions, theft, vandalism and which minimizes exposure to the public. Storage begins at the time the container is sealed.

(a) The waste must not provide a food source or breeding place for insects or rodents.

(b) The waste must be protected to maintain the integrity of the packaging and provide protection from weather conditions such as water, rain, and wind.

(c) The waste must be stored in a manner to prevent a release or discharge of the contents.

(2) Outdoor storage areas must be locked (for example: roll-off containers, sheds, trailers, van bodies, or any other storage area).

(3) Storage areas must allow access to authorized personnel only.

(4) Storage areas must be labeled with the universal biohazard symbol sign.

(5) Infectious waste must be maintained in a nonputrescent state using refrigeration when necessary.

(a) Generator onsite storage shall not exceed fourteen (14) days without refrigeration or thirty (30) days if maintained at or below 42 degrees Fahrenheit.

(b) Once infectious waste leaves the generator site, the waste must be delivered to a treatment facility within fourteen (14) days without refrigeration or thirty (30) days if maintained at or below 42 degrees Fahrenheit.

(c) Treatment facility onsite storage shall not exceed fourteen (14) days at ambient temperature or thirty (30) days if maintained below 42 degrees Fahrenheit; and.

(6) All floor drains in storage areas must discharge into a Department approved sanitary sewer system or be transported to a Department approved sewerage treatment facility or permitted infectious waste treatment facility.

(7) All ventilation in storage areas must be in compliance with applicable Department air quality requirements and minimize human exposure.

L. Disinfection Standards.

(1) Any material or surface which comes in contact with infectious waste must be disinfected prior to reuse.

(a) Reusable containers which have been used to contain infectious waste must be disinfected immediately after being emptied or treated along with the waste.

(b) Vehicle bodies which have been used to store or transport infectious waste must be disinfected immediately after unloading.

(c) Spillage of infectious waste must be disinfected immediately.

(2) Disinfection can be accomplished by appropriate use of an EPA registered disinfectant used according to the label instructions at the tuberculocidal strength.

(3) Drainage from decontamination processes shall discharge to a Department approved sanitary sewer system or be transported to a Department approved sewerage treatment facility or permitted infectious waste treatment facility.

M. Manifest Form Requirements For Generators.

(1) A generator who transports, or offers for transport, infectious waste for offsite treatment, storage, or disposal, must prepare a manifest using DHEC Form 2116 or another Department approved form and filled out in a legible manner according to the instructions for that form. The manifest form must accompany the waste at all times after leaving the generator's facility. The manifest form will include, but is not limited to:

(a) the name of the generator;

(b) the Department identification number (if applicable);

(c) the address of the site where the waste was generated;

(d) a general description of the nature of the waste being shipped;

(e) the number of containers of waste;

(f) the weight or volume (accurate to within ten (10) percent);

(g) a certification by the generator stating "This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation";

(h) a certification by the generator that the shipment does not contain regulated quantities of hazardous waste as defined by the S.C. Hazardous Waste Management Regulations;

(i) a certification by the generator that the shipment does not contain radioactive material or waste above levels determined in Section F(6)(d) of this Regulation;

(j) the name of the transporter who receives the waste from the generator or subsequent transporter and that transporter's Department issued transporter registration number;

(k) the date the transporter accepted the shipment;

(*l*) the date the treatment facility accepted the shipment onsite;

(2) The generator who offers regulated infectious waste for transport offsite shall ensure a manifest is initiated as required in (1) above.

(3) This generator shall sign by hand or other legally defensible signature where required in (1)(g), (h), and (i).

(4) The generator shall retain one copy of the manifest after the transporter has accepted the shipment.

N. Infectious Waste Transporter Requirements.

(1) Transporters of infectious waste which is generated, stored, transferred or treated within South Carolina must be registered with the Department prior to such activity unless otherwise provided by this regulation.

(2) Generators who transport their own infectious waste offsite, except those generators who qualify as small quantity generators in Section G of this regulation, must also comply with all applicable transporter requirements of this regulation.

(3) Transporters of infectious waste must comply with all applicable requirements of this regulation during transportation and when the waste is at a transfer facility.

(a) infectious waste may be transferred from one vehicle to another only at a designated transfer facility; and

(b) infectious waste may not be unloaded into fixed storage at a transfer facility.

(4) Transporters must also comply with the requirements of Sections I and J when they repack defective boxes of infectious waste.

(5) Transporters must also comply with applicable requirements of this regulation when they:

(a) store infectious waste, even in the course of transport, in which case the requirements of Section K must be met;

(b) remove infectious waste from reusable containers; or

(c) repackage or modify packaging of infectious waste.

(6) Transporters must develop a written infectious waste management plan which must address at a minimum:

(a) a spill plan;

(b) contingency plans for alternate treatment, storage and/or disposal sites;

(c) handling and storage of waste; and

(d) personnel health and safety training.

(7) A draft of the plan required in Section N (6) must accompany the annual registration application.

(a) The plan must meet the approval of the Department or be modified so that it will meet approval.

(b) After approval by the Department, the infectious waste management plan shall become part of the registration and must be adhered to by the registrant.

(c) Changes in this plan must be made by submittal of a written request to the Department which may approve or deny such request.

(8) Transporters shall prevent discharge of infectious waste from a transport vehicle into the environment.

(9) It is unlawful for any person to discharge infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment.

(10) The Department may require transporters to clean up and/or disinfect any infectious waste discharge that occurs during transportation or take such action as may be required by state, federal, or local officials so that the infectious waste discharge no longer presents a potential hazard to human health or the environment.

(11) Transport vehicles containing infectious waste must be managed to prevent access by unauthorized persons.

(12) [Reserved]

O. Transporter Registration Requirements.

(1) Each transporter or transfer facility operator must register with the Department on a form which includes at a minimum:

(a) the transporter's name;

(b) the transporter's mailing address;

(c) the name for each intermediate handling facility, transfer facility, or transportation related site that the transporter will operate at in South Carolina;

(d) the address for each intermediate handling facility, transfer facility, or transportation related site that the transporter will operate at in South Carolina;

(e) the telephone number for each intermediate handling facility, transfer facility, or transportation related site that the transporter will operate at in South Carolina;

(f) proof of financial responsibility for sudden and accidental occurrences in the amount of at least one million dollars ($1,000,000) per occurrence exclusive of legal defense costs. This financial responsibility may be established by any one or a combination of the following:

(i) evidence of liability insurance, either on a claim made or an occurrence basis, with or without the deductible, with the deductible, if any, to be on a per occurrence or per accident basis and not to exceed ten (10) percent of the equity of the registrant;

(ii) self insurance, the level of which shall not exceed ten (10) percent of equity of the registrant as evidenced by submission of financial information as required by the Department; or

(iii) other evidence of financial responsibility approved by the Department; and

(g) this statement signed by hand by the owner or his authorized agent: "I certify, under penalty of criminal and/or civil prosecution for making or submission of false statements, representations, or omissions, that I have read, understand, and will comply with the South Carolina Infectious Waste Management Regulation R.61–105."

(2) No person shall engage or continue to engage in transportation of infectious waste (except as outlined in Section N(2)) in South Carolina unless they register annually with the Department as an infectious waste transporter, and pay applicable fees as outlined in Section DD.

(a) Transporters must notify the Department in writing within thirty (30) days if any changes occur in the information required for registration as outlined in (1) above or if they terminate their business; and

(b) Transporters who fail to re-register by the expiration date of their registration must cease all infectious waste transport activities on the expiration date.

(c) A registration may be terminated or a new or renewal application may be denied by the Department for noncompliance by the transporter with any conditions of the registration, requirements of this regulation, or the Act.

(3) The financial responsibility required in section O(1)(f) above must be maintained. If any change occurs in a registered transporter's financial responsibility, he must cease to transport infectious waste and notify the Department immediately to determine when and how transportation may be resumed.

(4) Transporters will receive an Infectious Waste Transporter Number upon completion of the registration process. Use of a false, expired, or invalid registration number is prohibited.

(5) Transporter registration and Infectious Waste Transporter Numbers are not transferable.

(6) Transporters which neither pick up infectious waste nor deliver infectious waste within this state are exempt from registration. Transporters who only transport into or within this state regulated infectious waste packaged in accordance with United States Postal Service Domestic Mail Manual infectious waste packaging requirements are also exempt from registration.

P. Transporter Acceptance of Infectious Waste.

Transporter acceptance of infectious waste occurs when the waste is loaded onto the transport vehicle.

(1) Transporters shall accept for transport only infectious waste which is:

(a) packaged as required in Section I;

(b) labeled as required in Section J; and

(c) accompanied by a properly completed manifest, as required in Section R.

(2) Transporters must attach a waterproof identification label to the outside of each container of infectious waste they accept for transport. The label must be affixed in a manner which does not cover any other required labels or markings. This identification label must include but is not limited to:

(a) the transporter's Department issued identification number, or the transporter's name, address, and phone number; and

(b) [Reserved]

(3) If the transporter accepts loaded and sealed trailers from a broker or generator, that transporter does not have to assure proper packaging as required in Section I or proper labeling as required in Section J. However, the transporter must:

(a) assure that the load is accompanied by a properly completed manifest; and

(b) prevent discharges of infectious waste, especially fluids, from the cargo-carrying body.

Q. Transport Vehicle Requirements.

(1) Each vehicle used to transport infectious waste must meet at a minimum these requirements:

(a) the vehicle shall have a fully enclosed, leak resistant cargo-carrying body which protects the waste from animals, vectors, weather conditions, and minimizes exposure to the public;

(b) the containers of waste shall be loaded and unloaded so that no compaction or mechanical stress of the waste occurs during handling or during transit;

(c) the cargo-carrying body shall be maintained in a sanitary condition and disinfected immediately after each unloading and as spills are detected;

(d) the cargo-carrying body shall be designed to prevent discharges of infectious waste, especially fluids, into the environment;

(e) the cargo-carrying body shall be decontaminated of visible debris after each unloading;

(f) the cargo-carrying body shall have doors which close tightly and can be sealed with a tamper resistant seal or otherwise secured if left unattended while carrying infectious waste;

(g) identification must be permanently affixed to the cargo-carrying body on two sides and the back in letters a minimum of three (3) inches in height which state:

(i) the registered name of the transporter;

(ii) the transporter's Department issued registration number; and

(iii) the words INFECTIOUS WASTE, MEDICAL WASTE, or BIOHAZARDOUS WASTE.

(h) the biohazard symbol sign must be permanently affixed to the cargo-carrying body on two sides and the front and back.

(2) If a transporter transports or stores infectious waste and other solid waste in the same cargo-carrying body, each waste must be managed as infectious waste unless the waste is subject to Section (E)(2)(a-c).

(3) If a transport vehicle is used to store infectious waste, such storage must, at a minimum:

(a) be in a location which is inside a building with limited access and is locked when unattended; or

(b) be in a location outside which is secured by a barrier which limits access and must be locked when unattended;

(c) and meet the requirements of Section K.

(4) All drainage from the cargo-carrying body shall discharge directly or through a holding tank to a Department approved sanitary sewer system or approved container for appropriate treatment.

R. Manifest Requirements For Transporters.

(1) No transporter shall accept a shipment of infectious waste which is to be transported within South Carolina unless it is accompanied by an infectious waste manifest which has been completed according to the instructions for the Department approved form and signed by the generator.

(2) Before accepting for transport any infectious waste the transporter must:

(a) visually inspect the containers to assure proper packaging, if the waste is loaded by the transporter;

(b) return a copy of the manifest form to the generator before leaving the site.

(3) The transporter, transfer facility operator, and/or intermediate handling facility operator shall ensure that the manifest form accompanies the infectious waste at all times until unloaded for treatment.

(4) The transporter who delivers infectious waste within or into South Carolina must ensure delivery to a registered or properly permitted infectious waste management transporter, transfer facility, intermediate handling facility or treatment facility.

(5) The transporter, upon delivery of infectious waste to a permitted treatment facility, shall:

(a) retain a copy of the completed manifest for his records; and

(b) turn the remaining copies of the manifest over to the treatment facility.

(6) The transporter shall deliver the entire quantity represented on the manifest that he accepted from the generator or another transporter to another transporter or a destination facility.

(7) All transporters and/or management companies which list themselves as the generator on the manifest or a consolidated manifest must assume full responsibility of the generator(s) and must:

(a) attach a copy of the completed new manifest form to the original manifest form and retain a copy of the new and original manifest form; and

(b) maintain a transporter consolidation log indicating all shipments that have been consolidated.

S. Storage Tank Requirements.

(1) Liquid treatment residue generated during the embalming process may be stored in an underground or above ground storage tank located onsite at the generating facility. Tanks in operation at the time this regulation takes effect must meet the use, monitoring, record keeping, disposal, and clean-up requirements of this Section. Tanks installed after the date this regulation becomes effective must meet all requirements of these regulations.

(2) Storage tanks must meet the following conditions:

(a) A facility must notify the Department in writing before installing a tank to be used for storage of treatment residue. Notification should include facility name and address, number of tanks, and storage capacity;

(b) Tank materials of construction must be compatible with treatment residue to be stored;

(c) Tank must be installed and maintained in accordance with manufacturer's instructions;

(d) When treatment residue is removed from the tank, it must be pumped by a person licensed by the Department for the cleaning of disposal systems and sent directly to a regulated facility for further treatment or disposal;

(e) Tank must be monitored following pump events and with a frequency sufficient to demonstrate it is not leaking. Monitoring may be performed utilizing a dipstick, however monitoring must be performed when tank contents are sufficiently settled;

(f) The facility generating waste that is treated and stored in the tank must maintain a record of tank monitoring and pump events;

(g) Tank must be used exclusively for treatment residue storage; and

(h) Tank and records must meet all applicable state and federal requirements, including Industrial Wastewater and Disposal System Clean-out requirements.

(3) The Department may require the generating facility to clean up any treatment residue discharge that occurs during storage or take such action as may be required by state, federal, or local officials so that the treatment residue discharge no longer presents a potential hazard to human health or the environment.

T. Infectious Waste Treatment.

(1) Infectious waste must be treated prior to disposal except as indicated in Section G. After approved and adequate treatment, treatment residue must be disposed of in accordance with state and federal solid waste requirements. Any unused treatment media must be characterized, handled, and disposed of in accordance with applicable regulations.

(2) Treatment must be by one of the following treatment methods in accordance with this regulation and other applicable state and federal laws and regulations:

(a) incineration;

(b) steam sterilization;

(c) chemical disinfection;

(d) embalming fluid containing at least two (2) percent formaldehyde; or

(e) any other Department approved treatment method.

(3) Approval for other forms of treatment must be obtained from the Department and meet standards set at that time by the Department.

(4) The following infectious waste may be disposed of before treatment:

(5) Storage of infectious waste prior to treatment must be in accordance with Section K of this regulation.

(a) an approved liquid or semi-liquid waste other than microbiological cultures and stocks may be discharged directly into a Department approved wastewater treatment disposal system; and

(b) recognizable human anatomical remains may be disposed of by interment or donated for medical research.

(6) It is unlawful for any person to discharge infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment.

(7) Facilities that only treat liquid embalming waste with at least a two (2) percent formaldehyde solution and small quantity generators that treat, by an approved method onsite, infectious waste which they generate onsite are not required to be permitted as a treatment facility.

(8) Treatment of infectious waste must be monitored by use of biological indicators or laboratory culture of the treatment residue to ensure that pathogens have been adequately treated. Frequency of this testing shall be determined by the Department on a case-by-case basis or as outlined in this regulation.

(9) Products of conception must be incinerated, cremated, interred, or donated for medical research.

U. Infectious Waste Treatment Facility Standards.

(1) No person may operate an infectious waste treatment or disposal facility or generator facility without first obtaining a permit as required by this regulation except as exempted in section T. A separate permit shall be required for each site or facility although the Department may include one or more different types of facilities in a single permit if the facilities are collocated on the same site.

(2) All treatment facilities must treat the waste as indicated in Section T.

(3) Infectious waste treatment residue must not be disposed of until or unless Department approved monitoring methods confirm effectiveness of the treatment process.

(4) All treatment facilities must develop and submit to the Department for approval a standard operating procedure manual which will include at a minimum:

(a) unloading and handling procedures;

(b) safety procedures;

(c) emergency preparedness and response plans;

(d) receiving, record keeping, and reporting procedures;

(e) remedial action plans;

(f) quality assurance plans for treatment methods;

(g) radiological and hazardous waste monitoring procedures;

(h) procedures for identifying types and quantities of infectious waste received;

(i) contingency plans for use of alternate facilities; and

(j) procedures for disposition of treatment residues.

(5) Approval for acceptance of infectious waste at a treatment or disposal facility may be withdrawn by the Department for noncompliance with the standard operating procedure manual.

(6) When a facility ceases infectious waste management activities, it shall notify the Department in writing, immediately, and it shall thoroughly clean and disinfect the facility and all equipment used in the handling of infectious waste. All untreated waste shall be disposed of in accordance with the requirements of this regulation.

(7) In the event of an accidental spill of infectious waste the designated personnel at the facility shall:

(a) contain the spill to the area immediately affected;

(b) immediately disinfect the area which is contaminated;

(c) pick up, repackage as required or otherwise immediately remove the spilled material into the treatment system;

(d) record the incident in a bound log book, including the quantity spilled, personnel involved, and the nature and consequences of the event; and

(e) It is unlawful for any person to discharge infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment.

(8) All individuals involved with handling and management of waste shall receive thorough training in their responsibilities and duties. A training protocol shall be submitted to the Department at the time of application for a permit. Training documentation for individuals shall be submitted to the Department within thirty (30) days of completion.

(9) Permittees shall notify the Department in writing within thirty (30) days prior to any changes in ownership, operating control, name, or location. The Department may upon written request transfer a permit to a new owner or operator where no other change in the permit is necessary provided that a written agreement containing a specific date for transfer of permit responsibility and financial assurance between the current and new owner has been submitted to the Department.

(10) A facility receiving waste generated in a hospital or other generator which uses radioactive material must screen incoming waste for radioactivity as they arrive at the treatment facility. Such facilities must:

(a) use instrumentation which is approved by the Department for this purpose;

(b) have the operator properly trained on such equipment;

(c) have such equipment calibrated at least once a year by an authorized calibrator;

(d) maintain a log of quality assurance testing and calibration of such instrumentation; and

(e) report any and all incidents when radioactive materials are detected to the Department for guidance in dealing with the radioactive materials. The Department may allow a treatment facility to hold containers of waste containing radioactive material for radioactive decay after the facility has submitted procedures for appropriately managing the containers and has received approval from the Department. However, under no circumstance may a treatment facility solicit the receipt of radioactive material.

(11) Facilities shall schedule shipments of waste to prevent a backlog of loaded transportation vehicles at the facility or offsite. The number of loaded and unloaded transport vehicles stored onsite will be controlled by permit conditions.

(12) A facility receiving waste generated offsite must log-in transport vehicles as they arrive at the facility in a bound log book and note in this book if any shipments are rejected. The treatment facility must:

(a) disinfect the cargo-carrying compartment(s) immediately after unloading the waste; and

(b) clean out visible debris and immediately put debris into the treatment system.

(13) Incinerators must, in addition to items (1) through (12) above:

(a) provide complete combustion of the waste and packaging to carbonized or mineralized ash;

(b) comply with all applicable regulations issued by the Department; and

(c) receive authorization for disposal of treatment residue from the Department prior to disposition into a landfill located in this state, and said authorization shall be based on relevant analyses and requirements deemed necessary by the Department. Such authorization may be incorporated into a landfill permit.

(14) All steam sterilizers must, in addition to items (1) through (12) above.

(a) use Department approved indicator organisms in test runs to assure proper treatment of the waste. Indicator organisms must be used daily at a commercial facility and monthly at a generator facility in each steam sterilizer;

(b) record the temperature and time during each complete cycle to ensure the attainment of a temperature of 121 degrees Centigrade (250 degrees Fahrenheit) for 45 minutes or longer at fifteen (15) pounds pressure, depending on quantity and density of the load, in order to achieve sterilization of the entire load; (Thermometers shall be checked for calibration at least annually.)

(c) have a gauge which indicates the pressure of each cycle;

(d) use heat sensitive tape or other device for each container that is processed to indicate that the steam sterilization temperature has been reached. The waste will not be considered appropriately treated if the indicator fails;

(e) use the biological indicator *Bacillus stearothermophillus* placed at the center of a load processed under standard operating conditions to confirm the attainment of adequate sterilization conditions;

(f) maintain records of the procedures specified in (b), and (e) above for period of not less than three (3) years; and

(g) assure that treatment residues are disposed of in accordance with applicable State and Federal requirements.

V. Intermediate Handling Facilities Standards.

(1) No person may operate an infectious waste intermediate handling facility without first obtaining a permit as required by this regulation. A separate permit shall be required for each site or facility although the Department may include one or more different types of facilities in a single permit if the facilities are co-located on the same site.

(2) All intermediate handling facilities must develop and submit to the Department for approval a standard operating procedure manual which will include at a minimum:

(a) unloading and handling procedures;

(b) safety procedures;

(c) emergency preparedness and response plans;

(d) receiving, record keeping, and reporting procedures;

(e) remedial action plans;

(f) procedure for treatment of spills;

(g) radiological and hazardous waste monitoring procedures;

(h) procedures for identifying types and quantities of infectious waste received;

(i) contingency plans for use of alternate facilities; and

(j) procedures for disposition of treatment residues.

(3) Approval for acceptance of infectious waste at an intermediate handling facility may be withdrawn by the Department for noncompliance with the standard operating procedure manual.

(4) When a facility ceases infectious waste management activities, it shall notify the Department in writing, immediately, and it shall thoroughly clean and disinfect the facility and all equipment used in the handling of infectious waste. All untreated waste shall be disposed of in accordance with the requirements of this regulation.

(5) In the event of an accidental spill of infectious waste, the designated personnel at the facility shall:

(a) contain the spill to the area immediately affected;

(b) immediately disinfect the area which is contaminated;

(c) immediately pick up and repackage as required or treat the spilled material;

(d) record the incident in a bound log book, including the quantity spilled, personnel involved, and the nature and consequences of the event; and

(e) It is unlawful for any person to discharge infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment.

(6) All individuals involved with handling and management of waste shall receive thorough training in their responsibilities and duties. A training protocol shall be submitted to the Department at the time of application for a permit. Training documentation for employees shall be submitted to the Department within thirty (30) days of completion.

(7) Permittee shall notify the Department in writing within thirty (30) days prior to any changes in ownership, operating control, name, or location. The Department may upon written request transfer a permit to a new owner or operator where no other change in the permit is necessary provided that a written agreement containing a specific date for transfer of permit responsibility and financial assurance between the current and new owner has been submitted to the Department.

(8) Facilities shall schedule shipments of waste to prevent a backlog of loaded transportation vehicles at the facility or offsite. The number of loaded and unloaded transport vehicles stored onsite will be controlled by permit conditions.

(9) A facility receiving waste generated offsite must log-in transport vehicles as they arrive at the facility in a bound log book and note in this book if any shipments are rejected. The intermediate handling facility must:

(a) disinfect the cargo-carrying compartment(s) immediately after unloading the waste; and

(b) clean out visible debris and immediately put debris into the treatment system.

W. Permit Applications and Issuance.

(1) No person may expand or construct a new treatment facility without a obtaining an Infectious Waste Management permit issued by the Department. To obtain a permit, the applicant shall demonstrate the need for such a facility or expansion. To determine if there is a need, infectious waste generated outside of the state may not be considered without Department approval.

(2) The Department will determine and publish annually an estimate of the amount of infectious waste to be generated in South Carolina during the ensuing twelve months.

(3) The demonstration of need does not apply to:

(a) facilities owned by counties, municipalities, or public service districts which accept only infectious waste generated in this state;

(b) facilities that are owned or operated by the generator of the waste and this waste is generated in this state;

(c) generator facilities; or

(d) facilities currently operated under permits issued by the Department, or to the renewal of existing permits issued by the Department if there is no expansion of the capacity as prescribed in the conditions of the permit.

(4) No person may expand or construct a new intermediate handling facility without an Infectious Waste Management permit issued by the Department. Intermediate handling facility permit applicants do not have to demonstrate a need.

(5) To obtain an Infectious Waste Management Permit, the person must complete a permit application as designed by the Department. Permit applications will not be processed until they are deemed complete by the Department.

(6) A draft of the manual required in Section U (4) must accompany the permit application. The manual must meet the approval of the Department or be modified so that it will meet approval. After approval by the Department, the standard operating procedure manual shall become part of the permit and must be adhered to by the permittee. Changes in this manual must be made by submittal of a written request to the Department which may approve or deny such request.

(7) In addition to other requirements, a permit application for a treatment facility or intermediate handling facility must include at a minimum:

(a) an engineering report which, at a minimum, contains a description of the facility, the process and equipment to be used, the proposed service area, and storage of the waste;

(b) engineering plans and specifications which must, at a minimum, describe the architectural, mechanical, electrical, plumbing, heating, ventilating, process equipment, instrumentation and control diagrams, and performance specifications for all major equipment and control centers;

(c) the latitude and longitude of the facility;

(d) a topographic map (or similar map) extending one mile beyond the property boundaries of the source, depicting the facility and each of its intake and discharge structures; each of its infectious waste management, treatment, storage, or disposal facilities; those wells, springs, other surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant within the quarter-mile of the facility property boundary; and the 100-year flood plain;

(e) a written acknowledgment from the governing body of the city or town, and/or county in which the facility is to be located that the location and operation of the facility are consistent with all applicable ordinances;

(f) a description of the process to be used for treating, storing, handling, transporting and disposing of infectious waste, and the design capacity of these items;

(g) a description of the type of the infectious waste to be treated, stored, transported or disposed at the facility, an estimate of the quantity of such wastes to be treated, stored, transported, and disposed annually;

(h) a quality assurance and quality control report;

(i) a contingency plan describing a technically and financially feasible course of action to be taken in response to contingencies which may occur during construction and operation of the facility to include a description of how the waste will be managed to protect the waste from flood waters.;

(j) an identification of possible air releases and groundwater or surface water discharges;

(k) a waste control plan describing the manner in which waste will be received, stored, and otherwise managed;

(*l*) a plan outlining the flow of traffic associated with the facility;

(m) a closure plan which includes the estimated cost of closure;

(i) a closure cost estimate which must be based on the cost of hiring a third party to close the facility; and

(ii) a cost estimate which may not include any salvage value from the sale of any structures, equipment, and other assets.

(n) other information as may be required by the Department.

(8) The Permittee shall notify the Department in writing within thirty (30) days of any changes of the information required in (7) above or changes which would require modifications of the permit as issued.

(9) A permit may be terminated or a new or renewal application may be denied by the Department for noncompliance by the permittee with any conditions of the permit, requirements of this regulation, or the Act.

(10) In addition to conditions required in all permits, the Department shall establish conditions as required on a case-by-case basis, for the duration of the permits, schedules of compliance, monitoring, and to provide for and assure compliance with all applicable requirements of this regulation.

(11) Permits will be valid for the period stated on the permit. If the application for renewal is received as above, the permit will continue in force until the Department makes a permit decision.

(12) As a condition of approval for an Infectious Waste Management Permit, any person who owns or operates a facility or group of facilities for the treatment, storage, or disposal of infectious waste must demonstrate financial responsibility for bodily injury and property damage to third parties caused by sudden accidental occurrences arising from the operation of the facility or group of facilities and assure the satisfactory maintenance, closure, and postclosure care of any facility or group of facilities, and to carry out any corrective action which may be required by the Department. Such form and amount of financial responsibility shall be a permit condition specified by the Department. At any time, should the Department determine that the levels of financial responsibility required are not consistent with the degree and duration of risk associated with treatment, storage, or disposal at the facility or group of facilities, the Department may adjust the level of financial responsibility required as may be necessary to protect human health and the environment. This adjusted level will be based on the Department's assessment of the degree and duration of risk associated with the ownership or operation of the facility or group of facilities.

(13) The permittee must immediately notify the Department upon loss of the financial responsibility coverage. A permittee shall cease to treat or store infectious waste upon loss of financial responsibility coverage.

(14) A facility may receive only those waste streams for which it is permitted; however, a facility may request in writing to receive new waste streams which are subject to Department approval or denial.

X. Permit By Rule.

(1) All infectious waste generators which comply with the conditions of (2) below shall be deemed to have a permit by rule.

(2) To qualify for permit by rule the owner and/or operator of the facility shall:

(a) comply with all parts of the Act and this regulation except permitting procedures of Section W.

(b) demonstrate that more than seventy-five (75) percent (by weight, in a calendar year) of all infectious waste that is stored, treated or disposed of by the facility is generated onsite.

(c) assure that no activities at the facility involve the placing of infectious waste directly into the environment.

(d) notify the Department in writing that the facility is operating under a permit by rule and supply the following information:

(i) the name, mailing address, location address, and phone number of the facility;

(ii) type of businesses served;

(iii) the type of facility; and

(iv) the principal officer; and

(e) notify the Department in writing before onsite treatment activities begin.

(3) All infectious waste generators who treat infectious waste and are not exempted in Section T and not meeting the requirements of (2) above shall apply for an infectious waste treatment permit as outlined in Section W.

(4) Any facility deemed to have a permit by rule which fails to satisfy any of the conditions set forth in (2) above or this regulation may have its permit by rule revoked and must obtain a permit as outlined in Section W to continue to store, treat, or dispose of infectious waste.

Y. Manifest Form Requirements For Permitted Treatment Facilities.

(1) Treatment facilities must not accept infectious waste to be treated, stored, or otherwise managed unless accompanied by a Department approved manifest form if the waste is generated offsite.

(2) The owner or operator or his authorized agent of a treatment facility when accepting a manifested shipment shall:

(a) write on the manifest the number of containers accepted and the total weight;

(b) note any discrepancies greater than ten (10) percent of the container count on the manifest; and

(c) retain a copy of the completed manifest form for two (2) years.

(3) When any variation in piece count greater than one (1) percent or in weight greater than ten (10) percent is discovered, the owner or operator shall attempt to resolve the discrepancy with the waste generator or the transporter. If the discrepancy is not resolved, the owner or operator shall submit a letter to the Department, within five (5) days, of receipt of the waste, describing the nature of the discrepancy and the attempts the owner or operator has undertaken to reconcile it. The owner or operator shall include with this letter a legible copy of the manifest in question.

(4) If a facility receives any infectious waste from offsite which is not accompanied by a manifest, or which is accompanied by a manifest which is incorrect, incomplete, or not signed, the owner/operator must prepare and submit to the Department a written copy of a report within fifteen (15) days after receiving the waste. The ''Unmanifested Waste Report'' must include the following information:

(5) If a facility receives any infectious waste from offsite which is not accompanied by a manifest, the owner/operator must prepare and submit to the Department a written copy of a report within fifteen (15) days after receiving the waste. The ''Unmanifested Waste Report'' must include the following information:

(a) the name and address of the facility;

(b) the date the facility received the waste;

(c) the identification number or name and address of the generator and the transporter if available;

(d) a description and the quantity of the waste;

(e) the method of treatment, storage, or disposal of the waste;

(f) a certification signed by the owner operator of the facility or his authorized representative; and

(g) a brief explanation of why the waste was unmanifested, if possible.

Z. Reporting For Permitted Treatment Facilities.

(1) All commercial treatment facilities are required to submit the monthly fees and reports as required by the Act.

(2) All treatment facilities are required to submit an annual report to the Department, covering the period from January 1 through December 31 of each calendar year which shall be submitted to the Department by February 15 of the subsequent year. The report shall include but is not limited to:

(a) a description of the sources by state, and amounts of infectious waste treated;

(b) the method used to treat the waste; and

(c) the amount and disposition of the residue.

AA. Inspections and Record Keeping.

(1) Department representatives are authorized to enter and inspect any property or premises for the purpose of ascertaining compliance or noncompliance with this regulation.

(2) All generators, transporters, transfer facilities, intermediate handling facilities and treatment facilities handling infectious waste generated, treated, transported, or otherwise managed in the State shall maintain all records and manifest copies required by this regulation for a minimum of two (2) years in a location within South Carolina easily accessible to the Department during regular business hours and shall provide these records to the Department upon request. Records may be maintained in paper form or electronically.

(3) If the waste is no longer infectious because of treatment, the generator or permitted facility shall maintain a record of the treatment for two (2) years afterward to include the date and type of treatment, amount of waste treated, and the individual operating the treatment. Records for onsite treatment shall be maintained by the generator for a minimum of two (2) years in a location easily accessible to the Department and shall be provided to the Department upon request. Records may be maintained in paper form or electronically.

(4) If the waste is no longer infectious because of treatment, and the treatment residue is stored onsite in a tank, the generator shall maintain a record of monitoring and pump events for two (2) years afterward to include the date and type of monitoring, who conducted the monitoring, date and amount of waste pumped, and the name of the business or person that provided the pumping service. Pump event data may be in the form of a manifest or log. Records shall be maintained by the generator for a minimum of two (2) years in a location within South Carolina easily accessible to the Department and shall be provided to the Department upon request. Records may be maintained in paper form or electronically.

BB. Enforcement.

(1) Any person who violates any of the provisions of this regulation or any permit issued pursuant hereto, or any order issued by the Department or Board shall be subject to applicable civil, administrative, and criminal penalties as provided for in the Infectious Waste Management Act.

(2) Any registered generator or transporter, or permitted intermediate handling facility or treatment facility is subject to having its registration or permit suspended or revoked upon finding by the Department that:

(a) false or inaccurate information has been submitted in the application process;

(b) laws, Department orders, regulations, or registration or permit conditions have been violated;

(c) reports or other information required by the Department have not been submitted or inaccurately submitted; and/or

(d) lawful inspection has been refused.

CC. Variances.

(1) The Department may, upon written petition from any person who is subject to this regulation, grant a variance from one or more specific provisions of this regulation under the following conditions. The petitioner shall:

(a) identify the specific provisions of this regulation from which variance is sought;

(b) demonstrate that compliance with the identified provision would, on the basis of conditions unique and peculiar to the applicant's particular situation, tend to impose a substantial financial, technological, or safety burden on the petitioner or the public; and

(c) demonstrate that the proposed activity will have no significant adverse impact on the public health, safety, or welfare, the environment or natural resources and will be consistent with the provisions of the Infectious Waste Management Act.

(2) In granting any variance hereunder the Department may impose specific conditions reasonably necessary to assure that the subject activity will have no adverse impact on the public health, safety, or welfare, the environment or natural resources.

(3) Any variance granted by the Department may be immediately withdrawn when the Department finds on the basis of complaints, noncompliance with conditions of the variance or other information that the variance is not in the public interest or protective of human health and/or the environment, or that the petitioner has provided false or inaccurate information on which the variance was granted.

(4) Nothing herein shall be construed as a waiver of the Department's right to deny any petition for a variance.

DD. Fees Section.

Fees are outlined in the Environmental Protection Fees, Regulation 61–30.

EE. Appeals.

(1) A Department decision involving the issuance, denial, renewal, suspension, or revocation of a permit, license, certificate, or certification may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.

(2) Any person to whom an order is issued may appeal pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.

HISTORY: Added by State Register Volume 15, Issue No. 6, eff June 28, 1991; Amended by State Register Volume 24, Issue No. 5, eff May 26, 2000; State Register Volume 26, Issue No. 6, Part 1, eff June 28, 2002; State Register Volume 29, Issue No. 6, eff June 24, 2005; State Register Volume 34, Issue No. 6, eff June 25, 2010.

61–106. TANNING FACILITIES.

Editor's Note

Unless noted otherwise, the following constitutes the history for 61–106, 1.1 to 4.2.

HISTORY: Added by State Register Volume 16, Issue No. 3, eff March 27, 1992; Amended by State Register Volume 24, Issue No. 5, eff May 26, 2000; State Register Volume 32, Issue No. 5, eff May 23, 2008.

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PART I
GENERAL PROVISIONS

1.1. Purpose and Scope

1.1.1 These regulations provide for the registration and regulation of facilities and equipment that employ ultraviolet and other lamps for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

1.1.2 Nothing in these regulations shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of medical treatment or therapy prescribed and supervised by a physician who is licensed by the South Carolina Board of Medical Examiners.

1.2. Definitions:

As used in this regulation:

1.2.1 "Act" means Atomic Energy and Radiation Control Act, Section 13–7–10 et seq, 1976 Code of Laws of South Carolina.

1.2.2 "Affected Party" means a tanning registrant whom an enforcement action has been taken by the Department.

1.2.3 "Complaint" is a written document submitted to the Department addressing an existing or potential public health hazard.

1.2.4 "Consumer" means any individual who is provided access to a tanning facility that is required to be registered pursuant to provisions of this regulation.

1.2.5 "Department" means the South Carolina Department of Health and Environmental Control.

1.2.6 "Individual" means any human being.

1.2.7 "Inspection" means an official examination or observation, including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, or to investigate complaints or injuries.

1.2.8 "Investigation" means a visit by an authorized individual(s) to a registered or unregistered facility for the purpose of determining the validity of complaints or allegations received by the Department relating to this regulation.

1.2.9 "Minor" means any individual less than eighteen (18) years of age.

1.2.10 "Operator" means any individual designated by the registrant to operate or to assist and instruct the consumer in the operation and use of the tanning facility or tanning equipment. Under this definition, the term "operator" means any individual who conducts one or more of the following activities:

1) determining consumers' skin type;

2) determining the suitability for use of a tanning device by prospective consumers;

3) informing the consumer of the dangers of ultraviolet radiation exposure including photoallergic reactions and photosensitizing reactions;

4) determining consumer use of potentially photosensitizing agents;

5) assuring the consumer reads and properly signs all forms required by these regulations;

6) reviewing, signing, and ensuring required documentation is completed for minors or illiterate or visually impaired consumers;

7) maintaining required consumer exposure records;

8) recognizing and reporting consumer actual or alleged ultraviolet radiation injuries to the registrant;

9) instructing the consumer in the proper use of protective eyewear; and

10) setting timers which control the duration of exposure.

1.2.11 "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of these entities.

1.2.12 "Personal Use" means tanning equipment that is used solely by an individual and the individual's immediate family or permanent residents of the individual's place of residence. Immediate family is defined as the spouse, great-grandparents, grandparents, parents, brothers, sisters, children, grandchildren, great-grandchildren of either the owner of the tanning equipment or the spouse.

1.2.13 "Registrant" means any person who is registered with the Department as required by provisions of this regulation.

1.2.14 "Registration" means registering with the Department in accordance with provisions of this regulation.

1.2.15 "Sanitize" means the effective fungal, viral and bacterial treatment of surfaces of tanning equipment by an EPA-approved product that provides a sufficient concentration of chemicals and enough time to reduce the bacterial count, including pathogens, to an acceptable level.

1.2.16 "Tanning Equipment" means ultraviolet or other lamps and equipment containing such lamps intended to induce skin tanning through the irradiation of any part of the living human body with ultraviolet radiation.

1.2.17 "Tanning Facility" means any location, place, area, structure or business that provides consumers access to tanning equipment. For the purpose of this definition tanning equipment registered to different persons at the same location and tanning equipment registered to the same person, but at separate locations, shall constitute separate tanning facilities.

1.2.18 "Ultraviolet Radiation" means electromagnetic radiation with wavelengths in air between two hundred nanometers and four hundred nanometers.

1.3. Compliance with Other Laws:

The registrant shall comply with any other applicable federal, state and local regulations dealing with health, sanitation, safety standards and electrical standards.

1.4. Inspections:

All facilities are subject to inspection or investigation at any time, without prior notice, by individuals authorized by the Department. The inspection or investigation may be performed as a result of an injury, complaint, non payment of fees, or as the Department deems necessary.

1.5. Exemptions:

1.5.1 The Department may, upon application therefore or upon its own initiative, grant such exemptions or exceptions from the requirements of this regulation as it determines are authorized by law and will not result in undue hazard to public health and safety.

1.5.2 Any person is exempt from the provisions of this regulation to the extent that such person uses equipment other than tanning equipment that emits ultraviolet radiation incidental to its normal operation.

1.5.3 Any individual is exempt from the provisions of this regulation to the extent that such individual owns tanning equipment exclusively for personal use.

1.5.4 Tanning equipment, while in transit or storage incidental thereto, is exempt from the provisions of this regulation.

1.6. Additional Requirements:

The Department may, by order, impose upon any registrant such requirements in addition to those established in this regulation as it deems appropriate or necessary to minimize danger to public health and safety or property.

1.7. Violations:

The Department is authorized to assess monetary fines and or civil penalties for violations of the provisions of the Act or any regulation, temporary or permanent order, or final determination of the Department.

1.8. Enforcement Actions:

The Department may, upon proper notice to the registrant, impose a fine for failing to comply with these regulations or provisions of the Act, or when the Department deems a situation to constitute an existing or potential public health hazard.

1.9. Fees:

1.9.1 Application Fee:

1.9.1.1 Each registrant shall pay a nonrefundable initial application fee of fifty dollars upon submission of the "Application for Registration of Tanning Facilities" form.

1.9.2 Tanning Equipment Fee:

1.9.2.1 Each registrant shall pay fifty dollars for each piece of tanning equipment.

1.9.2.2 The tanning equipment fee shall be due upon initial assignment of a registration number and on July 15 of each year.

1.9.2.3 Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually or monthly by the Department.

1.9.2.4 Fees required by Section 1.9 for tanning equipment that is issued during a calendar year shall be prorated for the remainder of that year based on the date of issuance of the registration.

1.9.2.5 Persons failing to pay the fees required by Section 1.9 within sixty days from the billing date shall also pay a penalty of fifty dollars. If the required fees are not paid within ninety days of the billing date, the registrant shall be notified that his / her registration is revoked, and that any activities permitted under the authority of the registration must cease immediately or monetary fines and/or civil penalties will be levied.

1.10. Material False Statement:

It shall be a violation of these regulations to make a material false statement to the Department regarding information contained in the application for registration, information pertaining to an inspection or any other information required by any provision of these regulations.

1.11. Communications:

All communications and reports concerning these regulations, and registrations filed thereunder, shall be addressed to the Department at:

SC Department of Health and Environmental Control

Bureau of Radiological Health

2600 Bull Street

Columbia, SC 29201

1.12. Violations:

1.12.1 Assessment of monetary fines and or civil penalties will be based upon the severity of the public health risk:

Monetary and/or Civil Penalty Actions:	1st Offense	2nd Offense	3rd Offense
Failure to register and/or pay any fee.	$500.00	$1,000.00	$5,000.00
Ultraviolet radiation burn requiring medical attention and/or equipment-related injuries.	$1,000.00	$2,000.00	$4,000.00
Unsanitary conditions of tanning or tanning-related equipment that could result in the transmission of communicable diseases.	$1,000.00	$2,000.00	$4,000.00
Failure to provide and/or ensure use of Food and Drug Administration (FDA) approved equipment and eyewear.	$500.00	$1,000.00	$1,500.00
Use of medical lamps and/or noncompliant lamps or filters.	$1,000.00	$2,000.00	$3,000.00
Failure to operate a facility in a manner so as not to cause a potential overexposure to no-nionizing radiation or potential transmission of a communicable disease or injury.	$500.00	$1,000.00	$5,000.00

1.12.2 Any person to whom an order is issued may appeal it pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

1.13 Severability:

If any provision of this regulation or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the regulation that can be given effect without the invalid provision or application, and to this end the provisions of the regulation are severable.

PART II
REGISTRATION OF TANNING FACILITIES AND EQUIPMENT

2.1. Purpose and Scope:

This Part describes the requirements of facilities and equipment that use ultraviolet and other lamps for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

2.2. Application for Registration of Tanning Facilities:

2.2.1 Each person acquiring or establishing a tanning facility shall register the tanning equipment prior to beginning operation of such a facility.

2.2.2 The registrant shall submit DHEC form 0826, Registration of Tanning Equipment, to SC DHEC, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC 29201. Upon completion and receipt of DHEC form 0826, Registration of Tanning Equipment, the Department will issue a tanning facility registration number.

2.3. Issuance of Registration Document:

2.3.1 No person shall operate a tanning facility until the Department has issued a registration number or otherwise received notification from the Department.

2.3.2 Any facility found operating unregistered shall be subject to a Monetary Fine as described in Section 1.12.1, and/or Civil Penalties.

2.4. Transfer of Registration:

No registration shall be transferred from one person to another or from one tanning facility to another tanning facility.

2.5. Report of Change:

The registrant shall report to the Department, within thirty days, any changes of status affecting the tanning equipment or facility. Report of change of status shall be made in writing and forwarded to the Department.

2.6. Denial, Suspension or Revocation of Registration:

2.6.1 The Department may deny suspend, or revoke a registration:

1. for any material false statement on DHEC Form 0826 Registration of Tanning Equipment; in the application for registration or in the statement of fact required by provisions of this regulation;

2. for falsification or alteration of records required to be kept by this regulation;

3. for operation of the tanning facility in a manner that causes or threatens to cause hazard to the public health or safety;

4. for failure to allow authorized representatives of the Department to enter the tanning facility at reasonable times for the purpose of determining compliance with the provisions of this regulation, or an order of the Department;

5. for failure to pay any fees;

6. for failure to correct violations;

7. for violation of, or failure to observe any of the terms and conditions of this regulation, or an order of the Department;

8. when the current owner of the tanning facility has one or more of the following at another salon: outstanding compliance issues, a poor compliance history, outstanding fees or penalties due, or unresolved enforcement action.

2.6.2 A Department decision involving the issuance, denial, suspension, or revocation of a registration may be appealed by an affected person pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

2.6.3 The Department may terminate a registration upon receipt of a written request for termination from the registrant.

PART III
STANDARDS FOR THE TANNING FACILITY

3.1. Purpose and Scope:

This Part provides for the minimum public health requirements for tanning facilities that employ ultraviolet equipment for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

3.2. Ultraviolet Radiation Exposure:

3.2.1 Each registrant shall ensure that all individuals exposed to ultraviolet radiation will not be subjected to an overexposure of nonionizing radiation that results in a significant burning of the skin requiring medical attention.

3.2.2 A facility must be operated in a manner to prevent a potential overexposure to nonionizing radiation or potential transmission of a communicable disease or injury.

3.3. Sanitation:

3.3.1 The registrant shall ensure that the tanning equipment and protective eyewear required by this regulation are properly sanitized before each use. The sanitizer used shall be one intended and documented for use on the tanning equipment and protective eyewear. The sanitizer shall be mixed and used according to the manufacturer's instructions.

3.3.2 All surfaces of the tanning equipment must be maintained in a condition that does not compromise the effectiveness of sanitation.

3.3.3 A registrant shall not require a consumer to sanitize the tanning equipment or protective eyewear and shall not post any signs requesting such sanitation be performed by the consumer. However, this does not prevent a consumer from re-sanitizing the tanning equipment or protective eyewear if a consumer so chooses after the registrant has performed the sanitation.

3.4. Tanning Equipment:

3.4.1 The registrant shall use only tanning equipment manufactured in accordance with the specifications set forth in 21 CFR 1040.20, "Sunlamp products and ultraviolet lamps intended for use

in sunlamp products." The nature of compliance shall be based on the standards in effect at the time of manufacture as shown on the device identification label required by 21 CFR 1010.3.

3.4.2 All tanning equipment must be maintained to prevent injury or burn.

3.5. Protective Eyewear:

3.5.1 If a consumer does not provide protective eyewear, the registrant shall have compliant protective eyewear available for each consumer to use during any use of tanning equipment.

3.5.2 If a consumer fails to provide compliant protective eyewear and chooses not to use the protective eyewear available from the registrant, then the consumer shall not be allowed to tan.

3.5.3 Prior to initial exposure, the tanning facility operator shall instruct the consumer in the proper utilization of the protective eyewear required by this regulation, to include use in accordance with the manufacturer's design, instructions and approval.

3.5.4 Tanning facility operators shall ensure all protective eyewear is in optimal condition.

3.5.5 Tanning facility operators shall ensure the protective eyewear used by the consumer is used in accordance with its design.

3.5.6 The protective eyewear in this regulation shall meet the requirements of 21 CFR 1040.20 (c) (4) (4–1–87 edition).

3.6. Replacement of Ultraviolet Lamps, Bulbs or Filters:

3.6.1 The registrant shall only use lamps that have been certified with the Food and Drug Administration (FDA) as "equivalent" lamps under the FDA regulations and policies applicable at the time of the replacement of the lamps. The format for the equivalency document shall be in compliance with 21 CFR 1040.20 and shall be in the form of User Instructions.

3.6.2 The registrant shall maintain manufacturer's literature demonstrating the equivalency of any replacement lamps that are not identified as original equipment. The documents for any lamps currently in use shall be kept at the facility and shall be readily available for Department review.

3.6.3 Defective lamps or filters shall be replaced before further use of the tanning equipment.

3.6.4 Lamps and bulbs designated for "medical use only" shall not be used.

3.7. Use of Tanning Equipment by Minors:

3.7.1 The registrant shall not allow minors to use tanning equipment unless the minor provides a consent form signed by the minor's parent or legal guardian while witnessed by an operator or the owner of the tanning facility. The witness shall provide his/her name, signature, title and date on the consent form.

3.8. Warning Sign:

3.8.1 The following warning sign shall be conspicuously posted in the immediate proximity of each piece of tanning equipment. It shall be legible, and clearly visible, unobstructed by any barrier, equipment, or other item so that the consumer can easily view the warning sign before energizing this tanning equipment:

> **If you receive any injury from the use of this tanning device, such as a burn or other physical injury, report this injury immediately to a tanning equipment operator and to the SC Department of Health and Environmental Control, Bureau of Radiological Health, 2600 Bull Street, Columbia, SC 29201, or contact the Department by telephone at (803) 545–4400.**

PART IV
OPERATOR TRAINING

4.1. Purpose and Scope:

This Part provides the minimum training requirements for tanning equipment operators who employ ultraviolet and other lamps for the purpose of tanning the skin of the human body through the application of ultraviolet radiation.

4.2. Minimum Operator Training Requirements:

4.2.1 The operator shall ensure the tanning equipment is not operated in a manner to cause overexposure or injury to the consumer. Tanning equipment operators shall be trained at a minimum in the following areas:

1. the required subjects shall include, but not be limited to:

2. the requirements of these regulations, R.61–106 "Tanning Facilities;"

3. the proper procedures for the use and instruction in the use of protective eyewear;

4. recognition of injury or overexposure to ultraviolet radiation;

5. examples and detailed explanations of tanning equipment manufacturers recommended exposure schedules;

6. the Potential photosensitizing agents, to include food, cosmetics and medications, and the possibility of photosensitivity and photoallergic reactions;

7. the Emergency procedures to be followed in case of an actual or alleged ultraviolet radiation injury;

8. biological effects of ultraviolet radiation, to include the potential acute and long term health effects of ultraviolet radiation;

9. the human skin and the tanning process;

10. the public health reasons for avoiding overexposure and the dangers of overexposure;

11. operator training must be documented and available to the Department for review;

61–107. Solid Waste Management.

General. The Solid Waste Management regulations are promulgated pursuant to the provisions of the Solid Waste Policy and Management Act of 1991, which became effective on May 27, 1991, as Act No. 63 of 1991. These regulations are promulgated to achieve the purposes set forth in the Act, as codified in Section 44-96-10 et seq.

61–107.1. Solid Waste Management: Solid Waste Management Grants, Recycling Education Grants, and Waste Tire Grants.

A. Applicability.

The intent of this regulation is to establish procedures for disbursement of solid waste management grants, recycling education grants and waste tire grants to local governments or regions for solid waste management and recycling education in accordance with the intent of the legislature; to assist local governments, regions and public school districts in meeting the requirements of the Solid Waste Policy and Management Act of 1991 (Act 63).

B. Definitions.

1. "Advance funds" means monies approved for known costs to the applicant before the quarterly report is due.

2. "Eligibility" means the standard or criteria by which a county or region or applicant qualifies for grant funds, as determined by the Office and the appropriate Council or Committee. These standards shall include, but are not limited to, completeness of the grant application, proof of existing accumulated waste tire sites, proposed methods of remediation and plans for disposal.

3. "Grant agreement" means the binding contract between the Office and the applicant.

4. "Grant application" means the initial request form for a grant through the Office.

5. "Grants, base portions" means that part of the grant equalling at least twenty-five percent (25%) of the total available in any given grant period.

6. "Grants, incentive portions" means that part of the solid waste reduction grant and recycling education grant equalling at least seventy-five percent (75%) of the total available in any given grant period.

7. "Grant period" means twelve months from the time the grant agreement is properly executed by all parties.

8. "Local government" means any municipality, county, district or authority or any agency thereof which has jurisdiction over the collection, recycling, disposal or treatment of solid waste.

9. "Matching Funds" means funds committed for purposes set forth in this rule in an amount equalling the total solid waste reduction incentive portion of solid waste grants or recycling education grants incentive portion awarded to a local government or region. Matching funds include budgeted funds, funds in escrow, and funds expended on solid waste reduction or recycling education related program activities, but do not include in-kind contributions.

10. "Municipal solid waste" includes any solid waste resulting from the operation of residential, commercial, governmental, or institutional establishments that would normally be collected, processed and disposed through a public or private solid waste management service. The term includes yard trash and industrial solid waste.

11. "Office" means the Office of Solid Waste Reduction and Recycling.

12. "Population" means the 1990 census determination.

13. "Program" means the grant program established and administered by the Office of Solid Waste Reduction and Recycling.

14. "Region" means two (2) or more counties in South Carolina which have prepared, approved and submitted a regional concept application to the Office of Solid Waste Reduction and Recycling for grant funds.

15. "Solid Waste Management Grant Program" means the grant program established and administered by the Office of Solid Waste Reduction and Recycling.

16. "Temporary operating subsidy" means the use of grant funds for operational expenses of a solid waste reduction program or a recycling education program, including personnel costs, training costs, rental of facilities, and other similar expenses approved by the Office.

C. General Grant Application Requirements.

1. Requests for funding shall be submitted to the Office on application forms provided by the Office.

2. Applications received from local governments, regions or public school districts which have not expended or accounted for any unused grant funds from a previous grant shall be denied by the Office. The grant period shall run for twelve months from the date of the executed grant agreement. Applications from local governments, regions or public school districts which have not met their obligations under the terms of any previous grant agreements for funds under this rule shall also be denied by the Office.

D. Disbursement of Funds.

1. Upon receipt and approval of the application, the Office shall determine the exact amount of the grant award and prepare a grant agreement.

2. The grant agreement will be forwarded to the applicant to be signed by a local government official, region official or public school district official for execution.

3. The applicant may request advance funds through the application process; however, known needs must be documented before advance funds can be approved. Within at least thirty (30) days of the properly executed grant agreement by all parties the advance funds will be forwarded to the applicant.

4. Any local government, region or public school district receiving grant funds will report on the status of the grant. Each quarterly report shall include information for reimbursement of actual costs and be submitted fifteen (15) days from the end of the previous quarter. Quarters shall run January 1st through March 31st, April 1st through June 30th, July 1st through September 30th and October 1st through December 31st of each calendar year.

5. The Office has the right to terminate a grant award and demand refund of grant funds for non-compliance with the terms of the award or these rules. The Office shall declare the local government, region or public school district ineligible for further participation in the program until the local government, region or public school district complies with the terms of the grant award or these rules.

E. Grant Recordkeeping.

1. Each recipient of grant funds shall maintain accurate records of all expenditures of grant funds, and shall assure that these records are available for inspection and/or audit upon request by the Office. Records shall be kept until July 31, 1996.

2. Recordkeeping information as required by the Office shall be included on each quarterly report.

F. Specific Solid Waste Management and Recycling Education Grant Requirements.

1. The Office will make available grant application forms to all local governments, and to all public school districts within the State.

2. Upon receipt and approval of the grant application the Office shall determine the amount of the grant award and prepare the grant agreement. Payment of grant awards will be contingent upon receipt and approval of the grant agreement.

3. All local governments applying jointly shall enter into a regional agreement that designates a lead applicant and describes how the funds will be disbursed and used. Any agency or authority created by regional agreement for solid waste management or recycling education purposes is eligible to apply for grants. The applicant shall submit all required documents in place of the local governments which are party to the agreement. Such applications and submittals shall be equivalent to those required if each local government were applying individually.

4. Applicant shall provide to the Office information on any previous state or federal grant received for the purpose of solid waste management or recycling. This information shall include the grant amount and the grant period.

G. Eligibility Requirements.

1. All applications shall include the following information for the area to be serviced under the terms of the grant:

a. A description of the solid waste management project or public education recycling project for which grant funds are requested, including any business and accounting plans for such projects;

b. An estimate of the quantity, source and type of materials to be collected and recycled under the proposed program, including an explanation of the methods used to estimate this quantity. The quantity shall include the volume of out-of-state waste coming into the service area, but records of out-of-state waste volume shall be shown as a separate item on each quarterly report;

c. A description of all existing or proposed recycling facilities, collection centers or other related service centers located within the county, including ownership, capacity, type of facility and approximate service area of such facilities;

d. Evidence that the grant is needed to achieve the goals set forth in the Solid Waste Policy and Management Act of 1991. This information will require an explanation of how the existing private and public sector recycling programs and efforts will be incorporated into the recycling and education program;

e. A summary of all costs incurred, or to be incurred, in planning or implementing the recycling and solid waste management and recycling education projects;

f. A copy of any regional agreement into which local governments have entered to accomplish the purposes of this rule;

g. Any written contracts, written bids or written agreements which were entered to develop and implement the solid waste management and recycling program;

h. The measurable objectives of the recycling education program, and an explanation of how the education program will directly promote the use of existing or planned local recycling projects; and,

i. A description of the methods to be used in evaluating the success of the solid waste management and recycling education programs. Progress reports and methods used to measure the progress shall be included in the quarterly reports.

2. The grant application shall include a recycling plan for the entire population of the service area (incorporated and unincorporated) containing at least the following information:

a. An explanation of the manner in which the recycling program will be implemented;

b. A timetable for the continued development and implementation of the recycling program;

c. The estimated percentage of the population participating in various types of recycling activities;

d. The estimated percent reduction each year in municipal solid waste disposed at solid waste disposal facilities as a result of public and private recycling programs, including the estimated success rates, perceived reasons for the estimated success or failure, and the public and private sector recycling activities which are ongoing and most successful;

e. An identification and description of the facilities where solid waste is being disposed or processed, the remaining available permitted capacity of such facilities, any planned increases in the capacity of such facilities, and the anticipated effect of recycling programs on the type and size of such facilities;

f. A description and evaluation of solid waste that is being recycled including, but not limited to, glass, aluminum, steel, bimetallic materials, office paper, yard trash, newsprint, corrugated paper, plastics, white goods, waste tires and yard trash;

g. The anticipated and available markets or uses for materials collected through recycling programs;

h. The estimated costs of and revenue from operating and maintaining existing and proposed recycling programs. This does not include specific costs and revenues from privately operated recycling programs, but a summary of such costs and revenues is required if the applicant intends to provide funding for such programs;

i. A description of any recycling activities implemented or existing prior to the effective date of the grant regulations;

j. For those local governments whose comprehensive plans required under the Solid Waste Policy and Management Act of 1991 have been submitted at the time of application, an explanation of how the recycling programs relate to the future land use elements; sanitary sewer, solid waste, drainage, potable water, and natural groundwater aquifer properties; and capital improvements; and,

k. A description of how all special wastes will be managed.

H. Special Requirements.

1. The Office shall not approve any solid waste management project or recycling education project unless the project directly promotes the success of that project for which the grant was intended.

2. Effective May 27, 1993, no local government or region shall receive a solid waste management grant unless the operator of each solid waste management facility owned or operated by the local government or region has completed an operator training course approved by the Office, as required under the State Solid Waste Policy and Management Act of 1991.

3. Grants shall not be provided to any local government, region or public school district that does not demonstrate a good faith effort to meet the requirements of the Solid Waste Policy and Management Act of 1991.

I. Use of Solid Waste Management and Recycling Education Grant Funds.

1. Solid waste management grants and recycling education grants shall be used to provide funding for solid waste management program capital costs or recycling program capital costs, which include equipment purchases, solid waste scales, facility construction and other such costs approved by the Office, as part of the grant agreement.

2. Solid waste management and recycling education grants may also be used for operating subsidies, provided that the applicant demonstrates that such a use is necessary for the success of the program, and shall show how the subsidy will benefit the program. Within one (1) year of the award the applicant shall provide reasonable assurances that the program will be able to operate without a subsidy from this grant program.

3. Solid waste management grants and recycling education grants shall also be used for projects to assist local governments, regions or public school districts in recycling paper, glass, plastic,

construction and demolition debris, white goods, and metals and in composting and recycling the organic material component of municipal solid waste.

4. Solid waste management grants and recycling education grants shall be used to promote recycling, volume reduction, proper disposal of solid wastes, and market development for recyclable materials. Effective May 27, 1997, twenty-five percent (25%) of any grant monies available shall go to local governments, regions or public school districts which have met the solid waste reduction and recycling goals set forth in their solid waste management plans. Bonus grants must be used to fund activities which are related to solid waste management or recycling education.

5. All existing public and private recycling infrastructure shall be fully used to the extent possible when planning and implementing the local government, region or public school district solid waste management or recycling education programs. Funds shall not be used for duplicating existing private and public recycling programs unless the applicant demonstrates that such existing programs cannot be integrated into the planned solid waste management programs or recycling education programs.

6. Solid waste management grants shall be used to ensure that all solid waste management facilities in this State are sited, designed, constructed, operated and closed in a manner which protects human health and safety and the environment.

J. Allocation of Solid Waste Management Grant Funds and Recycling Education Grant Funds.

1. Effective November 1, 1991, monies used to fund the activities of the Office, grants to local governments, regions, research by state-supported educational institutions and public education programs shall include:

a. a two dollar fee ($2.00) on each battery sold in this state;

b. fifty cents (50¢) from a two dollar fee on each new tire sold in this State;

c. a two dollar fee ($2.00) on each white good sold in this State;

d. eight cents (8¢) on each gallon of oil sold in this State;

e. out-of-state solid waste disposal fees;

f. contributions and grants from public and private sources;

g. oil overcharge monies; and,

h. monies appropriated by the General Assembly.

2. Local governments or regions may contract with private entities with pre-approval from the Office to assist in carrying out their responsibilities.

3. Each eligible local government, region or public school district shall receive a pro-rata share, based on total serviced population, of the funds in the Solid Waste Trust Fund.

4. Region applications shall be given priority status.

K. Waste Tire Grant Funds Application Requirements and Allocation.

1. The Office will make available waste tire grant application forms to each local government.

2. No later than January 1, 1993, the Office shall determine the first year grant funds available for waste tire grants from the waste tire account of the Solid Waste Management Trust Fund. Each year thereafter, the Office shall determine the amount of funds available.

3. Each county or applicant making application for waste tire grant funds shall meet eligibility requirements as determined by the Office and the State Waste Tire Advisory Committee prior to approval of the application. Counties should also consider the advantages of a regional program prior to receiving grant approval.

4. Upon request, the Office shall provide technical assistance to a local government or region desiring assistance in applying for waste tire grants or choosing a method of waste tire management which would be an eligible use of the grant funds.

L. Use of Waste Tire Grant Funds.

1. Funds in the Waste Tire Grant Trust Fund must be used exclusively through May 27, 1994, to fund grants to a county or region to pay for the cost of disposal of the accumulated waste tires.

2. A waste tire grant must be awarded on the basis of an approved written grant application and properly executed grant agreement. The application must be submitted through the Office for the Waste Tire Grant Committee or appropriate committee to consider. The Committee shall review waste tire grant applications and make recommendations on grant awards to the State Solid Waste Advisory Council. Waste Tire grants must be awarded by the State Solid Waste Advisory Council. Upon the cessation of the State Solid Waste Advisory Council the Waste Tire Grant Committee shall make recommendations to the Office.

3. The Committee may approve waste tire grants to local governments or regions to assist only in the following:

a. constructing or operating a Tire Derived Fuel (TDF) burning facility for processing or building heat, electricity or other energy recovery;

b. constructing or operating, or contracting for the construction or operation of a waste tire treatment facility and equipment for disposal;

c. contracting for waste tire treatment facility services;

d. removing or contracting for the removal of waste tires; or,

e. performing or contracting for the performance of research designed to facilitate waste tire recycling or disposal.

4. Priority will be given to tire-derived-fuel (TDF) facilities that utilize existing combustion equipment and provide large volume uses.

M. Petroleum Grant Fund Allocation and Requirements.

1. Two-fifths (2/5) of the funds shall be used to establish incentive programs to encourage:

a. individuals who change their own oil to return their used oil to used oil collection centers;

b. the establishment and continued operation of collection centers which accept used oil; and,

c. the establishment and continued operation of recycling facilities which prepare used oil for reuses or which utilize used oil in a manner that substitutes for a petroleum product made from new oil.

2. Two-fifths (2/5) of the petroleum fund shall be used to provide grants for local government or regional projects that the Office determines will encourage the collection, reuse and proper disposal of used oil and similar lubricants. Local government or regional activities may include one or more of the following programs:

a. curbside pickup of used oil containers by a local government or its designee;

b. retrofitting of solid waste equipment to promote curbside pickup or disposal of used oil at used oil collection centers designated by the local government;

c. establishment of publicly operated used oil collection centers at landfills or other public places; or,

d. providing containers and other materials and supplies that the public can utilize in an environmentally sound manner to store used oil for collection and return to the used oil collection center.

3. One-fifth (1/5) of the funds shall be used for public education and research including, but not limited to, reuses, disposal and development of markets for used oil and similar lubricants.

4. The petroleum oil fee shall be imposed until the unobligated principal balance of the Petroleum Fund equals or exceeds three million dollars ($3,000,000.00). The Tax Commission shall be required to adjust the rate of the fee to reflect a full year's collection to produce the amount of revenue required in the fund. The increase or decrease in the fee made by the Tax Commission shall take effect for sales beginning on or after the first day of the third month following determination by the Commission.

N. Aggrieved Party Procedures.

1. Any party aggrieved by a grant decision of the Office may apply in writing within thirty (30) days of the decision to the State Solid Waste Advisory Council for a review of that decision.

2. Within forty-five (45) days of the original grant decision the Office shall inform the aggrieved party of the hearing date, place and time established to review the decision of the Office.

3. The State Solid Waste Advisory Council shall review the Office decision within sixty (60) days of the original grant decision date.

4. Upon the cessation of the State Solid Waste Advisory Council, grant decision reviews shall be heard by the appropriate review committee. The grant decision reviews shall be heard within the same time frame established for the State Solid Waste Advisory Council.

61–107.2. Solid Waste Management: Full Cost Disclosure.

A. Applicability.

This section applies to all local governments which provide solid waste management services.

B. Definitions.

1. "Collection" means the act of picking up solid waste material from homes, businesses, governmental agencies, institutions, or industrial sites.

2. "Composting Facility" means any facility used to provide aerobic thermophilic decomposition of the solid organic constituents of solid waste to produce a stable, humas-like material.

3. "County Solid Waste Management Plan" means a solid waste management plan prepared, approved, and submitted by a single county pursuant to Section 44-96-80 of the South Carolina Solid Waste Policy and Management Act of 1991.

4. "Department" means the South Carolina Department of Health and Environmental Control.

5. "Depreciation" means the decrease in value of property through wear, deterioration, or a decrease in usefulness (obsolescence).

6. "Facility" means all contiguous land, structures, other appurtenances and improvements on the land used for treating, storing, and/or disposing of solid waste. A facility may consist of several treatment, storage, and/or disposal operational units, including, but not limited to, one or more landfills, surface impoundments, or combination thereof.

7. "Full Cost Accounting" The use of an accounting system that isolates, and then consolidates for reporting purposes, the direct and indirect costs that relate to the operation of a solid waste management system.

8. "Incineration" means the use of controlled flame combustion to thermally break down solid, liquid, or gaseous combustible waste, producing residue that contains little or no combustible material.

9. "Industrial Waste" means solid waste that results from industrial processes including but not limited to, factories and treatment plants.

10. "Landfill" means a disposal facility or part of a facility where solid waste is placed in or on land, and which is not a land treatment facility, a surface impoundment, or an injection well.

11. "Local Government" means a county, any municipality located wholly or partly within the county, and any other political subdivision located wholly or partly within the county when such political subdivision provides solid waste management services.

12. "Materials Recovery Facility" means a solid waste management facility that provides for the extraction from solid waste of recoverable materials, materials suitable for use as a fuel or soil amendment, or any combination of such materials.

13. "Municipal Solid Waste Landfill" means any sanitary landfill or landfill unit, publicly or privately owned, that receives household waste. The landfill may also receive other types of solid waste, such as commercial waste, nonhazardous sludge, and industrial solid waste.

14. "Per Capita" means per unit of population or per person.

15. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

16. "Region" means a group of counties in South Carolina which is planning to or has prepared, approved, and submitted a Regional Solid Waste Management Plan to the Department pursuant to Section 44-96-80 of the South Carolina Solid Waste Policy and Management Plan of 1991.

17. "Regional Solid Waste Management Plan" means a solid waste management plan prepared, approved, and submitted by a group of counties in South Carolina pursuant to Section 44-96-80 of the South Carolina Solid Waste Policy and Management Act of 1991.

18. "Service Area" means the area in which the local government provides, directly or by contract, solid waste management services.

19. "Solid Waste" means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial mining, and agricultural operations and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered material, or solid or dissolved materials subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1964, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations, or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

20. "Solid Waste Disposal Facility" means any solid waste management facility or part of a facility at which solid waste is intentionally placed into or on any land or water and at which waste will remain after closure.

21. "Solid Waste Management Services" means all activities that are involved with trash and other waste collection, transportation, recycling and processing, and disposal.

22. "State Solid Waste Management Plan" means the plan which the Department of Health and Environmental Control is required to submit to the General Assembly and to the Governor pursuant to Section 44-96-80 of the South Carolina Solid Waste Policy and Management Act of 1991.

C. Full Cost Disclosure Regulations.

1. Not later than one (1) year after the effective date of this regulation and annually thereafter, each local government shall determine its full cost for its solid waste management services within its service area for the previous fiscal year.

2. Each local government shall publish annually, on or before October 1 of the following year, a notice in a newspaper of general circulation in its service area setting forth the full cost and the cost to residential and nonresidential users, on an average or individual basis, of its solid waste management services within its service area for the previous fiscal year. In calculating the costs, local governments must include costs charged to them by persons with whom they contract for solid waste management services.

3. Each local government shall provide to the Solid Waste Management Division of the Department by October 15, a copy of the public notice of solid waste management cost as it appeared in the newspaper of general circulation as required by Section 2. In addition, the local government shall provide to the Department by October 15, completed copies of Forms one (1) and two (2), "Solid Waste Management Services Total Cost Report", and Solid Waste Management Services Full Cost Accounting Summary of Costs Report", respectively, provided as the attachment to this regulation.

4. For local governments which provide collection, recycling and composting, transfer station services, or other waste management services, without providing final disposal facilities, "full cost" shall, at a minimum, include an itemized accounting of:

a. the cost of equipment, including, but not limited to, trucks, containers, compactors, parts, labor, maintenance, depreciation, insurance, fuel and oil, and lubricants for equipment maintenance;

b. the cost of overhead, including, but not limited to, supervision, payroll, land, office and building costs, personnel and administrative costs of running the waste management program, and support costs from other departments, government agencies, and outside consultants or firms;

c. the costs of employee fringe benefits, including, but not limited to, social security, worker's compensation, pension, and health insurance payments; and,

d. disposal costs and laboratory and testing costs.

5. For local governments which provide disposal services, "full costs" shall include, at a minimum, an itemized accounting of:

a. the cost of land, disposal site preparation, permits and licenses, scales, buildings, site maintenance and improvements;

b. the costs of equipment, including operation and maintenance costs such as parts, depreciation, insurance, fuel and oil, and lubricants;

c. the costs of labor and overhead, including, but not limited to, supervision, payroll office and building costs, personnel and administrative costs of running the solid waste management program, and support costs from, and studies provided by, other departments, government agencies, and outside consultants or firms;

d. the costs of employee social security, workers compensation, pension and health insurance payments; and,

e. disposal costs, leachate collection and treatment costs, site monitoring costs, including, but not limited to, sampling, laboratory and testing costs, environmental compliance inspections, closure and post-closure expenditures, and escrow, if required.

6. A person operating under an agreement to collect or dispose of solid waste within the service area of a local government or region shall assist and cooperate with the local government or region to make the calculations or to establish a system to provide the information required under this section. However, contracts entered into prior May 27, 1991, are exempt from the provisions of this regulation.

61–107.3. Solid Waste Management: Waste Tires.

Part I. General Provisions.

A. Applicability.

1. The requirements of this regulation apply to waste tire haulers, collectors, processors and disposers, except as specifically exempted.

2. The requirements of this regulation do not apply to a person using waste tires for agricultural purposes provided the tires are maintained so as to prevent and control mosquitoes and other public health nuisances as determined by the Department.

3. The requirements of this regulation do not apply to a tire manufacturer as related to the disposal only of tires generated in the course of its scientific research and development activities, so long as the waste tires are buried on the facility's own land or that of its affiliates or subsidiaries and the disposal facility is in compliance with all applicable regulations.

B. Definitions.

1. "Department" means the South Carolina Department of Health and Environmental Control.

2. "Local government" means a county, any municipality located wholly or partly within the county, and any other political subdivision located wholly or partly within the county when such political subdivision provides solid waste management services.

3. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

4. "Processed tire" means a waste tire that has been cut, shredded, burned, or otherwise altered so that it is no longer whole; or waste tires that have been baled or compacted. The term does not include tire products as described in the waste tire processing permit application and approved by the Department in the permit.

5. "Quantity" means either volume as measured by cubic yard, weight as measured in tons or pounds, or actual number of tires by type.

6. "Residual" means any liquid, sludge, metal, fabric, or by-product resulting from the processing or storage of tires. Residual does not include processed tires held for recycling or disposal.

7. "Solid waste management facility" means any solid waste disposal area, volume reduction plant, transfer station, or other facility, the purpose of which is the storage, collection, transportation, treatment, utilization, processing, recycling, or disposal, or any combination thereof, of solid

waste. The term does not include a recovered materials processing facility or facilities which use or ship recovered materials, except that portion of the facility that is managing solid waste.

8. "Tire" means a continuous solid or pneumatic rubber covering encircling the wheel of a motor vehicle, trailer, or motorcycle, as defined in S. C. Code Section 56–3–20(2), (4), and (13). It does not include an industrial press-on tire, with a metal or solid compound rim, which may be retooled.

9. "Tire derived product" means processed tire material that has been sold and removed from the processing facility.

10. "Tire disposal" means to deposit, dump, spill, or place any waste tire, processed tire, or residuals into or upon any land or water.

11. "Tire recycling" means any process by which waste tires, processed tires, or residuals are reused or returned to use in the form of products or raw materials.

12. "Waste tire" means a whole tire that is no longer suitable for its originally intended purpose because of wear, damage, or defect.

13. "Waste tires for agricultural purposes" means waste tires that are generated during the normal production of plants and livestock, and which are kept on-site for beneficial re-use.

14. "Waste tire collection facility" means a permitted facility or a facility exempted from the permit requirement, used for the temporary storage of waste tires.

15. "Waste tire generator" means any person whose action or process produces a waste tire, or whose action first causes a waste tire to become subject to regulation.

16. "Waste tire hauler" means a person engaged in the transportation of greater than fifteen (15) waste tires at one (1) time for the purpose of storage, processing, or disposal.

17. "Waste tire processing facility" means a site where equipment is used to recapture reusable by-products from waste tires or to cut, burn, or otherwise alter whole waste tires so that they are no longer whole. The term includes mobile waste tire processing equipment, waste tire pyrolysis units, and waste tire baling or compacting equipment.

18. "Wetlands" means those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.

C. Manifesting.

1. Any person who transports more than fifteen (15) tires at a time, shall document the transport of the tires using a South Carolina Waste Tire Manifest, or other document approved by the Department.

2. The manifest shall be used to track and certify the movement of waste tires from the point of origination to a permitted waste tire collection facility, a permitted solid waste management facility, or a permitted, or approved, waste tire processing facility.

3. The waste tire hauler shall sign the manifest and secure the signatures of both the waste tire generator and a representative of the waste tire collection, processing, or disposal facility to which the tires are delivered.

4. The manifest shall document the following:

a. The quantity of waste tires or processed tires collected;

b. The name, address, and contact information of the waste tire generator of the waste tires or processed tires;

c. The name, address, and contact information for the location to which the waste tires or processed tires were delivered;

d. The number of tires that were sorted for reuse; and,

e. The quantity of waste tires or processed tires that were delivered to the collection, processing or disposal facility.

5. Within thirty (30) days of collecting waste tires from a location, a waste tire hauler shall provide a completed, final manifest to the waste tire generator, documenting delivery to a waste tire collection, processing or disposal facility.

6. A waste tire hauler shall record and maintain a copy of the completed manifest for three (3) years. Manifests shall be available for inspection by Department personnel during normal business hours.

7. A waste tire collection, processing, or disposal facility shall retain a copy of the completed manifest for three (3) years, and shall make manifests available for inspection by Department personnel during normal business hours.

8. Local governments and their agents that haul waste tires only from designated residential recycling/convenience centers to the local government consolidation point, are exempt from the manifest requirements of this Part.

D. Penalties.

1. The Department may impose civil penalties not to exceed ten thousand dollars ($10,000), for each day of violation, for violations of the regulation.

2. A person who willfully violates this regulation is guilty of a misdemeanor and, upon conviction, must be fined not more than ten thousand dollars ($10,000) for each day of violation, or imprisoned for not more than one (1) year, or both.

3. If the conviction is for a second or subsequent offense, the punishment must be a fine not to exceed twenty-five thousand dollars ($25,000) for each day of violation, or imprisonment not to exceed two (2) years, or both.

E. Violations. Each day of noncompliance with an order issued pursuant to this section or noncompliance with a permit, regulation, standard, order, or requirement established under Section 44–96–170 of the South Carolina Solid Waste Policy and Management Act constitutes a separate violation.

F. Variances. Any request for a change to the adherence to a provision or provisions of this regulation, or to a permit issued pursuant to or in accordance with this regulation, shall be made in writing to the Department. The Department shall provide a written response to such a request. Variances will be granted at the discretion of the Department.

Part II. Waste Tire Hauler Requirements.

A. Applicability and Conditions.

1. The requirements of this section apply to haulers of waste tires and processed tires who haul more than fifteen (15) waste tires or passenger tire equivalents at any one (1) time.

2. Persons who use company-owned or company-leased vehicles to transport tire casings for the purposes of retreading between company-owned or company-franchised retail tire outlets and retread facilities owned or franchised by the same company are not considered waste tire haulers unless they also transport waste tires.

3. Local governments, that haul waste tires only from residential curbside collection programs or designated recycling/convenience centers to the local government consolidation point, are exempt from the hauler registration requirements of Part II of this regulation.

4. Waste tires shall be transported under such conditions and circumstances so as to control mosquitoes and prevent their spread.

5. A waste tire hauler shall deposit waste tires and processed tires at a permitted waste tire processing facility, permitted waste tire collection facility, permitted solid waste management facility, or at another site approved by the Department.

B. Registration.

1. No waste tire hauler may transport waste tires unless registered with the Department and issued a registration number.

2. Waste tire hauler registrations shall have an annual expiration date of March 1.

3. A new application for registration shall be submitted at least thirty (30) days before the hauler intends to begin transporting waste tires.

4. Renewal applications shall be submitted at least thirty (30) days before the expiration date of the existing registration.

5. The application shall be on a form provided by the Department, and shall contain at a minimum the following information:

a. The name and address of the hauling company and the names and addresses of the officers or owners of the hauling company;

b. Information on the locations in South Carolina or elsewhere to which the waste tires will be transported for storage, processing, or disposal;

c. Documentation that the applicant has secured financial assurance in accordance with Part II.D of this regulation; and,

d. For renewal applications, the annual report required in Part II.C of this regulation.

6. A person may submit one (1) application for registration of a fleet of multiple vehicles.

C. Annual Report.

1. Waste tire haulers shall submit to the Department, on a form to be provided by the Department, a completed annual report to reflect the information collected under Part I.C.

2. This report shall be submitted to the Department annually by March 1 of each year to reflect the previous calendar year.

D. Financial Assurance for Waste Tire Haulers.

1. Waste tire haulers that haul tires for compensation by other persons shall be required to provide financial assurance to pay for corrective action.

2. Waste tire haulers shall provide financial assurance in the amount of ten thousand dollars ($10,000).

3. The financial assurance shall be issued in favor of the Department and shall consist of one (1) or more of the following mechanisms: surety bond, irrevocable letter of credit, insurance, trust fund, corporate financial test, or other evidence of financial responsibility assurance approved by the Department.

4. The Department shall use the financial assurance when necessary to pay for clean-up or corrective action. Any money remaining after completion of clean-up and/or corrective action shall be returned to the person who posted the financial assurance.

5. Financial assurance requirements of Part II.D of this regulation do not apply to a local government that hauls waste tires.

Part III. Waste Tire Collection Facility Requirements.

A. General Requirements for Waste Tire Collection Facilities.

1. No person shall store more than one hundred twenty (120) waste tires or processed tires unless the waste tires or processed tires are:

a. Collected and stored at a permitted waste tire collection facility, in accordance with this regulation;

b. Collected and stored at a permitted solid waste management facility before processing and recycling or disposal in accordance with this regulation; or,

c. Managed as otherwise exempted by this regulation.

2. The operator of a waste tire collection facility shall not accept waste tires in excess of the storage limit defined in the facility permit. Each tire stored in excess of the permitted storage limit may be considered a separate violation of this regulation.

3. At least seventy-five (75) percent of the waste tires and processed tires that are both stored at the facility at the beginning of each calendar quarter, and delivered to the facility during each quarter, shall be removed from the facility during the quarter.

4. All waste tire collection facilities must comply with the requirements of this regulation, unless otherwise exempted or approved by the Department.

5. The owner or operator of a waste tire collection facility shall control mosquitoes and rodents so as to protect the public health and welfare and to prevent public health nuisances on or sourced from the facility. The owner or operator shall implement such mosquito control measures or other

pest control measures as may be required by the Department and/or local mosquito control program. Records shall be kept of all mosquito control activities and made available upon request.

B. Exemptions. The following activities do not require a collection facility permit if the designated waste tire sites are maintained so as to prevent and control mosquitoes or other public health nuisances as determined by the Department:

1. A tire retailing business storing less than one thousand (1,000) waste tires on the business premises; tires managed for resale do not count toward this limit provided they are segregated from waste tires and stored by size in a rack or stack not more than two rows wide, in such a manner as to allow the inspection of each individual tire;

2. A tire retreading business storing less than two thousand five hundred (2,500) waste tires on the business premises, or a tire retreading facility that is owned or operated by a person manufacturing tires in this state or a parent company or its subsidiaries manufacturing tires in this state;

3. A business that in the ordinary course of business, removes tires from motor vehicles, if less than one thousand (1000) of these tires are being stored on the business premises; or

4. A permitted solid waste management facility with less than two thousand five hundred (2500) waste tires temporarily stored on the business premises.

C. Location and Design Criteria.

1. All facilities shall comply with the minimum buffers listed below, as they exist at the time the permit application is received by the Department:

a. A minimum two hundred (200)-foot buffer shall be required from residences, schools, day-care centers, churches, hospitals, and publicly owned recreational park areas;

b. A minimum fifty (50)-foot buffer shall be required from property lines;

c. A minimum two hundred (200)-foot buffer shall be required from any body of water or any wetlands area; and,

d. A minimum two hundred (200)-foot buffer shall be required from public or private drinking water wells.

2. The Department may approve, with documented consent of all property owners within the buffer, less stringent buffers than those listed in this regulation.

3. The Department reserves the right to require more stringent buffers if it is determined, based on the location or operations, that more stringent buffers are necessary to protect health and the environment.

4. The Department's permit decision does not supersede, affect, or prevent the enforcement of a zoning regulation or ordinance within the jurisdiction of an incorporated municipality or county, or by an agency or department of this state.

5. Local governments may require siting criteria and buffer distances that are more stringent than the state regulations.

6. The Department may issue a variance to operate with less restrictive buffers with documented consent of all property owners within the buffer, or when the technology and practices of the operation justify the reduction. The request shall be made in writing to the Department.

7. Permitted facilities operating on the effective date of this regulation shall not be subject to the location criteria.

8. The facility shall be managed so that stormwater or floodwater is diverted around and away from the storage piles.

9. Access to the facility shall be controlled through the use of fences, gates, natural barriers, or other means approved by the Department.

10. The facility shall be bermed or given other adequate protection deemed necessary by the Department to keep liquid runoff from a potential tire fire from entering a body of water.

D. Operating Criteria.

1. A waste tire pile or processed tire pile shall have no greater than the following maximum dimensions:

a. Width: fifty (50) feet;

b. Area: ten thousand (10,000) square feet; and,

c. Height: fifteen (15) feet.

2. A fire lane fifty (50) feet wide shall be placed around the perimeter of each waste tire pile. Access to the fire lane for emergency vehicles must be unobstructed at all times.

3. The owner or operator of a waste tire facility shall control mosquitoes and rodents to protect public health and welfare. The owner or operator shall implement such mosquito control measures or other pest control measures as may be required by the Department and/or local mosquito control program. Records shall be kept of all mosquito control activities and/or preventive measures and shall be made available upon request.

4. If the facility receives tires from persons other than the operator of the facility, a sign shall be posted at the entrance of the facility that states operating hours, permit number, and emergency contacts.

5. No operations involving the use of open flames shall be conducted within fifty (50) feet of a waste tire pile.

6. An approach and access road to the waste tire facility shall be kept passable for emergency vehicles at all times.

7. An attendant shall be present when the waste tire facility is open for business and the facility shall be secured from public access when closed.

8. Fire protection services for the facility shall be assured through arrangements with local fire protection authorities. Documentation of these arrangements must be provided to the Department and made available upon request.

9. Communication equipment shall be maintained in working order at the waste tire facility to ensure that the site operator and other employees can contact local fire protection authorities in the event of an emergency.

10. The waste tire storage areas of the facility shall be kept free of grass, underbrush, and other potentially flammable material at all times.

11. The operator of the facility shall prepare and keep at the facility an emergency preparedness manual. The manual shall be updated at least once a year. The manual shall contain, at a minimum, the following elements:

a. A list of names and telephone numbers of persons to be contacted in the event of a fire, flood, or other emergency;

b. A list of the emergency response equipment at the facility, with the location of the equipment clearly shown on a facility map, and instructions for its use in the event of a fire or other emergency; and,

c. A description of the procedures to be followed in the event of a fire, including, but not limited to, procedures to contain and dispose of the oily material generated by the combustion of a large numbers of tires.

12. Upon becoming aware of a fire or an emergency that has potential off-site effects, the facility personnel shall immediately notify the Department. If the emergency occurs after normal business hours, the facility shall contact the Department through the Department's 24-Hour Emergency Response Number. Within two (2) weeks of any emergency involving potential off-site impact, the operator of the site shall submit to the Department a written report summarizing the emergency. This report shall describe the origins of the emergency, the actions that were taken to remediate the emergency, the results of the actions that were taken, and an analysis of the success or failure of the actions.

13. The operator of the facility shall maintain records of the quantity of waste tires and processed tires received at the site, stored at the site, and shipped from the site.

14. Waste tires stored indoors shall meet the same storage criteria as tires stored outdoors unless otherwise specified by the Department.

15. The storage of processed tires shall meet all of the storage criteria as stated in this Section.

16. The temperature of any above-ground piles of compacted, processed tires over one thousand (1,000) cubic yards in size shall be monitored to ensure that the temperature of the tires does not exceed 302 degrees Fahrenheit (150 degrees Celsius). Temperature control measures shall be instituted so that pile temperatures do not exceed 302 degrees Fahrenheit (150 degrees Celsius).

17. Any residuals from waste tire processing shall be managed so that the residuals are contained on-site; the residuals shall be stored temporarily and be controlled and disposed in a permitted solid waste management facility or properly recycled.

E. Application Requirements for Waste Tire Collection Facility Permits.

1. The application for a waste tire collection facility shall be on a form provided by the Department.

2. The application shall contain at a minimum the following:

a. Proof of ownership of the property upon which the waste tires are collected;

b. Site maps or other documents detailing the location and design criteria requirements of Part III.C;

c. An operational plan outlining the operational requirements of Part III.D;

d. A closure plan which shall include at a minimum the following:

(1) Schedule for removal of all waste, waste tires, or processed tires and residuals; and,

(2) Certification that all waste or processed tires remaining on site will be transported to a permitted processing or disposal facility and that closure shall be performed in accordance with Part V of this regulation; and

e. Documentation that the applicant has secured financial assurance in accordance with Part V of this regulation.

F. Record Keeping and Annual Reports.

1. The owner or operator of a waste tire collection facility shall record and maintain for three (3) years the following information regarding its activities:

a. For all waste tires and processed tires shipped from the facility, the name and waste tire hauler, registration number of the waste tire hauler who accepted the waste or processed tires for transport, the quantity of waste tires or processed tires shipped with that hauler, and the place where the waste or processed tires were deposited;

b. For all waste tires and processed tires received at the facility, the name and waste tire hauler registration number of the hauler who delivered the waste or processed tires to the facility, and the quantity of waste or processed tires received from that hauler; and,

c. For all waste tires removed for recapping, the quantity and type removed, and the name and location of the recapping facility receiving the tires.

2. The above records shall be available at the facility for inspection by Department personnel during normal business hours.

3. Owners and operators of waste tire collection facilities shall submit to the Department an annual report, by March 1, that reflects the information collected under Section F.1 above, and the information outlined below:

a. The facility name, address and permit number;

b. The calendar year covered by the report;

c. The total quantity and type of waste tires and processed tires received at the facility during the year covered by the report;

d. The total quantity and type of waste tires and processed tires shipped from the facility during the year covered by the report;

e. The general disposition of waste tires and processed tires; and,

f. The total quantity and type of waste tires and processed tires located at the facility on the first day of the calendar year.

Part IV. Waste Tire Processing Facility Requirements.

A. General Requirements for Waste Tire Processing Facilities.

1. No person shall operate a waste tire processing facility without a permit issued by the Department.

2. All waste tire processing facilities shall be operated in accordance with this regulation.

3. A waste tire processing facility shall not accept any waste tires for processing in excess of its permitted storage limit. The maximum allowable storage limit for processing facilities is thirty (30) times the daily through-put of the processing equipment used. Each waste tire or processed tire stored in excess of the permitted storage limit may be considered a separate violation of this regulation.

4. At least seventy-five (75) percent of the waste tires and processed tires that are both stored at the facility at the start of a calendar year, and are delivered to the facility during the year, shall be processed and removed from the facility during the calendar year.

5. All waste tire processing facilities shall comply with the location, design, and operational standards of this regulation unless otherwise exempted or approved by the Department.

6. A permitted solid waste management facility with less than two thousand five hundred (2500) waste tires temporarily stored on the facility premises is not required to obtain a waste tire processing permit prior to disposal, provided the waste tires are maintained in a manner that will prevent and control mosquitoes or other public health nuisances.

B. Location, Design and Operating Criteria.

1. All waste tire processing facilities shall comply with the location and design criteria of Part III.C of this regulation.

2. All waste tire processing facilities shall comply with the operating criteria of Part III.D of this regulation, unless otherwise exempted or approved by the Department.

C. Permit Requirements for Waste Tire Processing Facilities.

1. All applications for permits required by this regulation shall be submitted to the Department on forms provided by the Department. No construction of a proposed facility or equipment shall begin until all permits required by the Department are final.

2. The application for a waste tire processing facility shall be on a form provided by the Department, and shall contain at a minimum the following:

a. Proof of ownership of the property upon which the waste tire processing facility will be located;

b. Site maps or other documentation detailing the location and site design requirements of Part III.C of this regulation;

c. A plan outlining the operational requirements of Part III.D of this regulation;

d. A description of the tire processing equipment, including manufacturer's information, for determination of throughput;

e. A closure plan, which shall include at a minimum the following:

(1) A schedule for removal of all waste or processed tires and residuals; and,

(2) Certification that all waste or processed tires remaining on site will be transported to a permitted processing or disposal facility and that closure shall be performed in accordance with Part V of this regulation; and,

f. Documentation that the applicant has secured financial assurance in accordance with Part V of this regulation.

D. Record Keeping and Annual Reporting.

1. The owner or operator of a waste tire processing facility shall record and maintain for three (3) calendar years the following information regarding its activities:

a. For all waste tires and processed tires shipped from the facility, the name and waste tire hauler registration number of the waste tire hauler who accepted the waste tires or processed tires for transport, the quantity of waste tires or processed tires shipped with that hauler, and the place where the waste tires or processed tires were deposited;

b. For all waste tires and processed tires received at the facility, the name and waste tire hauler registration number of the hauler who delivered the waste tires or processed tires to the facility, and the quantity of waste tires or processed tires received from that hauler; and,

c. For all waste tires removed for recapping, the quantity and type removed, and the name and location of the recapping facility receiving the tires.

2. The above-referenced records shall be available at the site for inspection by Department personnel during normal business hours and made available by request.

3. Owners and operators of waste tire processing facilities shall submit to the Department a completed annual report, by March 1, on a form provided by the Department, that includes the information collected under Part IV. D.1 above, and the information outlined below:

a. The facility name, address and permit number;

b. The calendar year covered by the report;

c. The total quantity and type of waste tires and processed tires received at the facility during the calendar year covered by the report;

d. The total quantity and type of waste tires and processed tires shipped from the facility during the calendar year covered by the report;

e. The general disposition of waste tires and processed tires; and,

f. The total quantity and type of waste tires and processed tires located at the facility on the first day of the calendar year.

Part V. Financial Assurance and Closure Procedures for Permitted Facilities.

A. Financial Assurance Requirements.

1. Permitted waste tire facilities shall fund a financial assurance mechanism acceptable to the Department for completing final closure prior to accepting waste tires.

2. A final closure cost estimate, based on third party costs to complete closure by disposing of the maximum quantity of waste and processed tires at a permitted facility, shall be performed annually and adjusted annually, if necessary.

3. The financial responsibility requirements shall not apply to any local government or region comprised of local governments that owns and operates a municipal solid waste management facility, unless and until such time as federal regulations require such local governments and regions to demonstrate financial responsibility for such facilities.

4. The financial assurance shall be issued in favor of the Department and may consist of one (1) or more of the following mechanisms: surety bond, irrevocable letter of credit, insurance, trust fund, corporate financial test, or other evidence of financial responsibility assurance that is approved by the Department.

B. Closure Procedures. Waste tire collection and processing facilities shall close in accordance with the following procedures:

1. At least sixty (60) days prior to closure, written notice of intent to close and a proposed closure date shall be submitted to the Department;

2. Upon closing, immediately post closure signs at the facility;

3. All waste tires, processed tires, residuals, and any other waste at a facility shall be removed to a permitted processing or disposal facility and the waste handling areas shall be cleaned within ten (10) days of closure;

4. Within ten (10) days of closure, a Department inspection and approval of closure shall be requested; and,

5. Within sixty (60) days of closure, grade land to promote positive drainage and seed with native vegetation to prevent erosion.

C. Release of Financial Assurance. The Department shall release any remaining financial assurance upon verification by the Department that closure has been satisfactorily completed in accordance with this regulation.

HISTORY: Amended by State Register Volume 39, Issue No. 6, Doc. No. 4542, eff June 26, 2015.

61–107.4. Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals.

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Part I. General Provisions.

A. Applicability.

1. The purpose of this regulation is to establish minimum standards for the proper management of yard trimmings, land-clearing debris and other organic material; to encourage composting and

establish standards for the production of compost; and to ensure that operations are performed in a manner that is protective of public health and the environment.

2. Registered wood-grinding or composting facilities operating on the effective date of this regulation are subject to the following:

a. Registered facilities operating on the effective date of this amendment shall be subject to all provisions of the amended regulation with the exception of the location criteria outlined in Part III.C. Such an exception shall not apply to facilities that relocate or modify their permit or registration to include feedstocks other than Category One feedstocks, after the effective date of this amendment.

b. Within 90 days of the effective date of this amended regulation, operators of registered facilities shall send written notification to the Department of their intent to operate in compliance with the regulation or of their intent to cease and close their operations.

(1) Facilities intending to continue to operate as an exempt or conditionally exempt facility shall include in its notice a statement identifying its eligibility to operate as either an exempt facility or a conditionally exempt facility, a signed certification that activities will be conducted in accordance with this regulation, a request that its registration be terminated and, as appropriate, a request that its financial assurance mechanism be canceled.

(2) Facilities intending to operate as a permitted facility shall include in its notice a request that its registration, including any modifications approved in writing by the Department prior to the effective date of this amendment, be converted to a permit, and a certification that activities will be conducted in accordance with the regulation.

(3) Facilities intending to cease wood-grinding or composting activities shall provide written notice of intent to close in accordance with Part III.I of this regulation, and a proposed closure date.

c. Facilities shall achieve compliance with all provisions of this amendment within 270 days of its effective date, or close in accordance with the closure requirements of this regulation, unless otherwise approved by the Department.

d. In addition to the notice described above, a facility may be required to provide additional information to the Department to determine compliance with this regulation or to facilitate conversion of the registration to a permit.

3. The requirements of this regulation are not applicable to the grinding of pallets, packaging or other industrial sources of wood residuals.

4. The requirements of this regulation are not applicable to sewage sludge or industrial sludge generated and managed on site of a wastewater treatment facility permitted under authority of R.61–9, Water Pollution Control Permits, including sludges mixed with Category One feedstocks generated off-site of the facility.

B. Definitions.

For the purposes of this regulation, the following terms are defined as follows:

1. "Aerated Static Pile" means a composting process that uses a controlled air distribution system to either blow or draw air through the composting mass. No agitation or turning of the composting mass is performed.

2. "Aerobic" means the biological decomposition of organic substances in the presence of at least five percent oxygen by volume.

3. "Best management practices" (BMP) means schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of Waters of the State, Waters of the United States or wetlands.

4. "Buffer" means the regulatory minimum separation distance required for wood-grinding equipment, operational areas, storage areas, or boundaries of a wood-grinding or composting site to structures as listed in the regulation.

5. "Carbon-to-Nitrogen ratio" ("C:N Ratio") means the quantity of total carbon (C) in relation to the quantity of total nitrogen (N) in an organic material or composting mass.

6. "Composite sampling" means a single sample for laboratory analysis composed of multiple, well-blended point or sub-samples uniformly distributed throughout the entire volume that, after mixing, accurately represents an average or median value of the property or trait of interest for a batch or general mass of compost.

7. "Compost" means the humus-like product of the process of composting.

8. "Compost stability" refers to a specific stage or state of organic matter during composting as characterized by the inverse measure of the potential for a material to rapidly decompose.

9. "Compostable" means the capability of being decomposed by natural biological processes, and is approved by the Department as an acceptable feedstock.

10. "Compostable products" means manufactured items such as cups, plates and flatware for food service or bags and packaging intended for singular use that undergoes degradation by biological processes at a rate consistent with other known compostable materials and leaves no visually distinguishable or toxic residue. Only the materials that meet the relevant specifications of American Society for Testing Materials (ASTM) D6400 (plastics) or ASTM D6868 (coated papers and natural materials) shall be considered compostable products.

11. "Composting" means the aerobic biological decomposition of organic residuals under managed conditions and minimum time-temperature relationships resulting in compost.

12. "Composting mass" means the result of combining feedstocks in a formulaic recipe to achieve a Carbon-to-Nitrogen ratio, moisture content, and porosity within the mixture that facilitates rapid aerobic decomposition of the materials; the mixture of feedstocks is considered a composting mass until it meets the stability requirements of this regulation.

13. "Control" means having access to a property through part ownership, rental, lease, easement or other access agreement.

14. "Curing" means the process that follows composting in which the compost is matured to meet market conditions.

15. "Department" means the South Carolina Department of Health and Environmental Control (SCDHEC).

16. "Domestic septage" means either liquid or solid material removed from a septic tank, cesspool, portable toilet, Type III marine sanitation device, or similar treatment works that receives only domestic sewage. Domestic septage does not include liquid or solid material removed from a septic tank, cesspool, or similar treatment works that receives either commercial wastewater or industrial wastewater and does not include grease removed from a grease trap at a restaurant.

17. "Domestic sewage" means waste and wastewater from humans or household operations that is discharged to or otherwise enters a treatment works.

18. "Feedstock" means source separated, recovered organic material approved by the Department or listed in the Appendix to R.107.4 to be used in the production of compost, mulch or other product.

19. "Finished compost" means the product of a composting mass that has met the minimum time and temperature requirements for the composting method chosen and satisfies the stability requirements and applicable quality assurance and testing requirements for finished compost found in Part III.F of this regulation.

20. "Generated on site" means residuals produced on the same single tax map parcel or multiple tax parcels under the same ownership or control, upon which it is managed.

21. "Grinding" means the act of mechanically reducing the size of organic materials.

22. "Industrial sludge" means the solid, semi-solid, or liquid residue generated during the treatment of industrial wastewater in a treatment works. Industrial sludge includes, but is not limited to, scum or solids removed in primary, secondary, or advanced wastewater treatment processes, and a material derived from industrial sludge. Industrial sludge does not include ash generated during the firing of industrial sludge in an industrial sludge incinerator or grit and screenings generated during preliminary treatment of industrial wastewater in a treatment works. Industrial sludge by definition does not include sludge covered under 40 CFR 503 or R.61–9.503, Water Pollution Control Permits.

23. "Industrial solid waste" means solid waste generated by manufacturing or industrial processes that is not a hazardous waste regulated under subtitle C of the Resources Conservation and Recovery

Act (RCRA). The term does not include employee kitchen or cafeteria residuals, packaging waste or yard-trimmings generated on site of an industrial property.

24. "In-process material" means ground organics which have been incorporated into a composting mass and other material that is in the process of being cured, but has not yet achieved the status of finished compost.

25. "In-vessel composting" means a process in which decomposing organic material is enclosed in a drum, silo, bin, tunnel, or other container for the purpose of producing compost; and in which temperature, moisture and air-borne emissions are controlled, vectors are excluded and nuisance and odor generation minimized.

26. "Land-clearing debris" means material generated solely from land-clearing activities, including brush, limbs and stumps, but does not include solid waste from agricultural or silvicultural operations.

27. "Manure" means the fecal and urinary excreta of livestock, poultry, or fish and may also contain bedding, spilled feed, water, soil and other substances incidental to its collection. This definition does not include excreta from household animals such as dogs and cats.

28. "Mulch" means the organic, non-composted product rendered by grinding Category One feedstocks.

29. "Municipal solid waste" means discards from residential, commercial, institutional, and industrial sources which have not been separated at the source for recycling. Industrial process waste is excluded from the wastes that comprise municipal solid waste.

30. "On-site" means activities performed on property under the same ownership or control where the feedstocks were grown, produced or otherwise generated for recycling.

31. "Organic" means a substance derived from living organisms.

32. "Open burning" is defined to have the same meaning as used in Air Pollution Control Regulations and Standards R.61–62.1, Definitions and General Requirements, or any future amendments and currently means any fire or smoke-producing process which is not conducted in any boiler plant, furnace, high temperature processing unit, incinerator or flare, or in any other such equipment primarily designed for the combustion of fuel or waste material.

33. "Open dumping" means any unpermitted disposal or landfilling activity except as specifically exempted by regulation.

34. "Operational Area" means the area of a wood-grinding or composting facility where equipment maintenance, material storage, material processing, composting or curing activities are performed, or as otherwise specified by permit.

35. "Operator" means the person responsible for the overall operation of a wood-grinding or composting facility.

36. "Pathogen" means a disease-causing organism, such as fecal coliform, Salmonella bacteria, Ascaris parasite eggs, etc.

37. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

38. "Porosity" means the fraction of a material or mass that is void space.

39. "Putrescible" means material that contains organic matter capable of decomposition by microorganisms and of such a character and proportion that it causes obnoxious odors and the capability of attracting or providing food for birds and other animals.

40. "Residence" means any structure, all or part of which is designed or used for human habitation, that has received a final permit for electricity, permanent potable water supply, permanent sewage disposal, and a certificate of occupancy, if required by the local government.

41. "Residuals" means materials that have served their original, intended use and have been source separated and diverted for recycling, grinding or composting.

42. "Run-off" means any rainwater not absorbed by soil, that flows over land from any part of a facility.

43. "Sewage sludge" means the solid, semi-solid, or liquid residue generated during the treatment of municipal wastewater or domestic sewage in a treatment works. Sewage sludge includes, but is not

limited to, domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic or industrial sewage in a treatment works.

44. "Silvicultural" means produced from or pertaining to the care and cultivation of forest trees and timber, including bark and woodchips.

45. "Solid waste" means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

46. "Source separated" means segregated from solid waste at the point of generation to facilitate recycling.

47. "Thermophilic" means a biological stage in the composting process during which microorganisms break down proteins, fats, and complex carbohydrates such as cellulose at relatively high temperatures (ranging from 113 degrees Fahrenheit to 167 degrees Fahrenheit or 45 degrees Celsius to 75 degrees Celsius).

48. "Turn" means to physically manipulate the compost mass in order to aerate, decrease temperatures, and increase evaporation rates.

49. "Unauthorized material" means any feedstock or waste material that due to its feedstock category, characteristics, or volume, causes an exempt, conditionally exempt site or permitted facility to be in violation of this regulation or the permit conditions approved by the Department.

50. "Untreated wood" means raw wood or lumber that has not been chemically treated or painted.

51. "Vector" means a carrier that is capable of transmitting a pathogen from one organism to another including, but not limited to, flies and other insects, rodents, birds, and vermin.

52. "Waters of the State" means lakes, bays, sounds, ponds, impounding reservoirs, springs, wells, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Atlantic Ocean within the territorial limits of the State, and all other bodies of surface or underground water, natural or artificial, public or private, inland or coastal, fresh or salt, which are wholly or partially within or bordering the State or within its jurisdiction.

53. "Waters of the United States" means:

a. All waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters which are subject to the ebb and flow of the tide;

b. All interstate waters, including interstate wetlands;

c. All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sand flats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds that the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters:

(1) Which are or could be used by interstate or foreign travelers for recreational or other purposes;

(2) From which fish or shellfish are or could be taken and sold in interstate or foreign commerce; or

(3) Which are used or could be used for industrial purposes by industries in interstate commerce;

d. All impoundments of waters otherwise defined as Waters of the United States under this definition;

e. Tributaries of waters identified in paragraph a through paragraph f of this definition;

f. The territorial sea; and

g. Wetlands adjacent to waters (other than waters that are themselves wetlands) identified in paragraph a through paragraph f of this definition.

h. Waste treatment systems, including treatment ponds or lagoons designed to meet the requirements of the Clean Water Act, are not waters of the United States.

54. "Wetlands" means those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.

55. "Yard trimmings" means residuals consisting solely of vegetative matter resulting from maintenance or alteration of public, commercial, institutional or residential landscapes and tends to include grass clippings, leaves, discarded plants and weeds, which have been source separated and diverted for recycling.

C. Variances.

Any request for a change to the adherence to a provision or provisions of this regulation, or to a permit issued pursuant to or in accordance with this regulation, shall be made in writing to the Department. The Department shall provide a written response to such a request.

D. Violations and Penalties.

A violation of this regulation, or any permit or order issued pursuant to or in accordance with this regulation, subjects a violator to the issuance of a Department order, a civil enforcement action, or to a criminal enforcement action in accordance with S.C. Code Ann., Section 44–96–100, as amended.

E. Severability.

If, for any reason, any provision, paragraph, sentence, clause, phrase, or part of this regulation or application thereof, is declared by a court of competent jurisdiction as invalid, or unconstitutional, such judgment shall not affect, impair, or invalidate the remainder of this regulation or its application.

Part II. Exempted and Conditionally Exempted Activities.

The feedstock categories referenced in this part of the regulation are listed and characterized in the Appendix to R.61–107.4. For the purposes of Part II, a "site" shall mean one tax map parcel or multiple contiguous tax parcels under the same ownership.

A. Exempted Activities.

The activities below are exempted from the requirements of this regulation:

1. Backyard composting, when feedstocks generated on residential property by the property occupants are composted primarily for use on the same property;

2. Grinding or composting of Category One feedstocks by a person on property under their ownership, when the feedstocks are generated at that site;

3. Acceptance, storage, grinding or composting of only Category One feedstocks by a person on property under their ownership, when the combined total of unground feedstocks and in-process material on site at any given time is less than 80 cubic yards;

4. Wood grinding activities for maintenance and land-clearing activities by public agencies, public utilities, railroads, or their representatives, upon land they own or control;

5. Composting activities using only Category One and Category Two vegetative feedstocks by a person on property under their ownership, when the combined total of feedstocks and in-process material on site, at any given time, is less than five cubic yards;

6. Storage, grinding and composting activities required for emergency storm debris management at sites designated by state, county, and municipal government;

7. Composting activities or other organics management activities associated with farming operations when the material managed is produced from crops grown on a farm, and when the compost is produced primarily for use on property under the same ownership or control;

8. Limited duration events that involve processing or storage of organic residuals for distribution to the public, to include "Grinding of the Greens" and, as approved by the Department, other programs of a similar nature; and

9. Composting activities by a participant transitioning to or enrolled in the U.S. Department of Agriculture (USDA) National Organic Program, or other programs of a similar nature as approved by the Department, and the compost produced is primarily for use on property under control of the participant.

B. Conditionally Exempt Activities.

1. The following activities are exempt from the permitting requirements of this regulation, but shall comply with all requirements of Part II.B:

a. Management of only source separated Category One feedstocks by a person on property under their ownership, when the combined total of feedstocks and in-process material on site at any given time is less than 400 cubic yards.

b. Management of only source separated Category Two feedstocks or mixtures of Category One and Category Two feedstocks by a person on property under their ownership, when the combined total of feedstocks and in-process material on site at any given time is less than 40 cubic yards.

c. Management of only source separated Category Two feedstocks or mixtures of Category One and Category Two feedstocks generated on site of commercial, industrial, or institutional properties under the same ownership, when the combined total of feedstocks and in-process material on site at any given time is less than 400 cubic yards.

2. Conditionally exempt activities shall be performed in accordance with the minimum buffers listed below as measured from the operational area, to the listed entities:

a. A minimum 200-foot buffer shall be required from residences, schools, day-care centers, churches, hospitals and publicly owned recreational park areas unless otherwise waived with documented consent of all property owners within the buffer and made available to the Department upon request;

b. A minimum 50-foot buffer shall be required from property lines unless otherwise waived with documented consent of all property owners within the buffer and made available to the Department upon request;

c. A minimum 100-foot buffer shall be required from public and private drinking water wells.

3. The Department may issue a variance to operate with less restrictive buffers when the technology and practices of the operation justify the reduction. The request shall be made in writing to the Department.

4. All putrescible feedstocks shall be managed to prevent the escape of liquids and to suppress odors by immediately incorporating the feedstocks into the compost mass, an in-vessel composting unit, an air-tight container, or an enclosed building.

5. Best Management Practices shall be utilized to manage stormwater and to prevent impact to Waters of the State.

6. No feedstocks or other material piles may be placed or stored in standing water.

7. All feedstocks and other material piles onsite of the facility shall be monitored and managed to prevent fire.

8. Unauthorized material shall be removed from the facility for proper disposal no less than every seven days, except that putrescible waste shall be placed in an air-tight container immediately and removed from the facility within 72 hours.

9. Compost produced by conditionally exempt facilities using Category Two feedstocks shall not be offered for sale to the public unless it can be demonstrated to meet all applicable standards for compost quality under Part III.F of this regulation.

Part III. Permitted Facilities.

The feedstock categories referenced in this part of the regulation are listed and characterized in the Appendix to R.61–107.4.

A. Facility Types.

Facilities described below may not be operated without a permit, except as specifically exempted in Part II of this regulation:

1. Type One facilities. Type One facilities are facilities that grind or compost only source separated organic residuals described as Category One feedstocks.

2. Type Two facilities. Type Two facilities are those facilities that compost only source separated compostable materials described as Category Two feedstocks or mixtures of Category One and Category Two feedstocks, or any similar items specifically approved in writing by the Department.

3. Type Three Facilities. Type Three facilities are those facilities that:

a. Compost Category Three feedstocks or mixtures of Category Three feedstocks with other feedstock categories from the Appendix to R.61–107.4;

b. Compost feedstocks not listed in the Appendix to R.61–107.4, that pose a level of risk greater than Category Two feedstocks as determined and allowed, on a case-by-case basis, by permit from the Department; or

c. Produce compost using methods not specified in Part III.E.6 of this regulation and as allowed on a case-by-case basis by permit from the Department.

B. General Criteria

1. The siting, design, construction, operation, and closure activities for facilities shall conform to the standards set forth in this regulation, unless otherwise approved by the Department.

2. Facilities shall obtain the appropriate permit or permits from the Department in accordance with Part IV or Part V of this regulation, prior to the construction, operation, expansion, or modification of a facility.

3. The Department may approve a variance from the general, location, design or operating criteria, based upon the technology and practices of the operation.

4. All facilities shall be subject to inspections and evaluations of operations by a representative of the Department.

C. Location Criteria

1. All facilities shall comply with the minimum buffers, listed below, from the operational area of the facility, to the listed entities, as they exist at the time the permit application is received by the Department, except that an entity listed here shall be exempt from the buffer requirement to its own buildings.

a. For Type One facilities, for in-vessel composting or for composting performed in an enclosed building, a minimum 200-foot buffer shall be required from residences, schools, day-care centers, churches, hospitals and publicly owned recreational park areas; for all other Type Two or Three facilities, a minimum 1000-foot buffer shall be required.

b. For Type One facilities, a minimum 50-foot buffer shall be required from property lines; for Type Two or Three facilities, the buffer shall be at least 100 feet;

c. A minimum 100-foot buffer shall be required from any Waters of the U.S.;

d. A minimum 100-foot buffer shall be required from public or private drinking water wells;

e. A minimum 100-foot buffer shall be required from isolated wetlands; and

f. For Type Two or Type Three facilities, a minimum 10,000-foot buffer shall be required from any airport runway used by turbojet aircraft and a minimum 5,000-foot buffer from any airport runway used only by piston-type aircraft.

2. The Department may approve, with documented consent of all property owners within the buffer, less stringent buffers than those listed in Part III.C.1.a and Part III.C.1.b of this regulation.

3. The Department reserves the right to require more stringent buffers if it is determined, based on the site, feedstocks, or operations, that more stringent buffers are necessary to protect health and the environment.

4. The Department's permit decision does not supersede, affect, or prevent the enforcement of a zoning regulation or ordinance within the jurisdiction of an incorporated municipality or county, or by an agency or department of this state.

5. Local governments may require siting criteria and buffer distances that are more stringent than the state regulations.

D. Design Criteria

1. All facilities shall be designed to divert storm water from running onto the operational areas of a facility.

2. The operational area of all permitted Type One facilities shall ensure at least one foot of separation to groundwater.

3. The operational area of all permitted Type Two and Type Three facilities shall be a hard-packed all weather surface able to withstand various temperatures and allow for heavy equipment operation, without damage or failure. The working surface shall be:

a. A naturally occurring or engineered soil mixture with at least two feet separation to the seasonal high water table; or

b. A surface such as concrete or asphalt pad on an appropriate sub-base to support and prevent failure of the surface layer with at least one foot of separation to the seasonal high water table from the sub-base of the constructed surface; or

c. As otherwise approved by the Department.

4. Facilities may use borings to determine separation from the seasonal high water table.

5. The Department may impose more protective design criteria for the operational areas of Type Three facilities to ensure compatibility with the feedstocks in use and the structural integrity needed for the equipment used at the site.

6. Facility design shall ensure that each composting mass can be managed in accordance with the operational requirements of this regulation.

7. Access to all permitted facilities shall be controlled through the use of fences, gates, berms, natural barriers, or other means to prevent unauthorized dumping and access.

E. Operating Criteria

1. Site Control and Sign Requirements shall be as follows:

a. All permitted facilities shall control receipt of all materials.

b. All permitted facilities shall post signs in conspicuous places that are resistant to weather and fading of color in direct sunlight that:

(1) Identify the owner, operator, or a contact person and telephone number in case of emergencies,

(2) Provide the hours during which the facility is open for use; and,

(3) List the valid SCDHEC Facility I.D. numbers for the facility.

c. Facilities may accept only those materials as allowed by facility type and category as described in Appendix to R.61–107.4 or as otherwise specified in their permit application and approved in writing by the Department.

d. No material, including feedstocks or in-process material, may be stored at the permitted facility in excess of the maximum capacity allowed by permit.

e. No facility shall accept deliveries of feedstocks or other materials that will result in materials being stored in excess of the maximum capacity allowed by permit.

2. All wood-grinding activities shall assure that no debris is ejected onto neighboring properties.

3. Facilities shall use Best Management Practices to control run-on and run-off. An appropriate permit may be required prior to the discharge of any stormwater.

4. Open burning is prohibited except in accordance with Part VI. B of this regulation.

5. Pile sizes and spacing. All materials shall be maintained in such a way as to:

a. Allow the measurement of internal-pile temperatures of the compost mass as required,

b. Enable the compost mass to be turned as needed to result in the aerobic, thermophilic decomposition of the solid organic constituents of the feedstock,

c. Have sufficient space around piles of material to allow access of emergency fire-fighting equipment and procedures as described and approved in the facility operational plan,

d. Provide a safe working environment.

6. The operation of all composting facilities shall follow acceptable management practices for composting methods that result in the aerobic, thermophilic decomposition of the solid organic constituents of the feedstock. The following composting methods will be allowed:

a. Passive leaf composting, in which composting leaves collected by local government programs are managed with little manipulation of the materials after they are mixed and piled; turning shall be performed at least quarterly or as needed to prevent odors;

b. The windrow composting method, in which the following requirements apply: Aerobic conditions at 131 degrees Fahrenheit or 55 degrees Celsius or greater shall be maintained in the composting mass for at least 15 days. During the high temperature period, the composting mass shall be turned at least five times. The composting mass shall be turned before the internal temperature exceeds 160 degrees Fahrenheit or 71 degrees Celsius.

c. The aerated static pile composting method, in which the following requirements apply: Aerobic conditions shall be maintained during the composting process. The temperature of the composting mass shall be maintained at 131 degrees Fahrenheit or 55 degrees Celsius for at least three consecutive days; or

d. The in-vessel composting method, in which the temperature of the composting mass shall be maintained at a minimal temperature of 131 degrees Fahrenheit or 55 degrees Celsius for at least three consecutive days.

e. The use of other composting methods shall require written Department approval.

7. Temperature measurements shall be as follows:

a. The temperature of each composting mass shall be measured daily during the first week of active composting, and not less than weekly thereafter.

b. Temperature readings shall be taken every 50 feet along the length of a composting mass and from within the center of the mass.

c. In-vessel composting systems shall follow the manufacturer's recommendations for monitoring temperatures during active composting.

d. Intervals and methods for monitoring temperatures and any alternatives not stated in this regulation must be included in the operational plan and approved in writing by the Department.

e. A record of all temperature measurements taken shall be maintained and readily available to the Department upon request.

8. The moisture content in the composting mass shall be monitored regularly and managed to achieve desired results.

9. The working surface of the operational area of all permitted facilities shall be maintained to prevent standing water or uncontrolled releases.

10. Material Management shall occur as follows:

a. Grass clippings shall be incorporated into the composting mass within 24 hours of arrival at a ratio of no more than one part grass to three parts chipped or ground carbon-rich material by volume.

b. Food residuals and other putrescible, nitrogen-rich feedstocks shall be incorporated into the compost mass the same day of receipt or stored not more than 72 hours in closed, air-tight, and leak-proof containers.

c. If manure is stored more than three days, the manure shall be stored on a concrete pad or other impervious surface and covered with an acceptable cover to prevent odors, vector attraction, and runoff. The cover should be vented properly with screen wire to let the gases escape. The edges of the cover should be properly anchored.

d. Category Three feedstocks shall be incorporated into the compost mass upon receipt or stored in a manner which is described in the operational plan and approved by the Department.

e. Source separated feedstocks shall not be combined until incorporated into the compost mass, except as described in the operational plan and approved by the Department.

f. Feedstocks shall be thoroughly mixed into the compost mass in accordance with a formulaic recipe that optimizes Carbon-to-Nitrogen ratios, moisture content and porosity. Feedstocks with excessive moisture content shall be delivered onto a bed of woodchips or sawdust or otherwise managed to prevent escape of the liquids from the compost mass.

g. All operations shall be performed to prevent the re-introduction of pathogens into materials that have undergone, or are in the process of, pathogen reduction.

h. Unauthorized feedstocks and waste shall be removed from the facility for proper disposal no less than every seven days unless otherwise approved by the Department. Unauthorized putrescibles shall be placed in an air-tight container immediately and removed from the facility within 72 hours of receipt. The area designated for temporary storage of unauthorized waste at the facility shall be identified in the facility operational plan. The Department may require more frequent removal based on the nature or quantity of other unacceptable waste.

11. All material piles shall be monitored and managed to prevent fire as described in the facility operational plan.

12. Facilities shall identify any chemical changes to a feedstock, or changes to the chemical ratios of a feedstock, significant enough to alter the composting process or the quality of the compost produced, and shall request appropriate permit modifications from the Department for any operational plan changes required as a result of those changes.

13. Reporting and Records Retention shall be in accordance with the following:

a. Not less than once each month, facilities shall measure and record the amounts, in cubic yards, of feedstocks, in-process material and waste material on site at that time.

b. No later than September 1 of each year, all permitted facilities shall submit to the Department, an annual report on a form approved by the Department, for the prior fiscal year ending June 30. The report shall include the following information:

(1) The total amount in tons, either actual or estimated weight, of in-coming feedstock received yearly for each type of feedstock and the source for each;

(2) The total amount in tons, either actual or estimated weight, of mulch, compost or other material that on a yearly basis is:

(a) Produced;

(b) Transferred off-site as products such as mulch, compost or soil amendment;

(c) Transferred off-site for further processing; and,

(d) Disposed in a landfill and the reason for disposal.

c. The following information shall be maintained at all facilities that produce compost for sale or distribution to the public and made available to the Department upon request unless otherwise approved by the Department:

(1) Daily and weekly temperature readings and moisture observations of each composting mass that is formulated;

(2) Start-up dates for each composting mass that is formulated and the date for each time a composting mass is remixed or turned while composting;

(3) Number of days required to produce the end product, by type; and

(4) The results of all testing performed in accordance with the Quality Assurance requirements of this regulation and any corrective action taken to improve product quality to the standards in Part III.F.

d. Any changes in telephone numbers, names of responsible parties, addresses, etc. for a permitted facility shall be submitted to the Department within10 working days of the change.

e. Records shall be maintained by all facilities for a period of no less than three years and shall be furnished upon request to the Department or be made available at all reasonable times for inspection by the Department.

14. Any compost produced with Category Two or Category Three feedstocks and offered for sale or distribution to the public is required to meet the physical and biological standards listed in Part III.F.

15. Operational Plans.

All facilities shall be operated in accordance with this regulation and an operational plan developed specifically for the facility and approved by the Department in writing.

a. Facilities shall maintain an operational plan onsite of the facility and it shall be made available for inspection upon request by the Department.

b. Facilities requiring permits shall submit their operational plan to the Department along with the permit application. The Department may require changes to an operational plan when the Department has determined that the operation requires additional measures to protect human health and safety and the environment.

c. Facilities shall address all requirements of Part III.E and Part F in their operational plan, including at a minimum:

(1) A description of the anticipated source and composition of the incoming feedstocks;

(2) A description of the processes and methods that will be used to grind, compost, cure, store and otherwise manage material, including a description of production capabilities and equipment to be used;

(3) A description of the procedure for inspecting, measuring, and managing incoming feedstock and unacceptable waste.

(4) A description of the procedures for prevention and control of vector, odor, dust and litter specific to their geographic location and the types and amounts of feedstocks used in their operation;

(5) A description of the anticipated markets for end products;

(6) A quality assurance and testing plan for finished compost that describes:

(a) All of the parameters and protocols for obtaining, preserving, storing, and transporting samples to a South Carolina certified laboratory;

(b) The frequency of monitoring to assess temperature profiles during composting;

(c) The methods and processes used to determine stability of the compost; and

(d) Other protocols used to achieve quality assurance standards required in Part III.F;

(7) A fire prevention and preparedness document which includes:

(a) A description of the processes used to prevent fire, specific to their site design and operating criteria;

(b) A description of the procedures for control of fire specific to their site location, feedstock types, and operating criteria;

(c) The location of emergency equipment and fire suppressant materials;

(d) The emergency contact information for the local fire protection agency, and

(e) Documentation of arrangements with the local fire protection agency to provide fire-fighting services.

(8) A contingency plan describing facility operations in the event of equipment failure;

(9) A detailed closure plan to meet the requirements of Part III.I, including final closure cost estimate pursuant to Part III.H.2 of this regulation; and

(10) Any additional procedures implemented as a requirement of the Department as described in Part III.G.

16. Compost Program Manager Certification shall be secured and maintained as follows:

a. Unless otherwise approved by the Department, within 18 months of the effective date of this regulation, all permitted Type Two and Type Three facilities are required to have an operator or one or more employees classified as a manager or supervisor who is duly certified as a compost program manager.

b. Persons who have achieved and maintain compost manager certification by the U.S. Composting Council (USCC), the Solid Waste Association of North America (SWANA), or another Department-approved training program shall be deemed certified by the Department.

c. Documentation of Compost Program Manager Certification shall be maintained at all permitted Type Two and Type Three facilities and made available to the Department upon request unless otherwise approved by the Department.

F. Quality Assurance and Testing Requirements for Finished Compost

1. Any compost produced from Category Two or Category Three feedstocks and offered for sale or distribution to the public is required to meet the physical and biological standards listed in this section. Composite samples shall be collected, stored and analyzed in accordance with the procedures found in the U.S. Department of Agriculture publication "Test Methods for the Examination of Composting and Compost." (TMECC) or equivalent methodology recommended by the U.S. Environmental Protection Agency publication SW-846, "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods".

2. Compost from Type One facilities or compost made solely from Category One feedstocks with compliant records of time and temperature monitoring are presumed to meet the standard for biological contaminants and are not required to perform laboratory testing.

3. All compost for sale or distribution to the public and produced from feedstocks other than Category One must be tested and meet the designation of Class A Exceptional Quality Compost or be designated for legal disposal, additional processing, or other use as approved by state or federal agencies having appropriate jurisdiction.

4. Class A exceptional quality compost:

a. Contains less than two percent physical contaminants by dry weight analysis,

b. Has a stability index rating of stable or very stable,

c. Meets Class A pollutant limits found in Table 1, and

d. Meets standards of this regulation for pathogen reduction.

Table 1. Pollutant Standards: Maximum Allowable Concentration
(milligrams per kilogram dry weight)

Pollutant	**Class A**
Arsenic	41
Cadmium	39
Copper	1500
Lead	300
Mercury	17
Nickel	420
Selenium	100
Zinc	2800

5. The distribution and use of exceptional quality compost is unrestricted and the consumer shall be advised to apply the product at agronomic rates based on product analysis, except that the use and distribution of compost produced from feedstocks generated by facilities permitted pursuant to R.61–67, Standards for Wastewater Facility Construction, shall be subject to all applicable requirements of R.61–9.

6. Compost Testing Frequency. The frequency of laboratory testing for pollutants, biological contaminants, and physical contaminants shall be based on the volume of compost produced annually by the facility as indicated in Table 2:

Table 2. Compost Testing Frequency

Compost Quantity	Frequency
1–2500 tons	1 per quarter (or less as approved)

2501–6250 tons	1 per quarter
6251–17500 tons	1 per 2 months
17501 tons and above	1 per month

7. The composted product shall be analyzed for stability using methods as set forth in the USDA TMECC Section 05.08-A through Section 05.08-F and the Compost Stability Index Table 05.08–1.

8. All compost produced for sale or distribution is required by this regulation to meet the physical and biological contaminant standards in Table 3 by a testing method referenced in Section III.F.1 or an equivalent method allowed by the Department:

Table 3. Physical and Biological Contaminants Limits for Compost

Physical contaminants (man-made inerts)	Less than 2 percent dry weight basis
Biological Contaminants (pathogens)	
Fecal coliform	Less than 1,000 Most Probable Number (MPN) per gram, dry weight basis
Salmonella	Less than 3 MPN per 4 grams, dry weight basis

a. All product quality assurance testing for pollutant standards and biological contaminants required by this regulation or as requested by the Department shall be performed by a South Carolina certified laboratory and reported in a format acceptable to the Department.

b. All products marketed in South Carolina as a soil amendment or fertilizer shall be registered by the product manufacturer with the Clemson University Department of Plant Industry or as otherwise required by law or regulation.

G. Additional Requirements for Permitted Facilities.

1. The Department may impose more stringent requirements than those outlined herein when additional measures are necessary, on a case-by-case basis, to protect public health and the environment from any potentially adverse effects. These requirements include, but are not limited to:

a. Analysis of individual feedstocks to identify any characteristics that may require special management or permit conditions;

b. Feedstock selection; the Department may determine on a case-by-case basis that a material shall not be used as feedstock due to its pollutant content or concentration, the material variability from the source, or its potential for creating adverse environmental effects,

c. Testing frequency and parameters,

d. Location, design, and operating criteria,

e. Monitoring and reporting, including but not limited to, monitoring of groundwater, surface water, soil, plant tissue, feedstocks and/or finished products,

f. Surface or pad requirements, or

g. Other requirements as necessary such as site assessments, groundwater sampling, and corrective action when environmental contamination from a permitted facility is suspected or confirmed.

2. The permittee may request that the Department remove the additional requirements described in Part III.G.1 from a permit if, after two years, those processes are proven to the Department to be effective and those mixtures of feedstocks that are proven compatible for composting, as determined by the Department. In all cases, the Department shall retain the authority to determine the effectiveness of the process and/or feedstock mixture to ensure it is protective of human health, surface water standards, and groundwater standards.

H. Financial Assurance.

The requirements of this Section apply to all permitted facilities except those owned and operated by a local government, by a region comprised of local governments or by state or federal government entities whose debts and liabilities are the debts and liabilities of the State or the U.S.

1. Prior to accepting feedstocks, permitted facilities shall fund a financial responsibility mechanism as described in R.61–107.19, SWM: Solid Waste Landfills and Structural Fill Part I.E, and approved by the Department to ensure the satisfactory closure of the facility as required by this regulation.

2. The permittee shall calculate and declare the maximum amount in cubic yards of feedstocks, in-process material, and waste material that could be stored at the facility in their application for a permit. A final closure cost estimate is to provide funding for the third party costs to properly dispose of the maximum amount of material that the facility can store at any given time and perform any corrective action for soils and groundwater that the Department may require. The cost estimate shall account for tipping fees, material hauling costs, grading and seeding the site, labor, and the cost for soliciting third party bids to complete closure and restore the site to conditions acceptable to the Department.

a. The maximum capacity of a site shall be calculated in cubic yards assuming compliance with all buffers and spacing requirements. The Department shall use an average cost of disposal per ton of material in Class II landfills, as reported in the most recent Solid Waste Management Annual Report, when calculating the amount of financial assurance necessary for a site. The closure cost estimate shall be three times the cost to dispose the maximum capacity of the site in a Class II landfill.

b. During the active life of the facility, the permittee shall annually adjust the closure cost estimate when the disposal cost estimate increases substantially based on information published in the Solid Waste Management Annual Report.

c. The permittee shall increase the closure cost estimate and the amount of financial assurance provided if changes to the closure plan or site conditions increase the maximum cost of closure at any time during the site's remaining active life.

d. The permittee shall increase the closure cost estimate and the amount of financial assurance provided if a release to the environment occurs to include cost of groundwater monitoring, assessment and corrective action if the Department determines that these measures are necessary at any time during the active life of the facility. Financial assurance shall be maintained and adjusted annually until the Department agrees that environmental conditions meet applicable standards.

e. The permittee may reduce the closure cost estimate and the amount of financial assurance provided for proper closure if the cost estimate exceeds the maximum cost of closure at any time during the remaining life of the facility. The permittee shall submit justification for the reduction of the closure cost estimate and the amount of financial assurance to the Department for review and approval.

3. The registrant or permittee shall provide continuous coverage for closure until released from financial assurance requirements, pursuant to this regulation.

4. The Department may take possession of a financial assurance fund for failure to complete closure in accordance with Part III.I or failure to renew or provide an alternate acceptable financial assurance mechanism.

I. Closure.

All facilities will conduct final closure in accordance with the operational plan submitted to the Department and with the following requirements:

1. Operators of permitted facilities shall provide written notice of intent to close and their proposed closure date to the Department;

2. Upon closing, permitted facilities shall immediately post closure signs at the facility;

3. Unless otherwise approved by the Department, within 90 days after closing date, operators shall:

a. As appropriate, grade land to promote positive drainage and stabilize the site to prevent erosion,

b. Remove all feedstocks, finished product and wastes, except that mulch or Class A compost may be spread on the site to a maximum thickness of four inches if tilled into the soil prior to site stabilization, and

c. Appropriately manage all water collected in containment structures or ponds.

4. Permitted facilities with confirmed contamination shall amend their closure plan with post-closure corrective action requirements for approval by the Department when remediation activities at the facility continue beyond closure of the facility.

5. Permitted facilities shall request that the Department inspect and approve closure. Upon Department approval of proper closure, the permittee shall be released from financial assurance requirements.

J. Permit Violations.

The Department may take civil or criminal action or issue penalties in accordance with Part I.D of this regulation for a violation of a permit issued pursuant to or in accordance with this regulation.

K. Permit Revocation.

1. Whenever the Department finds that material or substantial violations demonstrate a disregard for, or inability to comply with, applicable laws, regulations, or requirements, and that these violations would make continuation of the permit not in the best interest of human health and safety or the environment, the Department may, after a hearing, amend or revoke the permit as appropriate and necessary.

2. For the purposes of Part III.K, "hearing" means a conference between the Department and a permittee, during which the permittee is given opportunity to respond to a written notice of alleged violation, and may be accompanied by legal and/or technical counsel.

3. If, after a hearing, the Department determines that permit revocation is warranted, an administrative order revoking the permit will be issued.

Part IV. Permit Application.

A. Permit Application Process. The applicant shall submit a permit application to the Department. The permit application shall include one hard and one electronic copy of the following in a format approved by the Department:

1. A completed and signed application form provided by the Department.

2. Tax map number for the site.

3. Proof of ownership or control of the property.

4. For Type Two or Type Three facilities, a signed statement from a South Carolina licensed professional engineer, on the form provided by the Department, certifying that the site design is compliant with the requirements of regulation.

5. A vicinity map that shows the location of the facility and the area that is within one mile of the property boundary.

6. A site plan on a scale of not greater than 100 feet per inch that shall, at a minimum, identify the following:

a. The facility perimeter, the operational area and all storage areas with measurements in feet;

b. Compliance with required buffers as outlined in Part III.C of this regulation;

c. Property lines, access roads, gates, fences, natural barriers or other Department approved means of preventing unauthorized access and dumping;

d. A topographical survey of the site depicting two-foot contours at a minimum, and six-inch contours for sites evaluated for consistency with South Carolina Coastal Zone Management Plan;

e. A description of any BMPs used for the management of storm water;

f. The location of, and distance to, any Waters of the U.S. on site of the facility or within the buffer areas described in Part III.C.

7. An operational plan that shall contain all items as required under Part III.E.15.

8. Any request for a variance as allowed by this regulation.

9. A final closure cost estimate pursuant to Part III.H.2 of this regulation, and documentation that the applicant has secured appropriate financial assurance.

B. Notice.

1. Within 15 days of submitting an application to the Department, the applicant shall give notice that he/she has requested a permit to operate to the county administrator, the county planning office,

and all owners of real property as they appear on the county tax maps, as contiguous landowners of the proposed permit area. This notice shall contain:

a. The name and address of the applicant;

b. The type of facility and what it will produce, for example, mulch, compost;

c. A detailed description of the location of the facility, using road numbers, street names, and landmarks, as appropriate;

d. A description of the feedstocks the facility will utilize;

e. Department locations (Central Office and appropriate Regional Office) where a copy of the permit application will be available for review during normal working hours; and

f. The Department address and contact name for submittal of comments and inquires.

2. The applicant shall provide evidence of Noticing as required in Part IV.B.1 to the Department.

3. A comment period of not less than 30 days from the date of Noticing will be provided prior to issuance of a Department Decision.

4. Notice of the Department Decision regarding the permit application will be sent to the applicant, to affected persons or interested persons who have asked to be notified, to all persons who commented in writing to the Department, and to the facility's host county. The use of certified mail to send Notice of the Department's Decision shall be at the discretion of the Department unless specifically requested in writing by an interested person.

C. Application Review and Permit Decision.

1. All information submitted to the Department shall be complete and accurate.

2. Whenever the applicant submits an incomplete application, the Department shall notify the applicant in writing. If the requested information is not provided within 180 days of receipt of the notification, the application may be denied.

3. The Department shall deny a permit for a facility that it has determined does not meet the requirements of this regulation.

4. The Department may attach additional conditions to a permit when the Department has determined that the operation requires safeguards to protect human health and safety or the environment.

D. Permit Modifications.

Permit modifications must be requested in writing and may not be implemented without prior written consent from the Department. The Department may require Noticing as described in Part IV.B of this regulation for modifications that impact the allowable feedstock categories, that impact buffers or that the Department determines may otherwise impact adjoining properties.

E. Transfer of Ownership.

The Department may, upon written request, transfer a permit, as appropriate, to a new permittee where no other change in the permit is necessary.

1. The proposed new owner of a permitted or registered facility shall, prior to the scheduled change in ownership, submit to the Department:

a. A one hard copy and one electronic copy of a completed permit application in a format approved by the Department.

b. A written agreement signed by both parties indicating the intent to change ownership or operating responsibility of the facility.

c. Documentation of financial assurance as required. The previous owner shall maintain financial assurance responsibilities until the new owner can demonstrate satisfactory compliance with Part III.H of this regulation.

2. The new owner shall submit legal documentation of the transfer of ownership of the facility within 15 days of the actual transfer.

Part V. General Permits.

A. General Permit Issuance. The Department may issue one or more general permits for facilities described as Type One and Type Two facilities.

1. A general permit shall, at a minimum, outline the following:

a. Noticing requirements, including Intent to Operate and public Noticing

b. Location, siting and design criteria

c. Operating, monitoring and reporting criteria

d. Financial assurance requirements

e. Closure requirements

2. A general permit pursuant to this Section, may be issued, modified, or terminated in accordance with applicable requirements, terms and conditions of this regulation.

3. The Department shall publish a notice of any general permit issued, modified or terminated.

B. Application for Coverage under a General Permit.

1. An operator seeking coverage under a General Permit shall request approval from the Department with a completed Notice of Intent form provided by the Department.

2. A Notice of Intent shall include signatures of the permit applicant and of the landowner, a signed certification that operations will be conducted in accordance with the General Permit, and evidence that the applicant has secured a Financial Assurance mechanism in accordance with Part III.H.

3. The applicant shall also provide a copy of the Notice of Intent to the appropriate local government.

4. A facility may begin operating under a General Permit after a written approval from the Department has been received by the facility operator. Written approval shall not be issued less than 30 days of the date of submission of the Notice of Intent.

C. Corrective Measures and General Permit Revocation.

1. Upon a determination by the Department and written notification that the facility operating under a general permit poses an actual or potential threat to human health or the environment, the Department may require the permittee to implement corrective measures as appropriate.

2. Approval to operate under a General Permit may be revoked for failure to comply with the conditions of the General Permit or this regulation.

a. Whenever the Department finds that material or substantial violations demonstrate a disregard for, or inability to comply with a general permit, and that these violations would make continuation of the approval to operate under a general permit not in the best interest of human health and safety or the environment, the Department may, after a hearing, revoke the approval to operate as appropriate and necessary.

b. For the purposes of Part V.C, "hearing" means a conference between the Department and a permittee, during which the permittee is given opportunity to respond to a written notice of alleged violation, and may be accompanied by legal and/or technical counsel, at the conference.

c. If, after a hearing, the Department determines that approval to operate under authority of a general permit should be revoked, an administrative order revoking the approval will be issued.

Part VI. Prohibitions.

A. Open dumping of land-clearing debris, yard trimmings and other organics is prohibited.

B. Open burning of land-clearing debris, yard trimmings and other organics is prohibited except as approved by the Department for emergency storm debris management or as allowed by Air Pollution Control Regulations and Standards R.61–62.2, Prohibition of Open Burning.

61–107.4 Appendix: Feedstock Categories

A. Feedstock Categories.

This Appendix defines categories of common organic feedstocks for composting. The feedstock characteristics of Carbon-to-Nitrogen ratio, moisture, pathogen content, source variability, non-compostable contaminants, trace metals and toxic metals content are considered when assessing appropriate facility design features and quality assurance monitoring necessary to produce beneficial products in an environmentally protective process. The Department will use these characteristics to assign the

category and level of risk posed for any feedstock not listed here. Any mixture of feedstocks for composting shall assume the level of risk for the most problematic feedstock in the mixture.

1. Feedstock Category One.

Category One feedstocks have a high Carbon-to-Nitrogen ratio and pose limited risk of contamination from pathogens, trace metals, hazardous constituents, or physical contaminants that are not compostable. These feedstocks also have low moisture content. Grass clippings have a lower Carbon-to-Nitrogen ratio than other Category One feedstocks, but are included in this category because they are commonly collected with leaf and limb debris. This category includes only:

a. Yard trimmings, leaves, and grass clippings;

b. Land-clearing debris;

c. Woodchips and sawdust from untreated and unpainted wood that has not been in direct contact with hazardous constituents;

d. Agricultural crop field residuals;

e. Compostable bags commonly used for collecting and transporting yard trimmings, leaves and grass clippings; and

f. Similar materials as specifically approved in writing by the Department.

2. Feedstock Category Two.

Category Two feedstocks have a lower Carbon-to-Nitrogen ratio than Category One feedstocks, have a high moisture content, and are more likely to contain pathogens, trace metals or physical contaminants that are not compostable. This category includes only the following source separated materials:

a. Non-meat food processing wastes, including marine shells and dairy processing wastes;

b. Produce and non-meat food preparation residuals generated by wholesale or retail sales establishments or food service establishments;

c. Plate scrapings including cooked meats generated by food service establishments;

d. Manufactured compostable products and waste paper products that are otherwise unsuitable for recycling;

e. Animal manures and materials incidental to its collection as defined in Part I.B of this regulation;

f. Residual organics from anaerobic digesters or other waste-to-energy conversion processes utilizing only Category One or Category Two feedstocks; and

g. Similar materials as specifically approved in writing by the Department.

3. Feedstock Category Three.

This category includes feedstocks that have the most risk from trace metals, source variability, physical contaminants, pathogens, and other properties that may be detrimental to plants, soils, or living organisms in high concentrations. These feedstocks require more intensive analysis and monitoring prior to being incorporated into the active composting area and require approval for composting by the Department on a case-by-case basis. This category includes:

a. Sewage sludge,

b. Industrial sludges,

c. Drinking water treatment sludge,

d. Fats, oils and greases (FOG),

e. Animal-derived residuals except as specifically identified in Section A.2 of this Appendix,

f. Residual organics from anaerobic digesters or other waste-to-energy conversion processes utilizing Category Three feedstocks,

g. Other industrially produced non-hazardous organic residuals not previously categorized in this Appendix, and

h. Other organic materials not prohibited below, as approved by the Department.

B. Prohibited Feedstocks. Composting of materials containing the following items is not allowable under this regulation:

1. Mixed municipal solid waste, except those activities under which after a two-year period of operation in compliance with a permit issued under authority of R.61–107.10, SWM: Research, Development, and Demonstration Permit Criteria, have been determined by the Department to have adequately achieved their objectives and satisfactorily protected public health, safety, and the environment;

2. Friable and non-friable asbestos as defined by R.61–86.1, Standards Of Performance For Asbestos Projects;

3. Biomedical or infectious wastes as defined by R.61–105, Infectious Waste Management;

4. Hazardous waste as defined by Resources Conservation and Recovery Act (RCRA), Public Law 94–580, and R.61–79, Hazardous Waste Management Regulations, promulgated pursuant to the South Carolina Hazardous Waste Management Act (SCHWMA), as amended, S.C. Code Ann. Section 44–56–10 et seq.;

5. Materials for compost or mulch production with Polychlorinated biphenyl (PCB) concentrations greater than quantifiable detection limits;

6. Source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended;

7. Radioactive material managed pursuant to R.61–63, Radiological Materials (Title A); and

8. Materials resulting from coal combustion, including but not limited to, fly ash, bottom ash, boiler slag and flue gas desulfurization materials.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4432, eff June 27, 2014.

61–107.5. Solid Waste Management: Collection, Temporary Storage and Transportation of Municipal Solid Waste.

A. Applicability.

1. This regulation is to establish minimum standards for the collection, temporary storage, and transportation of solid waste prior to processing, disposal, etc. of that waste. This regulation applies to any person who collects, temporarily stores, and/or transports municipal solid waste. Recovered materials are not subject to the requirements of this regulation.

2. Facilities collecting, temporarily storing, and transporting industrial solid waste generated solely in the course of normal operations on property under the same ownership or control as the facility are exempt from the requirements of this regulation.

B. Definitions.

1. "Collection" means the act of picking up solid waste materials from homes, businesses, governmental agencies, institutions, or industrial sites.

2. "Department" means the South Carolina Department of Health and Environmental Control.

3. "Discharge" means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of solid waste, including leachate, into or on any land or water.

4. "Flood plain" means the lowland and relatively flat areas adjoining inland and coastal areas of the mainland and off-shore islands including, at a minimum, areas subject to a one percent or greater chance of flooding in any given year.

5. "Industrial solid waste" means solid waste generated by manufacturing or industrial processes that is not a hazardous waste regulated under subtitle C of RCRA. Such waste may include, but is not limited to, waste resulting from the following manufacturing processes: Electric power generation; fertilizer/agricultural chemicals; food and related products/by-products; inorganic chemicals; iron and steel manufacturing; leather and leather products; nonferrous metals manufacturing/foundries; organic chemicals; plastics and resins manufacturing; pulp and paper industry; rubber and miscellaneous plastic products; stone, glass, clay, and concrete products; textile manufacturing; transportation equipment; and water treatment. This term does not include mining waste or oil and gas waste.

6. "Leachate" means the liquid that has percolated through or drained from solid waste or other man-emplaced materials and that contains soluble, partially soluble, or miscible components removed from such waste.

7. "Municipal solid waste" means any solid waste (including garbage, trash, and sanitary waste in septic tanks) derived from households (including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use recreation areas), generated by commercial establishments (stores, offices, restaurants, warehouses, and other nonmanufacturing activities, excluding industrial facilities) and nonhazardous sludge.

8. "Nonputrescible" means solid waste that contains no putrescible waste.

9. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

10. "Putrescible" means solid waste composed of items, such as foods, that will decompose and rot to produce a foul smelling odor.

11. "Recovered materials" means those materials which have known use, reuse, or recycling potential; can be feasibly used, reused, or recycled; and have been diverted or removed from the solid waste stream for sale, use, reuse, or recycling, whether or not requiring subsequent separation and processing, but does not include materials when recycled or transferred to a different site for recycling in an amount which does not equal at least seventy-five percent by weight of materials received during the previous calendar year.

12. "Solid waste" means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1964, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

13. "Solid waste storage container" as defined by this Regulation means large receptacles, e.g., green boxes, dumpsters, rolloff containers, which are used as a central collection point for the temporary storage of solid waste. This definition does not apply to storage containers used by a single family unit or to litter receptacles which are regulated under Code Section 16-11-700. Any solid waste storage container used at a food service facility, e.g. restaurants, etc., regardless of size, is subject to the requirements of this regulation.

14. "Temporary storage" as defined by this Regulation means the containment of solid waste for a period of not more than seven (7) days prior to the ultimate disposal of the waste, e.g., green boxes are used for temporary storage of solid waste.

15. "Vector" means a carrier that is capable of transmitting a pathogen from one organism to another including, but not limited to, flies and other insects, rodents, birds, and vermin.

16. "Vehicle" means any motor vehicle, water vessel, railroad car, airplane, or other means of transporting solid waste.

17. "Waters of the State" means lakes, bays, sounds, ponds, impounding reservoirs, springs, wells, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Atlantic Ocean within the territorial limits, and all other bodies of surface or underground water, natural or artificial, public or private, inland or coastal, fresh or salt, which are wholly or partially within or bordering the State or within its jurisdiction.

C. General Provisions.

1. The collection, temporary storage and transporting of municipal solid waste shall be conducted in a manner to:

a. Inhibit the harborage of flies, rodents, and other vectors;

b. Prevent conditions for transmission of diseases to man or animals;

c. Prevent blowing debris and particulates so as not to be injurious to human health and the environment;

d. Prevent water pollution and prevent the escape of solid waste or leachate to waters of the State; and,

e. Minimize objectionable odors, dust, unsightliness, and aesthetically objectionable conditions, and prevent the accumulation of materials in an untidy and unsafe manner so as to become a fire and safety hazard.

2. The collection, temporary storage and transportation of solid waste shall comply with all other State and local laws, ordinances, rules, regulations, and orders.

3. When putrescible waste is mingled with other solid waste, the entire load of solid waste shall be considered putrescible waste.

D. Collection of Municipal Solid Waste.

1. Organized collection, e.g., drop-off centers, convenience centers, green boxes, curbside, etc., of putrescible solid waste shall be at a frequency which ensures the prevention of hazards and nuisances to health and the environment. Curbside collection of putrescible waste from residences shall be no less often than one (1) day per week. Collection from solid waste storage containers for putrescible waste from residences, food service facilities, e.g., restaurants, etc., shall be no less often than two (2) days per week unless an extension is requested and approved by the Department. If the potential for nuisances and/or hazards to health and/or the environment are detected, the Department may require more frequent collection. Collection of putrescible solid waste from food service facilities, e.g., restaurants, etc., may require daily collection to ensure the prevention of hazards and nuisances.

2. Organized collection of nonputrescible municipal solid waste shall be at a frequency which ensures the prevention of hazards and nuisances to health and the environment, but no less often than one (1) day per week unless an extension is requested and approved by the Department. This weekly collection requirement does not apply to construction and demolition debris.

3. Collectors shall ultimately dispose of solid waste at facilities and/or sites permitted or registered by the Department for processing or disposal of that waste stream.

E. Municipal Solid Waste Storage Containers.

1. Municipal solid waste storage containers shall be properly maintained to inhibit the harborage of vectors and to minimize objectionable odors.

2. Municipal solid waste storage containers shall be of construction which is readily cleanable with proper drainage to prevent pooling of water.

3. Areas around municipal solid waste storage containers shall be properly maintained to prevent hazards to health and the environment. Collectors shall be responsible for cleaning up refuse spilled during collection. Residents, businesses and industries shall be responsible for keeping the area clean.

4. Municipal solid waste storage containers shall not be closer than fifty (50) feet horizontal distance from the normal highwater mark of any waters of the State unless special provision is made which prevents wastes, or drainage therefrom, from entering waters of the State.

5. Whenever possible, municipal solid waste storage containers shall not be located in a 100-year flood plain. Municipal solid waste storage containers located in a 100-year flood plain shall demonstrate that the container will not restrict the flow of the 100-year flood.

6. Municipal solid waste storage containers shall not be located within 100 feet of a ground water well.

F. Municipal Solid Waste Collection and Transportation Vehicles.

1. All vehicles used to collect and/or transport municipal solid waste shall be constructed and maintained so as to prevent dropping, sifting, or blowing or other escapement of solid waste from the vehicle.

2. Precautions shall be taken to prevent spillage or leakage during transport from all vehicles used to collect and/or transport municipal solid wastes that produce leachate.

3. All vehicles used to collect and/or transport putrescible solid wastes shall be emptied on a daily basis, unless an exemption is requested and approved by the Department.

4. Collection and transportation vehicles or other devices used in transporting putrescible solid waste shall be cleaned and maintained as often as necessary to prevent odors, insects, rodents, or other nuisance conditions.

5. The disposal of the waste water from the routine cleaning of municipal solid waste collection and transportation vehicles, i.e., the areas of the vehicle that come into contact with solid waste, shall be approved by the Department's Bureau of Water Pollution Control and the appropriate sewer system, if applicable, prior to disposal. Vehicles used only for the collection of inert waste, yard trash and land clearing debris are exempt from this subsection.

G. Violations and Penalties.

A violation of this regulation or any permit, order, or standard subjects the person to the issuance of a Department order, or to civil enforcement action in accordance with Code Section 48-1-330, or 44-96-450. Willful violation of this regulation or any permit, order, or standard subjects the person to the issuance of a Department order, or to criminal enforcement action in accordance with Code Section 48-1-320, or 44-96-450. A person to whom an order is issued may appeal it as a contested case pursuant to R.61-72 and the Administrative Procedures Act.

H. Severability.

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

61–107.6. Solid Waste Management: Solid Waste Processing Facilities.

A. Applicability.

1. This regulation establishes the procedures, documentation, and other requirements which must be met for the proper operation and management of all solid waste processing facilities, including the processing activities involving the unrecoverable solid waste at a Materials Recovery Facility. However, this regulation does not apply to Recovered Materials Processing Facilities.

2. Waste tire processing facilities and composting facilities shall comply with their respective regulations, unless otherwise specified by the Department.

3. Solid waste management facilities commonly referred to as "drop-off centers" or "convenience centers", designed for the receipt of solid waste, from personal, non-commercial vehicles, destined for delivery of such waste to another Solid Waste Management Facility (e.g. recycling, processing, treatment, disposal) will not be regulated as solid waste processing facilities.

4. Facilities processing solid waste generated in the course of normal operations on property under the same ownership or control as the solid waste processing facility are exempt from the requirements of this regulation.

B. Definitions.

1. "Applicant" means an individual, corporation, partnership, business association, or government entity that applies for the issuance, transfer, or modification of a permit under this regulation.

2. "Closure" means the discontinuance of operation by ceasing to accept, treat, store, or dispose of solid waste in a manner which minimizes the need for further maintenance and protects human health and the environment.

3. "Contingency plan" means a document acceptable to the Department setting out an organized, planned, and coordinated course of action to be followed at or by the facility in case of a fire, explosions, or other incident that could threaten human health and safety or the environment.

4. "Department" means the South Carolina Department of Health and Environmental Control.

5. "Disclosure statement" means a sworn statement or affirmation, the form and content of which shall be determined by the Department as required by Code Section 44-96-300.

6. "Financial responsibility mechanism" means a mechanism designed to demonstrate that sufficient funds will be available to meet specific environmental protection needs of solid waste management facilities. Available financial responsibility mechanisms include, but are not limited to, insurance, trust funds, surety bonds, letters of credit, personal bonds, certificates of deposit, financial tests, and corporate guarantees as determined by the Department by regulation.

7. ''Flood plain'' means the lowland and relatively flat areas adjoining inland and coastal areas of the mainland and off-shore islands including, at a minimum, areas subject to a one percent or greater chance of flooding in any given year.

8. ''Industrial solid waste'' means solid waste generated by manufacturing or industrial processes that is not a hazardous waste regulated under subtitle C of RCRA. Such waste may include, but is not limited to, waste resulting from the following manufacturing processes: Electric power generation; fertilizer/agricultural chemicals; food and related products/by-products; inorganic chemicals; iron and steel manufacturing; leather and leather products; nonferrous metals manufacturing/foundries; organic chemicals; plastics and resins manufacturing; pulp and paper industry; rubber and miscellaneous plastic products; stone, glass, clay, and concrete products; textile manufacturing; transportation equipment; and water treatment. This term does not include mining waste or oil and gas waste.

9. ''Leachate'' means the liquid that has percolated through or drained from solid waste or other man-emplaced materials and that contains soluble, partially soluble, or miscible components removed from such waste.

10. ''Materials recovery facility'' means a solid waste management facility that provides for the extraction from solid waste of recoverable materials, materials suitable for use as a fuel or soil amendment, or any combination of such materials.

11. ''Municipal solid waste'' means any solid waste (including garbage, trash, and sanitary waste in septic tanks) derived from households (including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use recreation areas), generated by commercial establishments (stores, offices, restaurants, warehouses, and other nonmanufacturing activities, excluding industrial facilities) and nonhazardous sludge.

12. ''Owner/Operator'' means the person who owns the land on which a solid waste management facility is located or the person who is responsible for the overall operation of the facility, or both.

13. ''Permit'' means the process by which the Department can ensure cognizance of, as well as control over, the management of solid wastes.

14. ''Person'' means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

15. ''Recovered materials'' means those materials which have known use, reuse, or recycling potential; can be feasibly used, reused, or recycled; and have been diverted or removed from the solid waste stream for sale, use, reuse, or recycling, whether or not requiring subsequent separation and processing, but does not include materials when recycled or transferred to a different site for recycling in an amount which does not equal at least seventy-five (75) percent by weight of materials received during the previous calendar year.

16. ''Recovered materials processing facility'' means a facility engaged solely in the recycling, storage, processing, and resale or reuse of recovered materials. The term does not include a solid waste handling facility; however, any solid waste generated by such facility is subject to all applicable laws and regulations relating to the solid waste.

17. ''Solid waste'' means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1964, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

18. ''Solid waste handling facility'' means any facility engaged in the handling of solid waste.

19. "Solid waste management facility" means any solid waste disposal area, volume reduction plant, transfer station, or other facility, the purpose of which is the storage, collection, transportation, treatment, utilization, processing, recycling, or disposal, or any combination thereof, of solid waste. The term does not include a recovered materials processing facility or facilities which use or ship recovered materials, except that portion of the facilities which is managing solid waste.

20. "Solid waste processing facility" means a combination of structures, machinery, or devices utilized to reduce or alter the volume, chemical, or physical characteristics of solid waste through processes, such as baling or shredding, prior to delivery of such waste to a recycling or resource recovery facility or to a solid waste treatment, storage, or disposal facility and excludes collection vehicles.

21. "Surface water" means lakes, bays, sounds, ponds, impounding reservoirs, springs, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Atlantic Ocean within territorial limits, and all other bodies of surface water, natural or artificial, inland or coastal, fresh or salt, public or private.

22. "Vector" means a carrier that is capable of transmitting a pathogen from one organism to another including, but not limited to, flies and other insects, rodents, birds, and vermin.

C. General Provisions.

1. The siting, design, construction, operation, closure, and post-closure activities of new or expanding solid waste processing facilities shall conform to the standards set forth in this regulation. The Department may, on a case by case basis, allow variances to the siting, design, construction, operation, closure, and post-closure requirements found in this regulation, for wastes regulated under R.61-107.11 only.

2. Within six (6) months of the effective date of this regulation, all owners and/or operators of existing solid waste processing facilities shall submit, to the Department, as-built plans of the existing facility.

3. Within twelve (12) months of the effective date of this regulation, existing facilities which receive solid waste for processing shall be required to conform with these regulations, unless otherwise approved by the Department.

4. The Department shall require a disclosure statement from the permit applicant in accordance with Code Section 44-96-300. Local governments and regions comprised of local governments are exempt from this requirement. The Department may accept one (1) disclosure statement for multiple facility permit applicants.

5. A permit shall be required for each site or facility although the Department may include one (1) or more different types of facilities in a single permit if the facilities are collocated on the same site.

6. Waste tire processing facilities and composting facilities shall comply with their respective regulations, unless otherwise specified by the Department.

7. The permittee of a solid waste processing facility shall notify the Department prior to transfer of ownership or operation of the facility during its operating life or during the post-closure care period. The Department will approve a reissuance of the permit to the new owner provided that the facility is in compliance and the new owner agrees in writing to assume responsibility in accordance with these regulations.

D. Permit Application Requirements and Design Criteria.

1. Prior to construction, modification, or operation of a solid waste processing facility a permit shall be obtained from the Department. The application shall be signed by an engineer duly licensed and registered under the laws of the State of South Carolina.

2. Any person wishing to obtain a permit from the Department to operate a solid waste processing facility, shall submit to the Department three (3) copies of the following documents:

a. A completed permit application, on a form provided by the Department;

b. An engineering report which shall include the following:

(1) an overall description of the facility;

(2) a description of the process and equipment to be used;

(3) a description of the proposed service area;

(4) a description of the types and quantities of waste to be processed;

(5) a description of the existing site;

(6) a description of the security measures, including but not limited to fences, gates, signs; and,

(7) the location of disposal or recycling facilities which will accept the processed waste;

c. Complete construction plans and specifications that at a minimum address the following:

(1) loading and unloading areas;

(2) access roads;

(3) processing areas;

(4) actual or calculated weight of all solid waste accepted at the facility;

(5) storage areas for incoming solid waste; and,

(6) a map showing the specific location, land use, and zoning within one-fourth (¼) mile of the boundaries of the proposed facility;

d. All tipping areas shall be located within an enclosed building or covered area and all waste shall be contained in the tipping area.

e. A design report for the facility which shall provide the technical details and specifications necessary to support the design plans;

f. A complete description of the personnel training program;

g. An identification of possible air releases and groundwater and surface water discharges that may occur;

h. A waste control plan describing the manner in which waste from the processing activities will be managed. The plan shall, at a minimum, address the following:

(1) ensure that the facility processes only waste specifically authorized by the Department;

(2) provide a program to identify, control, separate out, record, and prevent waste not authorized by the Department to be processed at the facility from being accepted at the facility. The plan shall include a description of how these wastes will be handled and disposed if received at the facility and shall include provisions to notify the Department by inclusion in the annual monitoring report of the receipt and disposal of such wastes. No permit will be issued until a waste control plan has been approved by the Department; and,

(3) identify the facilities approved by the Department that will receive the processed waste and a certification that such facilities have adequate capacity to manage the processed waste;

i. A quality assurance and quality control report. The facility owner or operator shall institute a control program (including measures such as signs, monitoring, alternate collection programs, passage of local laws, etc.) to assure that only solid waste authorized by the Department is being processed at the facility;

j. A written contingency plan. This plan shall set forth operating procedures to be employed during periods of non-operation (e.g. equipment breakdown) which will require standby equipment, extension of operating hours, or diversion of solid waste to other facilities;

k. A narrative description of the general operating plan for the facility, including the origin, composition and weight or volume of solid waste that is to be processed at the facility, the process to be used at the facility, the daily operational methodology of the process, the loading rate, the proposed capacity of the facility and the expected life of the facility. The plan shall include a descriptive statement of any materials recycling or reclamation activities to be operated in conjunction with the facility on incoming solid waste. The plan shall describe how the facility will meet all applicable regulatory requirements;

l. An operation and maintenance manual describing how the facility shall be maintained and operated in accordance with the intended use of the facility. Equipment in use at the facility shall be maintained in good working order;

m. A detailed closure plan which shall identify the steps necessary to close the facility. The plan may be amended at any time during the active life of the facility with Department approval. The

plan shall be amended whenever changes in operating plans or facility design affect the closure plan, or whenever there is a change in the expected year of closure;

n. A description and explanation of any restrictions the facility places on the materials it receives for processing; and,

o. A demonstration of financial responsibility. The owner or operator of each facility shall establish sufficient financial assurance to ensure satisfactory maintenance, closure, and post-closure of the facility; or to carry out any corrective action which may be required as a condition of a permit. Consideration shall be given to mechanisms which would provide flexibility to the owner or operator in meeting its financial obligations. The owner or operator shall be allowed to use combined financial responsibility mechanisms for a single facility and shall be allowed to use combined financial responsibility mechanisms for multiple facilities, utilizing actuarially sound risk-spreading techniques.

Local governments are exempt from this requirement until such time as federal regulations require local governments or regions to demonstrate financial responsibilities for such facilities and the Department promulgates regulations addressing this issue.

E. Location Requirements.

Location requirements addressed in this section apply to all solid waste processing facilities, unless otherwise approved by the Department.

1. Solid waste processing facilities shall be adjacent to or have direct access to roads which are of all weather construction and capable of withstanding anticipated load limits.

2. Solid waste processing facilities located in 100-year floodplains shall demonstrate that the facility will not restrict the flow of the 100-year flood.

3. The active waste handling area of a solid waste processing facility shall not be located within two hundred (200) feet of any surface water, excluding drainage ditches and sedimentation ponds.

4. A solid waste processing facility shall not be located within any wetlands as delineated and defined specifically as wetlands according to the methodology accepted by the U. S. Army Corps of Engineers and the U. S. Environmental Protection Agency.

5. The active waste handling area of a solid waste processing facility, shall not extend closer than one hundred (100) feet to any drinking water well.

6. Locations shall allow for sufficient room to minimize traffic congestion and allow for safe operation.

7. No solid waste processing unit shall extend closer than one hundred (100) feet to any property line.

8. The active waste handling area of a solid waste processing facility, shall not extend closer than two hundred (200) feet to residences, schools, hospitals and recreational park areas.

9. Facilities shall adhere to all Federal, State, and local zoning, land use and other applicable local ordinances.

F. Operations Criteria.

A solid waste processing facility shall be designed and operated according to the minimum criteria listed in this section.

1. Access Controls. The operator shall restrict the presence of, and shall minimize the possibility of any unauthorized entry onto the facility site. A statement of the days and hours of operation shall be posted at the entrance of the facility and access, except for Department and/or emergency personnel, shall be limited to those times when authorized personnel are on duty.

2. Reporting and Record Keeping Requirements. All facilities shall:

a. Notify the Department's District Director, in the district in which the facility is located, if an unscheduled total facility shutdown exceeds twenty-four (24) hours;

b. Prepare and submit to the Department an annual report in a form provided by or acceptable to the Department by October 15, for the previous fiscal year; and,

c. Maintain a copy of all required reports at the facility for a period not less than five (5) years, and make these reports available to Department personnel upon request.

3. Receipt and Handling of Solid Waste.

a. The facility is authorized to process only solid waste specified by Department permit. The weight and/or volume of all solid waste processed at the facility shall be recorded and incorporated into the annual report.

b. All delivered solid waste shall be processed and contained at a facility designed in a way to minimize the effects of weather, wind, and precipitation. External storage of putrescible solid waste is prohibited. No putrescible waste shall remain at the site at the end of each working day unless it is stored in a manner to promote vector control. Solid waste identified as nonputrescible recyclables or oversized, bulky, or untreatable solid waste may be temporarily stored outside, on the premises for a period not to exceed one (1) week unless an extension is requested and approved by the Department. Any solid waste that is stockpiled or remains in storage shall be maintained so as to not create a nuisance or a sanitary or environmental problem. Litter, odors, rats, insects, flies, mosquitos, and other vectors shall be prevented and controlled at the facility.

c. The tipping areas shall be constructed of low permeability materials (e.g. concrete, asphalt), provided with a water supply for cleaning purposes, and equipped with drains, pumps, or equivalent means to facilitate the removal of water for proper disposal.

d. The transfer structures, buildings, and ramps shall be constructed of materials that can be easily cleaned.

e. Leachate and washwater from a solid waste processing facility shall not be allowed to drain or discharge into waters of the State unless an effluent disposal permit (e.g. land application, or NPDES) is approved by the Department.

f. Solid waste processing facilities shall comply with all applicable Federal, State, and local air quality standards.

g. The processing facility shall arrange for delivery of any residual or other waste resulting from the processing to a disposal facility which is:

(1) permitted by the Department if located in South Carolina; or,

(2) permitted by the appropriate environmental regulatory agency if located in another state.

4. Process changes. The owner or operator shall receive approval from the Department in writing of all process changes before they are implemented. Process changes such as those made to increase the recovery of recyclable materials do not require approval. Permit modifications shall be required as deemed necessary by the Department.

5. Emergency preparedness. In addition to requirements set forth in the contingency plan, all processing facilities shall at a minimum:

a. Provide adequate aisle space to allow for emergency equipment;

b. Be equipped with the following:

(1) an internal communications system capable of providing immediate emergency instruction to facility personnel and an alarm system to notify facility personnel of an emergency condition;

(2) a device, such as a telephone (immediately available at the scene of operations) or a hand-held two-way radio, capable of summoning emergency assistance from local police departments, fire departments, and State or local emergency response teams;

(3) portable fire extinguishers, fire control equipment and spill control equipment; and,

(4) water available at adequate volume and pressure to supply water hose streams, automatic sprinklers, or water spray systems;

c. Test and maintain as necessary to assure its proper operation, all facility emergency equipment including, but not limited to, communications or alarm systems, fire protection equipment, spill control equipment, and personal safety equipment;

d. Provide immediate access for all personnel involved in the facility operation to an internal alarm or emergency communication device; and,

e. Provide for an emergency coordinator.

6. Guidelines for identifying items or materials that may not be accepted for processing. The guidelines shall ensure that the facility accepts and processes only waste specifically authorized by the Department to be processed at the facility.

7. Trained personnel shall be present at all times during the operation of the facility.

G. Monitoring and Reporting Requirements.

1. Should the Department confirm environmental and/or health problems associated with the facility, monitoring (including groundwater, surface water, and air quality monitoring and analyses, and product quality testing and analysis) may be required by the Department, as appropriate, and based on a case by case evaluation to ensure protection of the environment.

2. An annual report shall be submitted to the Department, by October 15, which includes at a minimum, the following information:

a. Sources, type, and total quantity in weight and/or volume of waste received at the facility for the previous year;

b. A description of the method and quantity of the distribution and/or disposal of the end product;

c. A description of the method and quantity of the distribution and/or disposal of unauthorized waste received at the facility;

d. The county in which the solid waste originated, or if the waste originated outside South Carolina, the county and the state; and,

e. The transporters of waste.

3. Records of all monitoring and reporting information shall be maintained for a minimum of at least five (5) years from the sample or measurement date, unless otherwise specified by the Department.

H. Closure and Post-Closure Procedures.

1. Financial Assurance.

Facilities shall fund a financial responsibility mechanism acceptable to the Department to ensure the satisfactory closure and post-closure care prior to accepting waste. A final closure cost estimate, based on third party costs to complete closure by disposing of the maximum quantity of material at a facility shall be calculated annually and adjusted annually, if necessary. Local governments are exempt from this requirement until such time as federal regulations require such local governments or regions to demonstrate financial responsibility for such facilities and the Department promulgates regulations addressing this issue.

2. Closure and Post-Closure Care Procedures.

Closure and post-closure procedures addressed in this section apply to all solid waste processing facilities.

a. At least sixty (60) days prior to closure, provide written notice of intent to close and a proposed closure date to the Department. The final quantity of solid waste shall be received no less than thirty (30) days prior to closure date.

b. Upon closing, the owner or operator shall immediately remove all solid waste and post signs at the facility which state that the facility is no longer in operation.

c. Within thirty (30) days after receiving the final quantity of solid waste, the owner or operator shall remove all solid waste and shall remove or treat all waste residues, contaminated soils and equipment in accordance with the approved closure plan, and notify the Department upon completion.

d. After receiving notification that the facility closure is complete, the Department will conduct an inspection of the facility. If all procedures have been correctly completed, the Department will approve the closure in writing, at which time the Department permit shall be terminated.

e. If the owner or operator demonstrates that not all contaminated soils can be practicably removed or treated, to below applicable standards, as required in paragraph (b) of this section, then the owner or operator shall submit for Department approval, a post-closure care plan.

I. Personnel Training Requirements.

Solid waste processing facility personnel training programs shall, at a minimum:

1. [Reserved]

2. identify the positions which will require training and a knowledge of the procedures, equipment, and processes at the facility;

3. describe how facility personnel will be trained to perform their duties in a way that ensures the facility's compliance with the regulations, including the proper procedures that shall be followed in the processing and handling of solid waste not authorized by the Department to be received at the facility; and,

4. be designed to ensure that facility personnel are able to respond effectively to emergencies by familiarizing them with emergency and safety equipment, emergency procedures and emergency systems.

J. Corrective Action Requirements.

If at any time, the Department determines that the solid waste processing facility poses an actual or potential threat to human health or the environment, the owner or operator shall implement a corrective action program reviewed and approved by the Department.

K. Violations and Penalties.

A violation of this regulation or any permit, order, or standard subjects the person to the issuance of a Department order, or to civil enforcement action in accordance with Code Section 48-1-330, or 44-96-450. Willful violation of this regulation or any permit, order, or standard subjects the person to the issuance of a Department order, or to criminal enforcement action in accordance with Code Section 48-1-320, or 44-96-450. A person to whom an order is issued may appeal it as a contested case in accordance with R.61-72 and the Administrative Procedures Act.

L. Permit Review.

A permit issued pursuant to this regulation shall be effective for the design and operational life of the facility, to be determined by the Department. At least once every five (5) years, the Department will review the environmental compliance history of each permitted solid waste processing facility.

1. If, upon review, the Department finds that material or substantial violations of the permit demonstrate the permittee's disregard for, or inability to comply with applicable laws, regulations, or requirements and would make continuation of the permit not in the best interests of human health and safety or the environment, the Department may, after a hearing, amend or revoke the permit, as appropriate and necessary. When a permit is reviewed, the Department shall include additional limitations, standards, or conditions when the technical limitations, standards, or regulations on which the original permit was based have been changed by statute or amended by regulation.

2. The Department may amend or attach conditions to a permit when:

a. There is a significant change in the manner and scope of operation which may require new or additional permit conditions or safeguards to protect human health and safety and the environment;

b. The investigation has shown the need for additional equipment, construction, procedures, and testing to ensure the protection of human health and safety and the environment; and,

c. The amendment is necessary to meet changes in applicable regulatory requirements.

M. Severability.

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Amended by State Register Volume 19, Issue No. 6, eff June 23, 1995.

61–107.7. Solid Waste Management: Transfer of Solid Waste.

A. Applicability.

1. This regulation is to establish minimum standards for facilities where solid waste is transferred from collection vehicles to other transportation units for movement to another solid waste management facility prior to its processing and disposal. In addition, this regulation is to ensure that no unpermitted discharges to the environment occur during the process of transferring solid waste.

2. Solid waste management facilities commonly referred to as ''drop-off centers'' or ''convenience centers'', designed for the receipt of solid waste from personal, non-commercial vehicles and destined for delivery to another Solid Waste Management Facility (e.g. recycling, processing, treatment, or ultimate disposal), will not be regulated as transfer stations. Facilities that handle only recovered materials are not subject to the requirements of this regulation.

3. Facilities transferring solid waste generated in the course of normal operations on property under the same ownership or control as the waste transfer facility are exempt from the requirements of this regulation.

B. Definitions.

1. ''Closure'' means the discontinuance of operation by ceasing to accept, treat, store, or dispose of solid waste in a manner which minimizes the need for further maintenance and protects human health and the environment.

2. ''Collection'' means the act of picking up solid waste materials from homes, businesses, governmental agencies, institutions, or industrial sites.

3. ''Construction'' means any physical modification to the site at which a potential or proposed solid waste management facility is to be located including, but not limited to, site preparation.

4. ''Contingency plan'' means a document acceptable to the Department setting out an organized, planned, and coordinated course of action to be followed at or by the facility in case of a fire, explosion, or other incident that could threaten human health and safety or the environment.

5. ''Department'' means the South Carolina Department of Health and Environmental Control.

6. ''Discharge'' means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of solid waste, including leachate, into or on any land or water.

7. ''Disclosure statement'' means a sworn statement or affirmation, the form and content of which shall be determined by the Department as required by Code Section 44-96-300.

8. ''Expansion'' means the process of increasing existing capacity of operations at an existing site when such increase is in conformity with the area served and scope of operations of the original permit.

9. ''Financial responsibility mechanism'' means a mechanism designed to demonstrate that sufficient funds will be available to meet specific environmental protection needs of solid waste management facilities. Available financial responsibility mechanisms include, but are not limited to, insurance, trust funds, surety bonds, letters of credit, personal bonds, certificates of deposit, financial tests, and corporate guarantees as determined by the Department by regulation.

10. ''Flood plain'' means the lowland and relatively flat areas adjoining inland and coastal areas of the mainland and off-shore islands including, at a minimum, areas subject to a one percent or greater chance of flooding in any given year.

11. ''Hazardous waste'' has the meaning provided in Section 44-56-20 of the South Carolina Hazardous Waste Management Act.

12. ''Infectious waste'' has the meaning given in Section 44-93-20 of the South Carolina Infectious Waste Management Act.

13. ''Leachate'' means the liquid that has percolated through or drained from solid waste or other man-emplaced materials and that contains soluble, partially soluble, or miscible components removed from such waste.

14. ''Owner/operator'' means the person who owns the land on which a solid waste management facility is located or the person who is responsible for the overall operation of the facility, or both.

15. ''Permit'' means the process by which the Department can ensure cognizance of, as well as control over, the management of solid wastes.

16. ''Person'' means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

17. ''Recovered materials'' means those materials which have known use, reuse, or recycling potential; can be feasibly used, reused, or recycled; and have been diverted or removed from the solid waste stream for sale, use, reuse, or recycling, whether or not requiring subsequent separation

and processing, but does not include materials when recycled or transferred to a different site for recycling in an amount which does not equal at least seventy-five percent by weight of materials received during the previous calendar year.

18. "Solid waste" means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1964, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

19. "Solid waste management facility" means any solid waste disposal area, volume reduction plant, transfer station, or other facility, the purpose of which is the storage, collection, transportation, treatment, utilization, processing, recycling, or disposal, or any combination thereof, of solid waste. The term does not include a recovered materials processing facility or facilities which use or ship recovered materials, except that portion of the facilities which is managing solid waste.

20. "Surface water" means lakes, bays, sounds, ponds, impounding reservoirs, springs, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Atlantic Ocean within territorial limits, and all other bodies of surface water, natural or artificial, inland or coastal, fresh or salt, public or private.

21. "Transfer station" means a combination of structures, machinery, or devices at a place or facility where solid waste is taken from collection vehicles and placed in other transportation units, with or without reduction of volume, for movement to another solid waste management facility.

22. "Transport" means the movement of solid waste from the point of generation to any intermediate point and finally to the point of ultimate processing, treatment, storage, or disposal.

23. "Vector" means a carrier that is capable of transmitting a pathogen from one organism to another including, but not limited to, flies and other insects, rodents, birds, and vermin.

24. "Vehicle" means any motor vehicle, water vessel, railroad car, airplane, or other means of transporting solid waste.

C. General Provisions.

1. The site, design, construction, and operation of all solid waste transfer stations shall conform to the standards as set forth in this regulation.

2. Any spillage or leakage of solid waste at a transfer station shall be contained on the storage site and unpermitted discharges to the environment shall be prohibited.

3. Sludges shall not be accepted at transfer stations and shall be transported directly to the disposal facility, disposal site or processing operation.

4. No person owning or operating a transfer station shall cause, suffer, allow, or permit the handling of regulated hazardous wastes or regulated infectious wastes at the transfer station.

5. Within six (6) months of the effective date of this regulation, all owners and/or operators of existing transfer stations shall submit to the Department as-built plans and specifications of the existing facility in accordance with Section D below.

6. Within twelve (12) months of the effective date of this regulation, existing facilities which transfer solid waste shall conform to the standards as set forth in this regulation unless otherwise approved by the Department.

7. If at any time, the Department determines that the solid waste transfer station poses an actual or potential threat to human health or the environment, the owner or operator shall implement a corrective action program. This program shall be approved by the Department prior to implementation.

8. The permittee of a solid waste transfer station shall notify the Department prior to transfer of ownership or operation of the facility during its operating life or during the post-closure care period. The Department will approve a reissuance of the permit to the new owner provided that the facility is in compliance and the new owner agrees in writing to assume responsibility in accordance with these regulations.

D. Permit and Application Requirements.

1. Prior to the construction, operation, expansion or modification of a solid waste transfer station, a permit shall be obtained from the Department.

2. Any person wishing to obtain a permit from the Department for the construction and/or operation of a solid waste transfer station shall submit three (3) copies of the following documents:

a. A completed permit application on a form provided by the Department;

b. A site plan. This plan shall include the following:

(1) Site conditions and projected use including all site structures, buildings, fences, gates, entrances and exits, parking areas, on-site roadways, and signs;

(2) Property boundaries, access roads, surface water bodies, wetlands as delineated and defined specifically as wetlands according to the methodology accepted by the U.S. Army Corps of Engineers and the U.S. Environmental Protection Agency, and the location of 100-year flood plain boundaries; and,

(3) Adjacent properties including the location of public and private water supplies on these properties;

c. A transportation plan specifying the number and type of transportation vehicles to be used, and how often solid waste will be transported to the disposal site or sites;

d. A plan for training equipment operators and other personnel concerning the operation of the facility;

e. A contingency plan describing alternate solid waste handling procedures for inoperable periods or delays in transporting solid waste;

f. A detailed closure plan which identifies the steps necessary to close the facility. The plan may be amended at any time during the active life of the facility with Department approval. The plan shall be amended whenever changes in operating plans or facility design affect the closure plan, or whenever there is a change in the expected year of closure;

g. A disclosure statement in accordance with the guidelines established by Code Section 44-96-300. The Department may accept one disclosure statement for multiple facility permit applicants. Local governments and regions comprised of local governments are exempt from submitting a disclosure statement; and,

h. The following items prepared by a South Carolina licensed professional engineer:

(1) Complete construction plans and specifications;

(2) Design calculations;

(3) A preliminary engineering report to include, but not be limited to, the following:

(a) An outline of proposed structures and areas designated for unloading and loading and the general process flow;

(b) A description of the general operating plan for the proposed facility including the origin, composition, and expected weight or volume of all solid waste to be accepted at the facility per day; the maximum time waste will be stored; where all wastes will be disposed; the capacity of the facility; the operating hours of the facility; how nonputrescible, recyclable waste will be handled; and, the expected life of the facility;

(c) A description of all machinery and equipment to be used, including the design capacity;

(d) A description of the facility's drainage system and water supply system; and,

(4) Upon completion of construction of the facility, certification that the facility was constructed in accordance with approved plans and specification.

3. The plans and specifications for a transfer station shall be in compliance with the design criteria as set forth in this regulation.

4. Prior to the issuance of a Department construction permit, a financial responsibility mechanism shall be submitted to the Department. The owner or operator of each facility shall establish sufficient financial assurance to ensure satisfactory maintenance, closure, and post-closure of the facility; or to carry out any corrective action which may be required as a condition of a permit. Consideration shall be given to mechanisms which would provide flexibility to the owner or operator in meeting its financial obligations. The owner or operator shall be allowed to use combined financial responsibility mechanisms for a single facility and shall be allowed to use combined financial responsibility mechanisms for multiple facilities, utilizing actuarially sound risk-spreading techniques. Local governments are exempt from this requirement until such time as federal regulations require local governments or regions to demonstrate financial responsibilities for such facilities and the Department promulgates regulations addressing this issue.

E. Design Criteria for Solid Waste Transfer Facilities.

The following criteria are required at all solid waste transfer facilities unless otherwise approved by the Department:

1. The active waste handling area of a transfer station shall not be located within one hundred (100) feet of any property line;

2. The active waste handling area of a transfer station shall not be located within two hundred (200) feet of any surface water excluding drainage ditches and sedimentation ponds;

3. The active waste handling area of a transfer station shall not be located within two hundred (200) feet of any residence, school, hospital or recreational park area;

4. The active waste handling area of a transfer station shall not be located within one hundred (100) feet of a drinking water well;

5. A transfer station shall not be located within any wetlands as delineated and defined specifically as wetlands according to the methodology accepted by the U.S. Army Corps of Engineers and the U.S. Environmental Protection Agency;

6. Facilities shall adhere to all State, Federal, and local zoning, land use, and other applicable local ordinances;

7. On-site roads and unloading areas shall be adequate in size and design to facilitate efficient unloading and loading of the collection and transportation vehicles and the unobstructed movement of vehicles;

8. The unloading, storage and loading surface areas shall be constructed of low permeability materials, e.g., asphalt, concrete, etc.; provided with a water supply for cleaning purposes; and, equipped with drains or pumps, or equivalent means to facilitate the removal of water for proper disposal;

9. Solid waste passing through a transfer station and intended for disposal in this State, shall be transferred only to a facility permitted or registered by the Department to receive that waste;

10. Tipping areas shall be located within an enclosed building or covered area and all waste shall be contained in the tipping area;

11. Exhaust removal systems shall be installed in enclosed areas and operated to provide adequate ventilation;

12. Access to the site shall be controlled through the use of fences, gates, berms, natural barriers, or other means approved by the Department;

13. At least one (1) sign shall be posted at each access point to the facility with the hours of operation and the types of solid waste accepted at the transfer station;

14. Whenever possible, solid waste transfer stations shall not be constructed in a 100-year flood plain. When a transfer station is located in a 100-year flood plain, the owner shall demonstrate that the facility will not restrict the flow of the 100-year flood; and,

15. Arrangements shall be made with a local fire department to provide fire fighting services, or fire fighting equipment shall be maintained on-site.

F. Operation Criteria.

The following operational requirements shall apply to all facilities that transfer solid waste:

1. Procedures for preventing unauthorized receipt of prohibited wastes shall be addressed in the contingency plan;

2. The transfer station shall maintain a neat and orderly appearance. The facility and the interior of the transportation vehicles where the waste is held shall be cleaned as often as necessary so as to control litter, odors, rats, insects and other vectors;

3. All floors shall be free from standing water. All drainage areas shall be discharged to a sanitary sewer or other management method acceptable to the Department;

4. A transfer station with permanent operating mechanical equipment shall have an attendant on duty at all times the facility is open;

5. Solid wastes identified as nonputrescible recyclables or oversized, bulky, or untreatable solid waste may be temporarily stored outside on the premises for a period not to exceed one (1) week, unless an exemption is requested and approved by the Department in the facility's general operation plan, and if it does not create a nuisance or a sanitary or environmental problem;

6. Adequate fire protection equipment shall be available at all times or arrangements made with a local fire department; and,

7. All putrescible wastes shall be removed for proper disposal within twenty four (24) hours of receipt unless an exemption is requested and approved by the Department in the facility's general operating plan. All solid wastes that are not transferred within twenty four (24) hours shall be stored in a manner to promote vector and odor control.

G. Monitoring and Record Keeping Requirements.

1. Should the Department confirm environmental and/or health problems associated with any solid waste transfer facility, monitoring (including groundwater, surface water, and air quality monitoring) may be required by the Department, as appropriate, and based on a case by case evaluation to ensure protection of the environment.

2. Transfer stations regardless of ownership shall maintain records of the amount of all solid waste accepted at the facility each day and where all wastes were disposed. This information may be maintained in a summary format. These records shall be maintained for no less than five (5) years and shall be made available to the Department upon request.

H. Closure and Post-Closure Procedures.

The following closure and post-closure procedures apply to all solid waste transfer stations:

1. At least sixty (60) days prior to closure, the owner or operator shall provide written notice of intent to close and a proposed closure date to the Department;

2. Upon closing, the owner or operator shall immediately post signs at the facility which state that the facility is no longer in operation and remove all solid waste from the facility;

3. Within thirty (30) days of closure, the owner or operator shall either remove or treat all waste residues, contaminated soils and equipment in accordance with the approved closure plan, and notify the Department upon completion;

4. After receiving notification that the facility closure is complete, the Department will conduct an inspection of the facility. If all procedures have been correctly completed, the Department will approve the closure in writing, at which time the Department permit shall be terminated; and,

5. If the owner or operator demonstrates that not all contaminated soils can be practicably removed or treated as required in paragraph 3. of this section, then the owner or operator shall submit for Department approval, a post-closure care plan.

I. Violations and Penalties.

A violation of this regulation or any permit, order, or standard subjects the person to the issuance of a Department order, or to civil enforcement action in accordance with Code Section 48-1-330, or 44-96-450. Willful violation of this regulation or any permit, order, or standard subjects the person to the issuance of a Department order, or to criminal enforcement action in accordance with Code

Section 48-1-320, or 44-96-450. A person to whom an order is issued may appeal it as a contested case pursuant to R.61-72 and the Administrative Procedures Act.

J. Permit Review.

Permits for solid waste transfer stations shall be effective for the design and operational life of the facility, to be determined by the Department. The Department shall review the permit for each solid waste transfer station at least once every five (5) years, unless otherwise specified by the Department.

1. If, upon review, the Department finds that material or substantial violations of the permit demonstrate the permittee's disregard for, or inability to comply with applicable laws, regulations, or requirements and would make continuation of the permit not in the best interests of human health and safety or the environment, the Department may, after a hearing, amend or revoke the permit, as appropriate and necessary. When a permit is reviewed, the Department shall include additional limitations, standards, or conditions when the technical limitations, standards, or regulations on which the original permit was based have been changed by statute or amended by regulation.

2. The Department may amend or attach conditions to a permit when:

a. There is a significant change in the manner and scope of operation which may require new or additional permit conditions or safeguards to protect human health and safety and the environment;

b. The investigation has shown the need for additional equipment, construction, procedures, and testing to ensure the protection of human health and safety and the environment; and,

c. The amendment is necessary to meet changes in applicable regulatory requirements.

K. Severability.

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

61–107.8. Solid Waste Management: Lead-Acid Batteries.

A. Applicability.

This regulation applies to the proper disposal, collection, and recycling of lead-acid batteries and small sealed lead-acid batteries.

B. Definitions.

1. "Collection" means the act of picking up solid waste materials from homes, businesses, governmental agencies, institutions, or industrial sites.

2. "Department" means the South Carolina Department of Health and Environmental Control.

3. "Lead-acid battery" means any battery that consists of lead and sulfuric acid, is used as a power source, and has a capacity of six (6) volts or more, except that this term shall not include a small sealed lead-acid battery.

4. "Small sealed lead-acid battery" means any lead-acid battery weighing twenty-five (25) pounds or less, used in non-vehicular, non-SLI (start lighting ignition) applications.

5. "Lead-acid battery collection facility" means a facility authorized by the Department of Health and Environmental Control to accept lead-acid batteries from the public for temporary storage prior to recycling.

6. "Small sealed lead-acid battery collection facility" means a facility authorized by the Department of Health and Environmental Control to accept small sealed lead-acid batteries from the public for temporary storage prior to recycling.

7. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

8. "Recovered Materials Processing Facility" means a facility engaged solely in the recycling, storage, processing, and resale or reuse of recovered materials. The term does not include a solid waste handling facility; however, any solid waste generated by such facility is subject to all applicable laws and regulations relating to the solid waste.

9. "Secondary lead smelter" means a facility which produces metallic lead from various forms of lead scrap, including used lead-acid batteries.

10. "Used lead-acid battery" means a battery which is of no use in its present state. This includes batteries which are regulated by R.61-79.266 Subpart G, Spent Lead-Acid Batteries Being Reclaimed.

11. "Used small sealed lead-acid battery" means any battery fitting the definition of a small sealed lead-acid battery and which is of no use in its present state.

C. General Provisions for Lead-Acid Batteries.

1. No person shall knowingly place a used lead-acid battery in mixed municipal solid waste, discard or otherwise dispose of a lead-acid battery, except by delivery to:

a. a lead-acid battery retailer or wholesaler;

b. a collection, recycling, or recovered material processing facility that is registered by the Department to accept lead-acid batteries; or,

c. a permitted secondary lead smelter.

2. No battery retailer shall knowingly dispose of a used lead-acid battery except by delivery to:

a. the agent of a lead-acid battery wholesaler or the agent of a permitted secondary lead smelter;

b. a vehicle battery manufacturer for delivery to a permitted secondary lead smelter;

c. a collection, recycling, or recovered material processing facility that is registered by the Department to accept lead-acid batteries; or,

d. a permitted secondary lead smelter.

3. A person selling lead-acid batteries or offering lead-acid batteries for retail sale in this State shall:

a. accept, at the point of transfer, lead-acid batteries from customers; and,

b. post written notice, either issued by or approved by the Department, at his place of business which must be at least eight and one-half inches by eleven inches (8 ½ x 11) in size and must contain the state recycling symbol and the following language:

(1) "It is illegal to put a motor vehicle battery in the garbage."

(2) "Recycle your used batteries."

(3) "State law requires us to accept motor vehicle batteries for recycling."

4. Any person selling lead-acid batteries at wholesale or offering lead-acid batteries for sale at wholesale shall accept, at the point of transfer, lead-acid batteries from customers.

5. The lead-acid battery retailer shall charge a five dollar ($5.00) refundable deposit for each battery sold for which a core is not returned to the retailer. The deposit shall be returned to the consumer if a core is returned to the same retailer within thirty (30) days.

6. The operation of a lead-acid battery collection, recycling or recovered material processing facility shall be in a manner to protect public health, safety and the environment. Leaking lead-acid batteries shall be stored in heavy duty plastic bags or other suitable containers capable of preventing discharge of acid.

D. General Provisions for Small Sealed Lead-Acid Batteries.

1. No person shall knowingly place a used small sealed lead-acid battery in mixed municipal solid waste, discard, incinerate or otherwise dispose of a small sealed lead-acid battery, except by delivery to:

a. a small sealed lead-acid battery retailer or wholesaler,

b. a collection, recycling, or recovered material processing facility that is registered by the Department to accept small sealed lead-acid batteries; or,

c. a permitted secondary lead smelter.

2. No battery retailer shall knowingly dispose of a used small sealed lead-acid battery except by delivery to:

a. the agent of a lead-acid battery wholesaler or the agent of a permitted secondary lead smelter;

b. a small sealed lead-acid battery manufacturing facility for delivery to a permitted secondary lead smelter;

c. a small sealed lead-acid battery importer for delivery to a permitted secondary lead smelter;

d. a facility designated by a small sealed lead-acid battery manufacturer or importer to accept small sealed lead-acid batteries for delivery to a secondary lead smelter;

e. a collection, recycling, or recovered material processing facility that is registered by the Department to accept small sealed lead-acid batteries; or,

f. a permitted secondary lead smelter.

3. The operation of a small sealed lead-acid battery collection, recycling or recovered material processing facility shall be in a manner to protect public health, safety and the environment. Damaged small sealed lead-acid batteries shall be stored in heavy-duty plastic bags or other suitable containers capable of preventing discharge of acid.

4. A person selling small sealed lead-acid batteries or offering small sealed lead-acid batteries for retail sale in this State shall post written notice, either issued by or approved by the Department, at his place of business which must be at least eight and one-half inches by eleven inches (8 ½ x 11) in size and must contain the state recycling symbol and the following language:

(1) "It is illegal to put a small sealed lead-acid battery in the garbage."

(2) "Recycle your used small sealed lead-acid batteries."

E. Registration Requirements.

1. Collection, recycling, and recovered material processing facilities shall register with the Department to accept lead-acid batteries and/or small sealed lead-acid batteries. Registrations shall be renewed no later than March 1, of each calendar year. This requirement does not apply to persons selling lead-acid batteries and/or small sealed lead-acid batteries or offering lead-acid batteries and/or small sealed lead-acid batteries for retail sale or wholesale, who accept lead-acid batteries and/or small sealed lead-acid batteries, at the point of transfer, only from customers.

2. Within 60 days of the effective date of this regulation, the owner and/or operator of all collection, recycling, and recovered material processing facilities accepting lead-acid batteries and/or small sealed lead-acid batteries, shall register with the Department. To be registered, the owner and/or operator shall submit to the Department, the name and location of the facility and the name, address and telephone number of the owner and/or operator of the facility.

3. Collection, recycling, and recovered material processing facilities not accepting lead-acid batteries and/or small sealed lead-acid batteries prior to the effective date of this regulation, shall register with the Department prior to accepting lead-acid batteries and/or small sealed lead-acid batteries. To be registered, the owner and/or operator shall submit to the Department, the name and location of the facility and the name, address and telephone number of the owner and/or operator of the facility.

F. Violations and Penalties.

Any person violating the provisions of Sections C. 1. and 2., shall be subject to a fine not to exceed two hundred dollars ($200.00). Each lead-acid battery improperly disposed shall constitute a separate violation.

G. Severability.

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Amended by State Register Volume 19, Issue No. 6, eff June 23, 1995.

61–107.9. Solid Waste Management: White Goods.

A. Applicability.

This regulation applies to the proper management and recycling or disposal of inoperative or discarded white goods.

B. Definitions.

1. "Department" means the South Carolina Department of Health and Environmental Control.

2. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

3. "White goods" include refrigerators, ranges, water heaters, freezers, dishwashers, trash compactors, washers, dryers, air conditioners, and commercial large appliances.

C. General Provisions.

1. Effective May 27, 1994, no person shall knowingly include white goods with other municipal solid waste that is intended for collection or disposal at a municipal solid waste landfill.

2. Effective May 27, 1994, no owner or operator of a municipal solid waste landfill shall knowingly accept white goods for disposal at such landfill. An owner or operator of a municipal solid waste landfill may accept white goods for temporary storage prior to shipment of such white goods to a recycling facility.

3. Prior to the recycling or disposal of white goods:

a. all ozone depleting compounds (e.g. chlorofluorocarbons) used as refrigerants shall be recovered in accordance with applicable Federal, State and local regulations.

b. all electrical components shall be removed and disposed in a manner consistent with Federal, State and local regulations.

4. White goods shall be stored in a manner to protect human health, safety and the environment and in accordance with Federal, State and local regulations.

D. Retailer Requirements.

All persons selling or offering white goods for sale at retail in South Carolina shall post written notice, at their place of business, notifying all customers that white goods may not be disposed by landfilling after May 27, 1994. The notice, either issued by or approved by the Department, shall be at least eight and one-half inches by eleven inches (8 ½ × 11) in size.

E. Violations and Penalties.

Any person violating the provisions of Sections C. 1. and 2., shall be subject to a fine not to exceed two hundred dollars ($200.00). Each white good improperly disposed shall constitute a separate violation.

F. Severability.

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

61–107.10. Solid Waste Management: Research, Development, and Demonstration Permit Criteria.

A. Applicability.

This regulation applies to solid waste management facilities, or parts of these facilities, proposing to utilize an innovative and experimental solid waste management technology or process.

B. Definitions.

1. "Department" means the South Carolina Department of Health and Environmental Control.

2. "Disclosure statement" means a sworn statement or affirmation, the form and content of which shall be determined by the Department and as required by Section 44-96-300.

3. "Permit" means the process by which the Department can ensure cognizance of, as well as control over, the management of solid wastes.

4. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

5. "Solid waste management" means the systematic control of the generation, collection, source separation, storage, transportation, treatment, recovery, and disposal of solid waste.

6. "Solid waste management facility" means any solid waste disposal area, volume reduction plant, transfer station, or other facility, the purpose of which is the storage, collection, transportation, treatment, utilization, processing, recycling, or disposal, or any combination thereof, of solid

waste. The term does not include a recovered materials processing facility or facilities which use or ship recovered materials, except that portion of the facilities which is managing solid waste.

C. General Provisions.

1. The Department may issue a research, development and demonstration permit for any solid waste management facility, or a part of the facility, which proposes to utilize an innovative and experimental solid waste technology or process for which permit standards for such activity have not been promulgated. Permits issued shall include such terms and conditions necessary to assure protection of human health, safety, and the environment and shall be for a period not to exceed two (2) years.

2. Nothing in this regulation creates exceptions to or authorizes the Department to grant variances from Federal and State laws and regulations and the Solid Waste Policy and Management Act.

3. The Department permit shall ensure the owner or operator provides for the receipt, storage, and disposal of only those types and quantities of solid waste that the Department deems necessary for purposes of determining the efficiency and performance capabilities of the technology or process and the effects of such technology or process on human health, safety and the environment.

4. The Department shall request a disclosure statement from the permit applicant in accordance with the guidelines established by Code Section 44-96-300. Local governments and regions comprised of local governments are exempt from this requirement.

D. Permit Requirements.

1. Prior to construction, modification, or operation of a solid waste research, development and demonstration facility, a permit shall be obtained from the Department. The application shall be signed by an engineer duly licensed and registered under the laws of the State of South Carolina.

2. Any person wishing to obtain a permit from the Department for a solid waste research, development and demonstration facility, shall submit to the Department three (3) copies of the following documents:

a. A completed permit application, on a form provided by the Department;

b. A detailed description of the proposed activity;

c. A description of the manner in which the permit applicant intends to provide for the management of solid waste in order to determine:

(1) the efficiency and performance capabilities of the technology or process;

(2) the effects of such technology or process on human health, safety and the environment; and,

(3) how the permit applicant intends to protect human health, safety and the environment in the conduct of the project;

d. A plan for assessing the effectiveness and environmental effect of the proposed facility;

e. A complete operational plan, including design details and a timetable for completing various phases of the facility from initiation of construction to completion of the project;

f. A demonstration of financial responsibility by the permit applicant through submission of proof of liability insurance or other form of financial surety deemed sufficient by the Department to meet the following: all responsibilities for closure of the research, development and demonstration facility; and/or all responsibilities in the case of a release of solid waste causing bodily injury or property damage to any third party, including contamination of groundwater and liability for environmental restoration resulting from negligence in operation. The owner or operator shall provide continuous coverage for closure or clean-up until released from financial responsibility requirements by certifying that closure or clean-up of the facility is complete.

g. A plan for corrective action utilizing conventional technology in the event of environmental, safety and/or health hazards.

3. If the Department deems necessary, additional requirements may be imposed to ensure protection to human health, safety, and the environment including, but not limited to:

a. monitoring;

b. operation;

c. financial responsibility;

d. closure;

e. corrective action; and,

f. reporting.

E. Location Requirements.

Location requirements addressed in this section apply to all solid waste research, development, and demonstration facilities, unless otherwise approved by the Department.

1. Facilities shall be adjacent to or have direct access to roads which are of all weather construction and capable of withstanding anticipated load limits.

2. Facilities located in 100-year floodplains shall demonstrate that the facility will not restrict the flow of the 100-year flood.

3. The active waste handling area shall not be located within two hundred (200) feet of any surface water, excluding drainage ditches and sedimentation ponds.

4. Facilities shall not be located within any wetlands as delineated and defined specifically as wetlands according to the methodology accepted by the U. S. Army Corps of Engineers and the U. S. Environmental Protection Agency.

5. The active waste handling area shall not extend closer than one hundred (100) feet to any drinking water well.

6. Locations shall allow for sufficient room to minimize traffic congestion and allow for safe operation.

7. The active waste handling area shall not extend closer than two hundred (200) feet to residences, schools, hospitals and recreational park areas.

8. The active waste handling area shall not extend closer than one hundred (100) feet to all property lines.

9. Facilities shall adhere to all Federal, State, and local zoning, land use and other applicable local ordinances.

F. Design and Operation Requirements.

A research, development, and demonstration facility shall be designed and operated according to the minimum criteria listed in this section.

1. The facility shall not be larger than the area needed to adequately test the new or unique technology.

2. No waste shall be processed or disposed at the facility after two (2) years from the initial processing or disposal of waste at the facility, unless a different period is stated in the Department permit. Activities involving the management of solid waste at the facility prior to the issuance of the research, development, and demonstration permit, may be continued provided a valid Department permit for such activities is in effect.

3. Quarterly reports shall be prepared and submitted to the Department concerning the effectiveness and environmental effect of the facility.

4. If during the life of the permit, the Department determines that the facility is causing or is likely to cause harm to public health, safety or to the environment, the facility shall take appropriate action to prevent or eliminate the practice which is causing the hazard.

5. Trained personnel shall be present at all times during the operation of the facility.

G. Reporting Requirements.

1. Quarterly reports shall be submitted to the Department, within thirty (30) days of the end of each calendar quarter. The report shall include at a minimum, the following information:

a. Source, type, and total quantity in weight and/or volume of waste received at the facility for the previous quarter;

b. A description of the method and quantity of the distribution and/or disposal of the waste;

c. The weight and/or volume of each material recycled or marketed as a result of the process; and,

d. A report concerning the effectiveness and environmental effect of the facility.

2. Within ninety (90) days from the expiration of the permit, or within another period established by the Department, the owner or operator shall submit to the Department an analysis of the effectiveness and environmental effect of the facility.

H. Departmental Evaluation of Analysis.

1. The Department will review the quarterly reports and other relevant data to determine if the facility is satisfactorily achieving its objectives and if the facility is adequately protecting public health, safety, and the environment.

2. If after two (2) years, the Department determines that the facility adequately achieved its objectives and satisfactorily protected public health, safety, and the environment, the Department subsequently may promulgate regulations or criteria regarding the technology or process in accordance with the authority granted the Department by the Solid Waste Policy and Management Act. Prior to the Department establishing such regulations or criteria, the Department may issue written approval for the continuance of the technology or process.

I. Violations and Penalties.

A violation of this regulation subjects the person to the issuance of a Department order, or to civil or criminal enforcement action by the Attorney General's Office. In addition, the Department may impose reasonable civil penalties not to exceed ten thousand dollars ($10,000.00) for each day of violation of the provisions of this regulation, including any order, permit or standard. A person to whom an order is issued may appeal it as a contested case in accordance with R.61-72 and the Administrative Procedures Act.

J. Severability.

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

61–107.12. Solid Waste Management: Solid Waste Incineration and Solid Waste Pyrolysis Facilities.

Part I. Applicability, Definitions, and General Provisions.

A. Applicability.

1. This regulation establishes the procedures, documentation, and other requirements which must be met for the proper operation and management of all solid waste incineration facilities, including all solid waste pyrolysis facilities, and waste-to-energy facilities burning solid waste used for energy recovery.

2. Facilities incinerating solid waste generated in the course of normal operations on property under the same ownership or control as the solid waste incineration facility are exempt from the requirements of this regulation. This exemption includes industrial boilers and furnaces that burn industrial by-products generated on-site, or on properties under the same ownership or control. Air curtain incinerators burning only yard-trimmings and land-clearing debris generated on-site, or generated on properties under the same ownership or control, are exempt from the requirements of this regulation. Air curtain incinerators used for emergency storm debris management at sites designated by state, county and municipal government are exempt from the requirements of this regulation.

3. Industrial boilers and industrial furnaces that burn Refuse-Derived Fuel (RDF) only, or burn RDF with a fossil fuel or wood are exempt from the requirements of this regulation.

4. Facilities that treat contaminated soils pursuant to other regulations are exempt from the requirements of this regulation.

5. Disposal of hazardous waste from conditionally exempt small quantity generators at solid waste incinerators is prohibited unless the incinerator is permitted under the South Carolina Hazardous Waste Management Regulations.

6. Government owned and operated incineration facilities that are used by an agency such as police, customs, agricultural inspection or a similar law enforcement agency to destroy illegal or prohibited goods, are exempt from the requirements of this regulation, but must comply with other applicable federal, state and local requirements.

7. Facilities using air curtain incinerators that never store more than four hundred cubic yards of clean wood, yard and land-clearing debris consisting of only untreated natural wood debris, untreated or unfinished wood waste, or a mixture of these specific waste stream on site at any given time, are conditionally exempt from the permitting requirements of this regulation when the conditions of subsections Part II.B., C., E., and F. of this regulation are maintained by the facility.

B. Definitions.

1. "Air curtain incinerator" means an incinerator that operates by forcefully projecting a curtain of air across an open chamber or pit in which burning occurs. Incinerators of this type can be constructed above or below ground and require a refractory lined chamber or pit.

2. "Applicant" means an individual, corporation, partnership, business association, or government entity that applies for the issuance, transfer, or modification of a permit under this article.

3. "Ash" means the solid residue from the incineration of solid waste.

4. "Closure" means the discontinuance of operation by ceasing to accept, treat, store, or dispose of solid waste in a manner which minimizes the need for further maintenance and protects human health and the environment.

5. "Commercial solid waste" means all types of solid waste generated by stores, offices, restaurants, warehouses, and other nonmanufacturing activities, excluding residential and industrial solid wastes.

6. "Department" means the South Carolina Department of Health and Environmental Control.

7. "Disclosure Statement" means a sworn statement or affirmation, the form and content of which shall be determined by the Department and as required by Code Section 44–96–300.

8. "Financial assurance mechanism" means a mechanism designed to demonstrate that sufficient funds will be available to meet specific environmental protection needs of solid waste management facilities. Available financial assurance mechanisms include, but are not limited to, insurance, trust funds, surety bonds, letters of credit, certificates of deposit, and financial tests as determined by the Department by regulation.

9. "Incineration" means the use of controlled flame combustion to thermally break down solid, liquid, or gaseous combustible wastes, producing residue that contains little or no combustible materials.

10. "Incinerator" means any engineered device used in the process of controlled combustion of waste for the purpose of reducing the volume, and/or reducing or removing the hazardous potential of the waste charged by destroying combustible matter leaving the noncombustible ashes, material and/or residue.

11. "Industrial boiler" means a boiler that produces steam, heated air, or other heated fluids for use in a manufacturing process.

12. "Industrial furnace" means any of the following enclosed devices that are integral components of manufacturing processes and that use controlled flame devices to accomplish recovery of materials or energy:

a. Cement kilns;

b. Lime kilns;

c. Aggregate kilns;

d. Phosphate kilns;

e. Coke ovens;

f. Blast furnaces;

g. Smelting, melting and refining furnaces (including pyrometallurgical devices such as cupolas, reverberator furnaces, sintering machines, roasters, and foundry furnaces);

h. Titanium dioxide chloride process oxidation reactors;

i. Methane reforming furnaces;

j. Pulping liquor recovery furnaces;

k. Combustion devices used in the recovery of sulfur values from spent sulfuric acid; and,

l. Such other devices as the Department may determine on a case-by-case basis using one or more of the following factors:

(1) The design and use of the device primarily to accomplish recovery of material products;

(2) The use of the device to burn or reduce raw materials to make a material product;

(3) The use of the device to burn or reduce secondary materials as effective substitutes for raw materials, in processes using raw materials as principal feedstocks;

(4) The use of the device to burn or reduce secondary materials as ingredients in an industrial process to make a material product;

(5) The use of the device in common industrial practice to produce a material product; and,

(6) Other factors, as appropriate.

13. ''Industrial solid waste'' means solid waste generated by manufacturing or industrial processes that is not a hazardous waste regulated under subtitle C of RCRA. Such waste may include, but is not limited to, waste resulting from the following manufacturing processes: Electric power generation; fertilizer/agricultural chemicals; food and related products/by-products; inorganic chemicals; iron and steel manufacturing, leather and leather products; nonferrous metals manufacturing/foundries; organic chemicals; plastics and resins manufacturing; pulp and paper industry; rubber and miscellaneous plastic products; stone, glass, clay, and concrete products; textile manufacturing; transportation equipment; and water treatment. This term does not include mining waste or oil and gas waste.

14. ''Local government'' means a county, any municipality located wholly or partly within the county, and any other political subdivision located wholly or partly within the county when such political subdivision provides solid waste management services.

15. ''Medical waste,'' for the purposes of this regulations, means infectious waste as defined in South Carolina Infectious Waste Management Regulation 61–105.E.

16. ''Permit'' means the process by which the Department can ensure cognizance of, as well as control over, the management of solid wastes.

17. ''Putrescible wastes'' means solid waste that will rapidly decompose with the potential to cause odor and attract vectors.

18. ''Pyrolysis'' means the chemical decomposition of a material by heat in the absence of oxygen.

19. ''Recovered materials'' mean those materials which have known use, reuse, or recycling potential; can be feasibly used, reused, or recycled; and have been diverted or removed from the solid waste stream for sale, use, reuse, or recycling, whether or not requiring subsequent separation and processing. At least seventy-five percent (75%) by weight of the materials received during the previous calendar year must be used, reused, recycled, or transferred to a different site for use, reuse, or recycling in order to qualify as a recovered material.

20. ''Refuse Derived Fuel (RDF),'' for the purpose of this regulation, means a type of fuel produced from solid waste by separating some, or all, of the noncombustible from the combustible portions, shredding and classifying the waste by size. This includes all classes of RDF including low-density fluff RDF through densified RDF and pelletized RDF.

21. ''Region'' means a group of counties in South Carolina which is planning to or has prepared, approved, and submitted a regional solid waste management plan to the Department pursuant to Section 44–96–80.

22. ''Residential solid waste'' means solid waste (including garbage, trash, and sanitary waste from septic tanks) derived from households (including single and multiple residences.)

23. ''Solid waste'' means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and from community activities. This term does not include solid or dissolved material in

domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1964, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

24. "Solid waste management" means the systematic control of the generation, collection, source separation, storage, transportation, treatment, recovery, and disposal of solid waste.

25. "Solid waste management facility" means any solid waste disposal area, volume reduction plant, transfer station, or other facility, the purpose of which is the storage, collection, transportation, treatment, utilization, processing, recycling, or disposal, or any combination thereof, of solid waste. The term does not include a recovered materials processing facility or facilities which use or ship recovered materials, except that portion of the facilities which is managing solid waste.

26. "Special waste" means nonresidential and commercial solid wastes, other than regulated hazardous wastes, that are either difficult or dangerous to handle and require unusual management, including, but not limited to, those waste contained in Code Section 44–96–390(A).

27. "Vector" means a carrier that is capable of transmitting a pathogen from one organism to another including, but not limited to, flies and other insects, rodents, birds, and vermin.

28. "Waste-to-energy facility," for the purposes of this regulation, means a facility that uses an enclosed device using controlled combustion to thermally break down solid, liquid, or gaseous combustible solid waste to an ash residue that contains little or no combustible material and that produces electricity, steam, or other energy as a result. The term does not include facilities that primarily burn fuels other than solid waste even if such facilities also burn some solid waste as a fuel supplement. The term also does not include facilities that burn vegetative, agricultural, or silvicultural wastes, clean dry wood, methane or other landfill gas, wood fuel derived from construction or demolition debris, or waste tires, alone or in combination with fossil fuels."

29. "Waters of the United States" means:

a. All waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters which are subject to the ebb and flow of the tide;

b. All interstate waters, including interstate wetlands;

c. All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sand flats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds that the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters:

(1) Which are or could be used by interstate or foreign travelers for recreational or other purposes;

(2) From which fish or shellfish are or could be taken and sold in interstate or foreign commerce; or

(3) Which are used or could be used for industrial purposes by industries in interstate commerce;

d. All impoundments of waters otherwise defined as Waters of the United States under this definition;

e. Tributaries of waters identified in paragraph a through paragraph f of this definition;

f. The territorial sea;

g. Wetlands adjacent to waters (other than waters that are themselves wetlands) identified in paragraph a through paragraph f of this definition; and,

h. Waste treatment systems, including treatment ponds or lagoons designed to meet the requirements of the Clean Water Act, are not waters of the United States.

C. General Provisions.

1. No permit to construct a new solid waste incineration facility may be issued by the Department unless the proposed facility is consistent with the local or regional solid waste management plan and the state solid waste management plan. Consistency determinations shall be made in accordance with the state and county or regional solid waste management plans in effect on the date that a complete application is received by the Department. This subsection must not apply to industrial facilities managing solid waste generated in the course of normal operations on property under the same ownership or control as the waste management facility. However, these facilities shall be consistent with the applicable local zoning and land use ordinances, if any, provided that the industrial facility is not a commercial solid waste management facility. Prior to the issuance of a permit for a new or expanded facility, the Department shall approve an allowable capacity based on the local or regional solid waste management plan, the facility's design capacity, and the following criteria:

a. No solid waste incineration facility with a daily capacity in excess of six hundred (600) tons shall be permitted within the State.

b. No solid waste incineration facility with a daily capacity in excess of one hundred (100) tons shall be permitted to be sited within three (3) miles of another such facility.

2. The siting, design, construction, operation, closure, and post-closure activities of new or expanding solid waste incineration facilities shall conform to the standards set forth in this regulation, the facility's permit and in R.61–107.17. Solid Waste Management: Demonstration of Need.

3. A permit obtained from the Department pursuant to these regulations, or an exemption from permitting pursuant to these regulations, does not exempt the incineration facility from the necessity of obtaining other Department required permits (e.g. air quality, water pollution control).

4. No person owning or operating an incineration facility shall cause, suffer, allow, or permit the handling of regulated hazardous wastes or regulated infectious wastes at the incineration facility, unless the facility is specifically permitted for such wastes.

5. The Department shall require a disclosure statement from the permit applicant in accordance with Code Section 44–96–300. Local governments and regions comprised of local governments are exempt from this requirement. The Department may accept one (1) disclosure statement for multiple facility permit applicants.

6. A permit shall be required for each site or facility although the Department may include one or more different types of facilities in a single permit if the facilities are co-located on the same site.

7. Construction of an incinerator shall not be initiated until all required approvals are obtained.

8. The permittee of a solid waste incineration facility shall notify the Department prior to transfer of ownership or operation of the facility during its operating life or during the post-closure care period. The Department will approve a reissuance of the permit to the new owner provided that the facility is in compliance and the new owner agrees in writing to assume responsibility in accordance with these regulations. The Department must receive a disclosure statement and proof of financial assurance for the new permittee before a permit can be reissued.

9. Facilities that have a valid Department permit for managing hazardous or infectious waste, may request to be exempted from certain portions of this regulation.

Part II. Requirements for Air Curtain Incineration Facilities.

A. Permit Application Requirements.

1. Prior to the construction, modification, or operation of an air curtain incineration facility, a permit shall be obtained from the Department pursuant to these regulations. The application shall be signed by an engineer duly licensed and registered under the laws of the State of South Carolina.

2. Any person wishing to obtain a permit pursuant to these regulations, to operate an air curtain incineration facility, shall submit to the Department, one (1) printed copy and a digital copy of the following documents:

a. A completed permit application, on a form provided by the Department;

b. An operating report which shall include the following:

(1) A detailed description of the facility, including, but not limited to, structures, access roads, on-site roads, parking areas, loading and unloading areas, storage areas for incoming waste and non-combustible waste generated by the incinerator, fences, and gates;

(2) A description of the disposal location or any re-use or recycling planned for the ash residue;

(3) A map showing the specific location, land use, and zoning within one-fourth (1/4) mile of the boundaries of the proposed facility, and distances to any locations from which a buffer is required;

(4) A site plan, on a scale of not greater than two hundred (200) feet per inch, designating the property boundaries and all existing and proposed structures and access roads;

(5) Detailed engineering plans and specifications for the incinerator and other related machinery; and,

(6) A description of the manner in which waste waters, if any, from the facility will be managed.

c. An itemized closure cost estimate, prepared by a third party acceptable to the Department, which projects the expenses for closure activities listed in the closure plan, using cost estimates as calculated in accordance with Part IV.B.2 of this regulation. The cost estimate will declare the maximum amount of incoming waste and ash which may be located at a facility at any given time.

3. Public Noticing Requirements for Air Curtain Incineration Facilities. Noticing for air curtain incineration facilities shall be in accordance with Part III. A.3 of this regulation, except that notice shall be given to the county administrator, the county planning office, and all owners of real property as they appear on the county tax maps, as contiguous landowners of the proposed permit area.

B. Design Requirements for Air Curtain Incineration Facilities.

1. All facilities shall be adjacent to or have direct access to roads that are of all-weather construction and capable of withstanding anticipated load limits.

2. The active waste handling area of the facility and burn trench shall have separation from the groundwater table at all times.

3. No facilities shall be located within the 100-year floodplain.

4. The active waste handling area of the facility shall not be located within five hundred (500) feet of any waters of the U.S.

5. All facilities shall be in compliance with the U.S. Army Corps of Engineers and the U.S. Environmental Protection Agency requirements concerning wetlands.

6. The active waste handling area of the facility shall not extend closer than one hundred (100) feet to any drinking water well.

7. Locations shall allow for sufficient room to minimize traffic congestion and allow for safe operation.

8. No facility shall extend closer than one hundred (100) feet to any property line.

9. The active waste handling area of a facility, shall not extend closer than five hundred (500) feet to residences, schools, day-care centers, hospitals or recreational park areas.

10. Facilities shall adhere to all Federal and State rules and regulations and all local zoning, land use and other applicable local ordinances.

11. Facilities shall be equipped with portable fire extinguishers, fire control equipment and spill control equipment.

C. Operations Criteria for Air Curtain Incineration Facilities.

1. Air curtain incinerators may burn only clean wood, yard-trimmings and land-clearing debris consisting of only untreated natural wood debris, untreated or unfinished wood waste, or a mixture of these specific waste streams.

2. The operator shall restrict the presence of, and shall minimize the possibility for any unauthorized entry onto the facility. A statement of the days and hours of operation shall be posted at the entrance of the facility and access, except for Department and/or emergency personnel, shall be limited to those times when authorized personnel are on duty.

3. Receipt and handling of solid waste:

(a) The facility is authorized to process only solid waste authorized by Department permit. The weight of all solid waste received at the facility shall be recorded and incorporated into the annual report.

(b) Storage and/or processing of putrescible waste is prohibited.

(c) Wastes shall be stored so as to prevent a fire hazard.

4. Trained personnel shall be present at all times during the operation of the facility.

5. The ash from all air curtain incineration facilities shall be properly managed and disposed, as approved in the facility permit, immediately after removal from the air curtain incinerator.

D. Reporting Requirements. Facilities with air curtain incinerators shall report annually to the Department by October 15 for the previous fiscal year (July 1 through June 30), which includes at a minimum, the following information:

1. Total quantity in tons of solid waste received at the facility for the previous fiscal year;

2. The county in South Carolina in which the solid waste originated, or the state, if the waste originated outside South Carolina;

3. The transfer station, if applicable; and,

4. A description of the method and quantities of the solid waste, ash, and non-acceptable waste transported off-site for disposal or reuse or recycling.

E. Closure Requirements. All air curtain incineration facilities shall comply with the closure and post-closure procedures as specified in Part IV.A of this regulation.

F. Training Requirements. All air curtain incineration facilities shall comply with personnel training requirements in Part IV.C of this regulation.

Part III. Requirements for Solid Waste Incineration Facilities, Including Pyrolysis Facilities. This Part applies to all facilities using incineration technologies, including pyrolysis, except for Air Curtain Incineration facilities permitted in accordance with the requirements in Part II of this regulation.

A. Permit Application Requirements.

1. Prior to the construction, modification, or operation of a solid waste incineration facility, a permit shall be obtained from the Department pursuant to these regulations. The application shall be signed by an engineer duly licensed and registered under the laws of the State of South Carolina.

2. Any person wishing to obtain a permit pursuant to these regulations, from the Department to operate a solid waste incineration facility, shall submit to the Department, one printed copy and a digital copy of the following documents:

a. A completed permit application, on a form provided by the Department;

b. An engineering report which shall include the following:

(1) An overall description of the facility;

(2) A description of the process and equipment to be used;

(3) A description of the area and proposed population which will be served by the facility;

(4) A description of the types and quantities of solid waste to be accepted;

(5) A description of the existing site. Any existing site conditions that will be utilized during the operation of the proposed incinerator shall be identified as existing on the plan including, but not limited to, structures, access roads, on-site roads, parking areas, loading and unloading areas, fences, and gates;

(6) A description of the security measures, including, but not limited to fences, gates, and signs;

(7) The location of storage areas for incoming waste, incinerator ash, precipitator waste, and other non-combustible waste generated by the incinerator;

(8) A description of any re-use or recycling planned for the ash residue; and,

(9) An identification of the ultimate disposal location for all facility-generated waste residues including, but not limited to, ash residues, and non-combustible waste, and the proposed alternate disposal locations for any unauthorized waste types, which may have been unknowingly accepted;

c. Complete engineering plans and specifications that, at a minimum, address the items listed below:

(1) A map showing the specific location, land use, and zoning within one-fourth (1/4) mile of the boundaries of the proposed facility;

(2) Drawings of buildings and other structures, on a scale no greater than one (1) foot per quarter inch, showing types of construction, layout, and dimensions for unloading, storage, and processing areas;

(3) A site plan, on a scale of not greater than two hundred (200) feet per inch, designating the property boundaries and all existing and proposed structures and access roads;

(4) Weighing of all solid waste to be accepted at the facility;

(5) Storage areas for incoming solid waste and out-going ash;

(6) Detailed engineering plans and specifications for the incinerator and other related machinery; and,

(7) Detailed engineering plans and specifications for leachate control and related equipment;

d. A complete description of the personnel training program that meets the requirements of Part IV.C of this regulation;

e. An ash management plan that at a minimum addresses the following:

(1) Identification of the facility approved by the Department that will receive the residue; and,

(2) A certification that the facility shall have adequate capacity to handle such residue;

f. A description of the manner in which waste waters, if any, from the facility will be managed;

g. A quality assurance and quality control report. The facility owner or operator shall institute a control program (including measures such as signs, monitoring, alternate collection programs, passage of local laws, etc.) to assure that only solid waste authorized by the Department is being processed at the facility;

h. A written contingency plan which describes a technically and financially feasible course of action to be taken in response to contingencies during the construction and/or operation of the facility. The contingency plan shall be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous constituents to air, soil, or surface water;

i. A narrative description of the general operating plan for the facility, including the origin, composition and weight of solid waste that is to be processed at the facility, the process to be used at the facility, the daily operational methodology of the process, the loading rate, the proposed capacity of the facility and the expected life of the facility. The plan shall include a descriptive statement of any materials recycling or reclamation activities to be operated in conjunction with the facility, either on the incoming solid waste or the out-going residue. The plan shall describe how the facility will meet all applicable regulatory requirements;

j. An operation and maintenance manual describing how the facility shall be maintained and operated in accordance with the intended use and permit of the facility. The manual shall include, but not be limited to, the following:

(1) A description of the proposed procedures for the operation of each major facility component;

(2) Procedures to be followed during startup and scheduled and unscheduled shutdown of operations;

(3) Identification of the operating variables for the process and any control devices used to detect a malfunction or failure, the normal range of these variables, and a description of the method of monitoring; and the sequence of responsible action in the event that the equipment and instruments exceed normal operating ranges;

(4) Methods and schedules to check operation of control equipment and instrumentation, including a list of all equipment and instruments requiring calibration and a schedule of proposed calibration intervals. All process instruments shall be calibrated no less than once per year. Process control instruments shall be maintained in an operable condition;

(5) A description of the proposed measures to control dust, noise, litter, odor, rodents and insects at the facility;

(6) An inventory and location of all facility records and as-built drawings; and,

(7) An estimate of the type, quantity, and on-site storage of fuels needed for the facility;

k. A detailed closure plan which shall identify the steps necessary to close the facility. The plan will describe how all wastes, residues (including ash, scrubber waters and sludge) will be removed from the incinerator facility, including ductwork, piping, air pollution equipment, and surfaces that have contacted waste. The plan will also describe the procedures to dismantle and remove contaminated components of the incinerator facility when relocation or disposal of the component parts is preferred to closure in place. The plan may be amended at any time during the active life of the facility with Department approval. The plan shall be amended whenever changes in operating plans or facility design affect the closure plan, or whenever there is a change in the expected year of closure;

l. An itemized closure cost estimate, prepared by a third party acceptable to the Department, which projects the expenses for closure activities listed in the closure plan and declares the maximum amount of incoming waste and ash which may be located at a facility at any given time and remain in compliance with all federal, state and local permits applicable to the site. Financial assurance requirements for permitted facilities are found in Part IV.B of this regulation; and,

m. A waste control plan that, at a minimum, addresses the items outlined below. Facilities that receive only municipal solid waste are exempt from items (2)(a) & (b) below.

(1) Waste approval procedures for making the determination of whether to approve or refuse proposed waste streams;

(2) Waste screening procedures and a time frame for making the determination of whether to accept or reject shipments of incoming waste streams to include procedures for:

(a) Verifying that the profile sheets provided by the generators match all shipped containers; and,

(b) Conducting extended verification testing on each shipment of incoming waste;

(3) Waste disposal procedures for the proper handling, storage, and disposal of all unauthorized wastes; and,

(4) Record keeping procedures for maintaining documentation related to the acceptance, rejection, storage, operational data, and proper disposal of all wastes received by the facility. Records shall be maintained for a minimum of five (5) years and shall be made available to the Department upon request.

3. Public Noticing Requirements for Permitted Incineration Facilities.

a. Within fifteen (15) days of submitting an application to the Department, the applicant shall give notice that he/she has requested a permit to operate. Notice shall be given to the county administrator, the county planning office, and all owners of real property as they appear on the county tax maps, as landowners within one (1) mile of the proposed permit area. This notice shall contain:

(1) The name and address of the applicant;

(2) The type of facility and what it will accept for incineration;

(3) A detailed description of the location of the facility, using road numbers, street names, and landmarks, as appropriate;

(4) Department locations (Central Office and appropriate Regional Office) where a copy of the permit application will be available for review during normal working hours; and

(5) The Department address and contact name for submittal of comments and inquires.

b. The applicant shall provide evidence of Noticing as required in Part III.A.3 to the Department.

c. A comment period of not less than thirty (30) days from the date of Noticing will be provided prior to issuance of a Department decision.

d. Notice of the Department decision regarding the permit application will be sent to the applicant, to affected persons or interested persons who have asked to be notified, to all persons who commented in writing to the Department, and to the facility's host county. The use of certified mail to send Notice of the Department's decision shall be at the discretion of the Department unless specifically requested in writing by an interested person.

B. Design Requirements. Design requirements addressed in this section apply to all solid waste incineration facilities, unless otherwise approved by the Department.

1. Solid waste incineration facilities shall be adjacent to or have direct access to roads that are of all weather construction and capable of withstanding anticipated load limits.

2. Solid waste incineration facilities shall not be located within the 100-year floodplain.

3. The active waste handling area of a solid waste incineration facility shall not be located within five hundred (500) feet of any waters of the U.S.

4. Solid waste incineration facilities shall comply with the U.S. Army Corps of Engineers and the U.S. Environmental Protection Agency requirements concerning wetlands.

5. The active waste handling area of a solid waste incineration facility shall not extend closer than five hundred (500) feet to any drinking water well. The active waste handling area of the facility and all ash management areas shall have separation from the groundwater table at all times.

6. Locations shall allow for sufficient room to minimize traffic congestion and allow for safe operation.

7. No solid waste incineration facility shall extend closer than one hundred (100) feet to any property line.

8. The active waste handling area of a solid waste incineration facility shall not extend closer than one thousand (1000) feet to residences, schools, day-care centers, hospitals or recreational park areas.

9. Solid waste incineration facilities shall adhere to all Federal and State rules and regulations and all local zoning, land use and other applicable local ordinances.

10. The tipping, loading and unloading areas shall be:

a. Constructed with a minimum slope of 1%;

b. Constructed of impervious materials, e.g., asphalt, concrete;

c. Provided with a water supply for storage and transfer area cleaning purposes; and,

d. Equipped with drains, pumps, or equivalent means to facilitate the removal of water for proper disposal.

11. The transfer structures, buildings, and ramps shall be constructed of materials that can be easily cleaned.

12. The solid waste storage area and tipping area must include fire detection and protection equipment.

13. Leachate and washwater from a solid waste incineration facility shall not be allowed to drain or discharge into waters of the State unless an effluent disposal permit (e.g. land application or NPDES) is approved by the Department.

14. Emergency Preparedness. In addition to requirements set forth in the contingency plan, all solid waste incineration facilities shall at a minimum:

a. Provide adequate aisle space to allow for emergency equipment;

b. Be equipped with the following:

(1) An internal communications system capable of providing immediate emergency instruction to facility personnel and an alarm system to notify facility personnel of an emergency condition;

(2) A device, such as a telephone (immediately available at the scene of operations) or a handheld two-way radio, capable of summoning emergency assistance from local police departments, fire departments, and State or local emergency response teams;

(3) Portable fire extinguishers, fire control equipment and spill control equipment; and,

(4) Water available at adequate volume and pressure to supply water hose streams, automatic sprinklers, or water spray systems.

C. Operations Criteria. A solid waste incineration facility shall be designed and operated according to the minimum criteria listed in this section, unless otherwise approved by the Department.

1. All incinerators shall be operated in a manner so as to prevent the creation of a public health nuisance or potential health hazard. Litter, odors, rats, insects, flies, mosquitos, and other vectors shall be controlled at the facility.

2. All solid waste containing putrescible wastes shall be processed within seventy-two (72) hours of receipt unless an exemption is requested and approved by the Department in the facility's general operating plan.

3. All solid waste containing putrescible wastes that will not be processed on site shall be transferred to a permitted disposal facility within seventy-two (72) hours of its receipt.

4. Prior to initial operation of a new incinerator, the Department shall be notified so that an inspection may be made of the facility to determine conformance with the approved plans.

5. The incineration facility shall be operated and maintained so as to minimize interference with other activities in the area.

6. Access Controls. The operator shall restrict the presence of, and shall minimize the possibility for any unauthorized entry onto the facility. A statement of the days and hours of operation shall be posted at the entrance of the facility and access, except for Department and/or emergency personnel, shall be limited to those times when authorized personnel are on duty.

7. Receipt and Handling of Solid Waste.

a. The facility is authorized to process only solid waste authorized by Department permit. The weight of all solid waste received at the facility shall be recorded and incorporated into the annual report.

b. Outside storage and/or processing of putrescible waste is prohibited.

c. Unauthorized or untreatable solid waste may be temporarily stored on the premises for a period not to exceed one week; the facility may request an exemption to the one week limit to be incorporated in its general operating plan. The facility must ensure that waste does not create a nuisance or a sanitary or environmental problem.

d. Wastes shall be stored so as to prevent a fire hazard.

8. Process Changes. The owner or operator shall receive approval from all appropriate Department program areas in writing of all process changes before they are implemented. Permit modifications shall be required as deemed necessary by the Department.

9. Emergency Preparedness.

a. All solid waste incineration facilities shall at a minimum:

(1) Test and maintain as necessary to assure its proper operations, all facility emergency equipment including, but not limited to, communications or alarm systems, fire protection equipment, spill control equipment, and personal safety equipment;

(2) Provide immediate access for all personnel involved in the facility operation to an internal alarm or emergency communication device; and,

(3) Provide for an emergency coordinator.

b. The contingency plan shall be implemented immediately whenever there is a fire, explosion, or release of hazardous constituents which could threaten human health or the environment, and the Department immediately notified using the 24-hour emergency response telephone number.

c. Any unscheduled shutdown that exceeds twenty-four (24) hours shall be reported to the Department's Environmental Quality Control Regional Office of the region in which the facility is located.

10. Guidelines shall be established for identifying any items or materials that shall be removed prior to the incineration process.

11. Trained personnel shall be present at all times during the operation of the facility.

D. Monitoring and Reporting Requirements.

1. Monitoring may be required by the Department, as appropriate, and based on a case-by-case evaluation to ensure protection of the environment.

2. An annual report, on a form provided by, or acceptable to, the Department, shall be submitted to the Department by October 15 for the previous fiscal year (July 1 through June 30,) which includes at a minimum, the following information:

a. Type (i.e., residential, medical, commercial, industrial, special, and other) and total quantity in tons of solid waste received at the facility for the previous fiscal year;

b. The county in South Carolina in which the solid waste originated, or the State if the waste originated outside South Carolina;

c. The transfer station, if applicable; and,

d. A description of the method and quantities of the solid waste, ash, and non-acceptable waste transported off-site for disposal or reuse or recycling.

3. A report containing the following information for ash residue sampling and analyses as outlined in Part IV.D of this regulation, shall be submitted to the Department within sixty (60) days of sample collection:

a. The date and place of sampling and analysis;

b. The names of the individuals who performed the sampling and analysis;

c. The sampling and analytical methods utilized;

d. The results of such sampling and analyses; and,

e. The signature and certification of the report by an appropriate authorized agent for the facility.

4. Upon implementation of the contingency plan, the owner or operator shall immediately notify the Department (using the 24-hour emergency response telephone number) and note, in the operating record and the annual report, the time, date, and details of the incident. Upon request, a written report shall be submitted to the Department that includes the following information:

a. The name, address and telephone number of the operator and the facility;

b. The date, time and type of incident (e.g., fire, explosion, etc.);

c. The type and quantity of materials involved;

d. The extent of injuries, if any;

e. An assessment of actual or potential hazards to human health or the environment, where this is applicable;

f. The estimated quantity and disposition of solid waste, liquids, or material recovered that resulted from the incident; and,

g. The procedures or equipment available to prevent a recurrence of the reported event.

5. Records of all monitoring and reporting information, pursuant to these regulations, shall be maintained for a minimum of at least five (5) years from the sample or measurement date, unless otherwise specified by the Department. These reports shall be made available to Department personnel upon request.

Part IV. General Requirements.

A. Closure and Post-Closure Procedures.

Closure and post-closure procedures addressed in this section apply to all solid waste incineration facilities.

1. At least sixty (60) days prior to closure, provide written notice of intent to close and a proposed closure date to the Department. The final quantity of solid waste shall be received no less than thirty (30) days prior to closure date.

2. Upon closing, the owner or operator shall immediately post signs at the facility which state that the facility is no longer in operation.

3. Within thirty (30) days after receiving the final quantity of solid waste, the owner or operator of a conditionally exempt facility shall remove all solid waste and shall remove or treat all waste residues, contaminated soils and equipment. Within thirty (30) days after receiving the final quantity of solid waste, the owner or operator of a permitted facility shall remove all solid waste and shall remove or

treat all waste residues, contaminated soils and equipment in accordance with the approved closure plan, and notify the Department upon completion.

4. After receiving notification that the facility closure is complete, the Department will conduct an inspection of the facility. If all procedures have been correctly completed, the Department will approve the closure in writing, at which time the Department permit shall be terminated.

5. If the owner or operator demonstrates that not all contaminated soils can be practicably removed or treated as required in paragraph 3. of this section, then the owner or operator shall submit for Department approval, a post-closure care plan.

B. Financial Assurance Requirements.

1. The requirements of this section apply to all permitted solid waste incineration facilities. Local governments are exempt from this requirement until such time as federal regulations require such local governments or regions to demonstrate financial responsibility for such facilities and the Department promulgates regulations addressing this issue. Prior to accepting wastes, facilities shall fund a financial assurance mechanism acceptable to the Department to ensure the satisfactory maintenance and closure of the facility. The acceptable mechanisms to fund financial assurance requirements are described in R.61–107.19, SWM: Solid Waste Landfills and Structural Fill Part I.E.

2. The amount of financial assurance required shall be based on a third party itemized cost estimate to complete the facility closure plan as approved in the facility permit and the costs for tipping fees and hauling the maximum amount of material that the facility can store at any given time, to a suitable landfill for disposal. The closure cost estimate shall include the costs of labor, equipment, and soil amendments to properly grade and seed the site and the costs for soliciting third party bids to complete the closure. The Department shall use an average cost of disposal per ton of material, as reported in the most recent Solid Waste Management Annual Report.

3. During the active life of the facility, the permittee shall annually adjust the closure cost estimate when the disposal cost estimate increases substantially based on information published in the Solid Waste Management Annual Report.

4. The permittee shall increase the closure cost estimate and the amount of financial assurance provided if changes to the closure plan or site conditions increase the maximum cost of closure at any time during the site's remaining active life.

5. The permittee shall increase the closure cost estimate and the amount of financial assurance provided if a release to the environment occurs to include cost of groundwater monitoring, assessment and corrective action if the Department determines that these measures are necessary at any time during the active life of the facility. Financial assurance shall be maintained and adjusted annually until the Department agrees that environmental conditions meet applicable standards.

6. The permittee may reduce the closure cost estimate and the amount of financial assurance provided for proper closure if the cost estimate exceeds the maximum cost of closure at any time during the remaining life of the facility. The permittee shall submit justification for the reduction of the closure cost estimate and the amount of financial assurance to the Department for review and approval.

7. The registrant or permittee shall provide continuous coverage for closure until released from financial assurance requirements, pursuant to this regulation.

8. Default by Permittee. The Department may take possession of a financial assurance fund if the permittee fails to:

a. Complete closure in accordance with the Department approved facility closure plan;

b. Complete corrective action; or,

c. Renew or provide alternate acceptable financial assurance as required.

9. Prior to taking possession of financial assurance funds, the Department shall:

a. Issue a notice of violation or order alleging that the permittee has failed to perform closure in accordance with the closure plan or permit requirements; and,

b. Provide the permittee seven (7) days prior notice and an opportunity for a hearing.

C. Personnel Training Requirements. Solid waste incineration facility personnel training programs pursuant to these regulations, shall at a minimum:

1. Identify the positions which will require training and a knowledge of the procedures, equipment, and processes at the facility;

2. Describe how facility personnel will be trained to perform their duties in a way that ensures the facility's compliance with these regulations, including the proper procedures that shall be followed in the processing and handling of solid waste not authorized by the Department to be received at the facility;

3. Be designed to ensure that facility personnel are able to respond effectively to all emergencies, including different types of fires, by familiarizing them with the contingency plan, emergency and safety equipment, emergency procedures and emergency systems; and,

4. Documentation of training. The following records of training shall be maintained at the facility:

a. The job title for each position at the facility related to solid waste management and the name of the employee filling each job;

b. A written job description for each position listed under paragraph 4.a. of this section. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or unit, but must include the requisite skill, education, or other qualifications, and duties of employees assigned to each position;

c. A written description of the type and amount of both introductory and continuing training that will be given to each person filling a position listed under paragraph 4.a. of this section; and,

d. Records that document the training or job experience required under this section that has been given to, and completed by, facility personnel.

5. Training records on current personnel shall be kept until closure of the facility; training records on former employees shall be kept for at least three (3) years from the date the employee last worked at the facility. Personnel training records may accompany personnel transferred within the same company.

D. Ash Residue Requirements. Permanently located air curtain incinerators are exempt from the requirements of this section. However, the ash from these facilities shall be properly disposed immediately after removal from the incinerator.

1. Sampling and Analysis Requirements and Procedures.

a. Ash residue generated by a solid waste incinerator shall be sampled and analyzed according to the current Environmental Protection Agency (EPA) acceptable methodology for determining the hazardous nature of the ash being disposed.

b. The required analyses of all residual ash, shall be performed in accordance with the conditions of the solid waste management facility permit and current solid waste management regulations. The analyses shall be performed separately on the bottom ash and the fly ash, unless the bottom ash and fly ash are combined, in which case the combined ash shall be sampled and analyzed.

c. At a minimum, the ash residue at a new incineration facility shall be sampled and analyzed:

(1) Prior to the initial disposal of ash from the facility;

(2) Monthly for the first six (6) months of incineration operations at the facility;

(3) Semi-annually during the remaining life of the facility; and,

(4) At any time there is a change in the waste stream being incinerated.

d. At a minimum, the ash residue at an existing incineration facility shall be sampled and analyzed semi-annually.

e. If the Department deems necessary, more stringent sampling and analysis may be required.

f. A sampling and analysis plan shall be submitted to and approved by the Department, along with the ash residue management plan that identifies both the sample collection and analytical protocols that must be used to obtain representative samples of ash residue.

g. All analyses performed pursuant to this section shall be conducted by a laboratory certified by the Department.

h. The results of all such analyses shall be submitted to the Department no later than sixty (60) days after testing. Records shall be maintained at the facility for a period not less than five (5) years, and be available to Department personnel upon request.

2. Contents of the Ash Management Plan.

a. Prior to the construction and/or operation of a solid waste incinerator, an ash residue management plan shall be submitted to and approved by the Department.

b. The ash residue management plan shall describe the methods, equipment, and structures necessary to prevent the uncontrolled dispersion of ash residue considering potential pathways of human or environmental exposure including, but not limited to, inhalation, direct contact, and potential for groundwater and surface water contamination.

c. The ash residue management plan shall address the handling, storage, transportation, treatment, and disposal or reuse or recycling of ash residue as described in this section.

d. Handling. The owner and/or operator shall design, construct, operate, and maintain ash handling systems that ensure that ash residue (whether bottom ash, fly ash or combined ash) is properly wetted or contained to ensure that dust emissions are controlled during on-site and offsite storage, loading, transport, and unloading. The ash residue shall be wet enough so the surface of the ash remains damp after unloading at a landfill.

e. Storage.

(1) The owner and/or operator shall provide sufficient on-site ash residue storage capacity to ensure that facility operations continue during short term interruptions of ash residue transportation and/or disposal. The quantity of residue stored on-site shall be limited to no more than seven (7) times the daily design output.

(2) Residue stored on-site may be either:

(a) Stored in watertight, leak resistant containers located inside a building or enclosed structure. Prior to storage, free liquid shall be allowed to drain from the ash residue. Liquid drained during this process shall be collected and disposed in an approved waste water disposal system. Loaded containers may be stored outside of a building or enclosed structure if all free-liquid has been drained and the container is sealed and covered to prevent rain water infiltration or airborne emissions; or,

(b) Stored on-site in a waste pile which is located in an enclosed structure. The residue shall be placed on an impermeable base. A runoff management system shall be provided to collect and control the free liquid that is allowed to drain from the ash residue.

f. Transportation. Ash residue shall be drained of free liquid prior to transport. Ash residue transportation containers or vehicles shall be watertight and leak resistant and shall be designed and constructed such that any closures at or near the bottom are sealed to prevent leakage under normal transportation conditions. Closures shall be fitted with gaskets or materials that will not be deteriorated by the ash. The transport vehicle shall be enclosed or covered to prevent the top surface of the load from becoming dried. Provisions shall be made to wash vehicle tires and/or body to prevent ash from tracking onto roadways.

g. Disposal. Disposal of all ash generated by the facility shall be in accordance with standards set forth by Department regulations.

h. Reuse or Recycling. This section applies to ash residue in the form of bottom ash only, fly ash only, or combined ash that is proposed to be reused or recycled as an ingredient or as a substitute for a raw material.

(1) The owner and/or operator shall demonstrate to the Department's satisfaction that the resulting material: has a known market or disposition; and, that contractual arrangements have been made with a second person for use as an ingredient in a production process and that this person has the necessary equipment to do so.

(2) The owner and/or operator shall also:

(a) Chemically and physically characterize the ash residue and each finished product or products and identify the quantity and quality to be marketed;

(b) Describe the proposed method of application or use, available markets and marketing agreements;

(c) Demonstrate that the intended use will not adversely affect the public health, safety, welfare and the environment;

(d) If the use of the ash residue includes the mixing with different types of materials, a description of each product mixture shall be provided; and,

(e) Provide the Department with a copy of any information regarding the reuse or recycling of ash residue.

(3) The reuse or recycling of ash residue does not relieve the owner and/or operator from compliance with other monitoring requirements specified in this regulation.

E. Corrective Action Requirements. If at any time, the Department determines that the solid waste incineration facility poses an actual or potential threat to human health or the environment, the owner or operator shall implement a corrective action program reviewed and approved by the Department.

F. Violations and Penalties. A violation of this regulation or violation of any permit, order, or standard subjects the person to the issuance of a Department order, or a civil or criminal enforcement action in accordance with Code Section 44–96–450. In addition, the Department may impose reasonable civil penalties not to exceed ten thousand dollars ($10,000.00) for each day of violation of the provisions of this regulation, including violation of any order, permit, or standard.

G. Permit Review. A permit issued pursuant to this regulation shall be effective for the design and operational life of the facility, to be determined by the Department. At least once every five (5) years, the Department will review the environmental compliance history of each permitted solid waste incineration facility.

1. If, upon review, the Department finds that material or substantial violations of the permit issued pursuant to these regulations, demonstrate the permittee's disregard for, or inability to comply with applicable laws, regulations, or requirements and would make continuation of the permit not in the best interests of human health and safety or the environment, the Department may, after a hearing, amend or revoke the permit, as appropriate and necessary. When a permit is reviewed, the Department shall include additional limitations, standards, or conditions when the technical limitations, standards, or regulations on which the original permit was based have been changed by statute or amended by regulation.

2. The Department may amend or attach conditions to a permit when:

a. There is significant change in the manner and scope of operation which may require new or additional permit conditions or safeguards to protect human health and safety and the environment;

b. The investigation has shown the need for additional equipment, construction, procedures, and testing to ensure the protection of human health and safety and the environment; and,

c. The amendment is necessary to meet changes in applicable regulatory requirements.

H. Severability. Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Amended by State Register Volume 23, Issue No. 5, eff May 28, 1999; State Register Volume 40, Issue No. 6, Doc. No. 4614, eff June 24, 2016.

Editor's Note

In 2017, in III.A.2.(c)(1), an extraneous "1/4" was deleted to correct a scrivener's error.

61–107.14. Solid Waste Management: Municipal Solid Waste Landfill Operator's Certification.

A. Applicability. This regulation establishes minimum training and certification requirements for operators of municipal solid waste landfills and municipal solid waste incinerator ash landfills.

B. Definitions.

1. "Department" means the South Carolina Department of Health and Environmental Control.

2. "Municipal solid waste" means any solid waste (including garbage, trash, and sanitary waste in septic tanks) derived from households (including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use recreation areas), generated by commercial establishments (stores, offices, restaurants, warehouses, and other nonmanufacturing activities, excluding industrial facilities) and nonhazardous sludge.

3. "Municipal solid waste incinerator ash landfill" means any landfill or landfill unit, publicly or privately owned, that receives the solid residue from incinerators that burn municipal solid waste.

4. "Municipal solid waste landfill" means any sanitary landfill or landfill unit, publicly or privately owned, that receives household waste. The landfill may also receive other types of solid waste, such as commercial waste, nonhazardous sludge, and industrial solid waste.

5. "Operator" for the purposes of this regulation, means any person, including the owner, who is principally engaged in, or is in charge of, the actual operation, supervision, and maintenance of a municipal solid waste landfill or a municipal solid waste incinerator ash landfill and includes the person in charge of a shift or period during any part of the day. Operators will be classified by the following two (2) categories:

a. "Manager" means the person(s) with responsibility for the overall management of the facility; and,

b. "Supervisor" means the person(s) with supervisory responsibility for a specific facility site or shift.

6. "Sanitary landfill" means a land disposal site employing an engineered method of disposing of solid waste on land in a manner that minimizes environmental hazards and meets the design and operation requirements of State regulations.

7. "Workers" for the purposes of this regulation, means the persons performing the daily maintenance activities at the landfill.

C. General Provisions.

1. No person shall perform the duties of manager or supervisor of a municipal solid waste landfill or a municipal solid waste incinerator ash landfill (MSWIAL) unless he/she is duly certified by the State of South Carolina as a Landfill Operator.

2. Landfill operator's training and certification requirements shall be classified by the following categories:

a. Manager; and,

b. Supervisor.

3. Municipal solid waste landfill and MSWIAL managers and supervisors shall be trained and tested by a Department-approved training program and upon satisfactory completion of the course material and examination, shall be certified by the Department.

4. Operator certification examinations:

a. The operator certification examinations will be based on the appropriate basic operator training course curriculum.

b. An applicant who completes the training course but fails to pass the required examination within one year of the initial employment date shall not work in the capacity of a manager or supervisor at a municipal solid waste landfill and/or a MSWIAL until repeating the Department-approved operator's certification course and subsequently passing the certification examination.

5. All Department issued operator's certifications shall be renewed every three (3) years.

6. A certified manager or supervisor shall be on duty during all hours of operation of a municipal solid waste landfill and a MSWIAL.

7. Certified managers and supervisors shall refuse waste deemed unacceptable for that landfill.

D. Manager.

1. The manager of a landfill shall successfully complete a Department-approved training course and examination within one (1) year of the initial employment date.

2. Managers who have current Solid Waste Association of North America (SWANA or GRCDA) certification may request reciprocity for South Carolina certification, in lieu of completing the required training course and examination. The request for reciprocity shall be made within ninety (90) days from the initial employment date into the manager position. Documentation, i.e. a copy of SWANA or GRCDA Certification, verification of initial employment date, and a request for reciprocity shall be submitted to the Department. If the employee fails to submit the request within

the allotted ninety (90) day timeframe, he/she shall be required to successfully complete the training course, pursuant to Item D.1. above, in order to remain in the manager landfill position.

3. Fifteen (15) contact hours of continuing education, or 1.5 continuing education units (CEUs) from an approved source shall be completed by the manager prior to each renewal. The manager shall request and receive Department approval for the courses. Acceptability of courses for earning CEUs as required for certification renewal shall be determined by the Department. CEUs shall not be carried over from a three (3) year period into the next three (3) year renewal period.

4. CEUs and certification renewal:

a. The manager shall be responsible for submitting the following information concerning earned CEUs in order to maintain accurate Department records for certification renewal:

(1) Manager's name and certification number; and,

(2) A copy of the certificate, or other documentation indicating completion of a specific course and the number of CEUs earned.

b. Failure to earn the required number of CEUs and/or report this information to the Department shall result in revocation of certification.

5. Managers shall be knowledgeable of the following areas:

a. Regulations in reference to:

(1) Federal;

(2) State:

(a) agency responsible;

(b) definitions; and,

(c) requirements;

(3) OSHA—Safety to include:

(a) compliance with Hazard Communication Standard (29 CFR 1910.1200) and all other OSHA standards;

(b) carrying out the Emergency Response Plan; and,

(c) ensuring that all safety precautions are observed;

b. Role of municipal solid waste landfills in reference to:

(1) Generation of solid wastes;

(2) Physical and chemical composition and decomposition of waste;

(3) Waste identification in reference to:

(a) solid waste;

(b) hazardous waste; and,

(c) infectious waste; and,

(4) Handling of special wastes;

c. Landfill development phase to include:

(1) Site selection;

(2) Waste decomposition:

(a) landfill gas generation and migration;

(b) leachate generation and migration; and,

(c) control;

d. Landfill operations phase to include:

(1) Monitoring equipment and systems;

(2) Cover systems;

(3) Liners; and,

(4) Personnel and equipment concerns;

e. Landfill closure phase to include:

(1) Complying with engineering design for closure;

(2) Long term maintenance;

(3) Environmental monitoring;

(4) End uses;

(5) Final cover design; and,

(6) Vegetation; and,

f. Landfill post-closure to include financing closure and post-closure care.

6. Managers shall ensure that landfill workers are provided proper training.

E. Supervisor.

1. The supervisor of a landfill shall successfully complete a Department-approved training course and examination within one (1) year of the initial employment date.

2. Supervisors who have current SWANA or GRCDA certification may request reciprocity for South Carolina certification, in lieu of completing the required training course and examination. The request for reciprocity shall be made within ninety (90) days of the initial employment date into the supervisor position. Documentation, i.e. a copy of SWANA or GRCDA Certification, verification of initial employment date from the landfill manager, and a request for reciprocity shall be submitted to the Department. If the employee fails to submit the request within the allotted ninety (90) day timeframe, he/she shall be required to successfully complete the training course, pursuant to Item 1. above, in order to remain in the supervisor landfill position.

3. Six (6) contact hours of continuing education or 0.6 CEUs, shall be acquired by the supervisor prior to each renewal. The supervisor shall request and receive Department approval for the courses. Acceptability of courses for earning CEUs as required for certification renewal shall be determined by the Department. CEUs shall not be carried over from a three (3) year period into the next three (3) year renewal period.

4. CEUs and certification renewal:

a. The supervisor shall submit the following information concerning earned CEUs:

(1) Supervisor's name and certification number; and,

(2) A copy of the certificate indicating completion of a specific course and the number of CEUs earned.

b. Failure to earn the required number of CEUs and/or report this information to the Department shall result in revocation of certification.

5. The certified supervisor shall be knowledgeable of the following functions:

a. Waste identification in reference to:

(1) Different types of waste;

(2) Types of permitted wastes for identification and approval purposes;

(3) Response to non-permitted wastes; and,

(4) Monitoring the waste stream;

b. Equipment operation and preventive maintenance to include:

(1) Checking equipment prior to operation;

(2) Operating equipment to standards; and,

(3) Performing preventive maintenance;

c. Safety:

(1) Identification and use of personal protective equipment;

(2) Compliance with Hazard Communication Standard (29 CFR 1910.1200) and all other OSHA standards;

(3) Safe operation of equipment/tools;

(4) The Emergency Response Plan; and,

(5) Ensuring that all safety precautions are observed;

d. Landfill operation phase to include:

(1) Operating face requirements;

(2) Traffic control at the working face;

(3) Techniques for spreading and compacting waste;

(4) Cover application; and,

(5) Proper handling of special wastes;

e. Landfill development phase to include:

(1) Ability to read, interpret, and implement operational and design plans; and,

(2) Determination of elevations;

f. Monitoring in reference to:

(1) Ensuring the integrity of monitoring equipment and systems; and,

(2) Identifying the basic functions of monitoring systems;

g. Planning daily operations;

h. Landfill closure phase to include compatibility of daily operations with engineering design for closure;

i. Landfill post-closure to include compatibility of daily operations with post-closure plans; and,

j. Regulatory knowledge to ensure compliance with:

(1) Department inspection criteria for landfills; and,

(2) Basic permit requirements.

6. Supervisors shall ensure that workers are properly trained.

F. Worker.

1. Workers shall receive on-the-job training by either a contracted trainer approved by the Department or the employee's certified supervisor(s).

2. The required basic worker's training shall address the following areas, at a minimum:

a. Waste identification in reference to:

(1) Different types of waste; and,

(2) Types of permitted wastes;

b. Equipment operation and prevention maintenance to include:

(1) Checking equipment prior to operation;

(2) Operating equipment to standards; and,

(3) Performing preventive maintenance;

c. Safety in reference to:

(1) Identification and use of personal protective equipment;

(2) Compliance with Hazard Communication Standard (29 CFR 1910.1200) and all other OSHA standards;

(3) Operation of equipment/tools safely; and,

(4) Worker responsibilities under the Emergency Response Plan; and,

d. Landfill operation phase to include:

(1) Operating face requirements;

(2) Traffic control at the working face;

(3) Techniques for spreading and compacting waste;

(4) Cover application; and,

(5) Proper handling of special wastes.

3. Department staff will observe worker performance to determine compliance with requirements.

G. Disciplinary Action. Disciplinary action against a certified operator may be taken on any of the following grounds:

1. Gross negligence or a continued pattern of incompetence in the practice as a certified operator;

2. Intentionally violating or inducing another to violate the rules and permit conditions applicable to landfill operation;

3. Failure to take appropriate corrective action concerning violations documented during Department inspection(s);

4. Failure to submit required records of operation or other reports or monitoring data as required under applicable permits or Department regulations;

5. Making any false statement, representation, or certification on any application, record, report or document required to be maintained or submitted under any applicable permit or regulation of the Department;

6. Failure to ensure adequate training and supervision of landfill workers; and,

7. Failure to refuse unacceptable waste.

H. Disciplinary Sanctions Allowable and Procedures for Disciplinary Action.

1. Disciplinary action shall be based on the severity of the violation incurred as determined by the Department. Action shall consist of either:

a. Probation under specified conditions relevant to the specific grounds for disciplinary action. Additional education or training, or reexamination may be required as a condition of probation; or,

b. Revocation of an operator's certification for a specified timeframe as determined by the Department.

2. The following procedure shall be followed when disciplinary action is initiated:

a. A Department written notice shall be given to an operator against whom disciplinary action is being taken; and,

b. Within fifteen (15) days from receipt of written notification of disciplinary action by the Department, the operator may appeal it as a contested case pursuant to R.61-72 and the Administrative Procedures Act.

I. Severability. Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Added by State Register Volume 18, Issue No. 5, eff May 27, 1994.

61–107.15. Solid Waste Management: Land Application of Solid Waste.

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A. Applicability.

1. The purpose of this regulation is to establish appropriate application rates, frequency of application, and monitoring requirements for the uniform surface spreading or mechanical incorporation of non-hazardous solid waste on, or into, soil that is being used for agricultural, silvicultural and horticultural production. This regulation also applies to the application of solid waste on land that is being reclaimed to enhance its aesthetic value or to reduce environmental degradation. The land application of non-hazardous solid waste shall be for beneficial agricultural, silvicultural and horticultural purposes and not used as a means of disposal.

2. This regulation does not apply to the land application of solid or dissolved material in domestic sewage, industrial sludges, or water treatment sludges.

3. The application of commercial fertilizer, as defined in the South Carolina Fertilizer Law of 1954, S. C. Code Section 46-25-20 et seq. and animal manure during normal agricultural, silvicultural and horticultural operations is exempt from the requirements of this regulation.

4. Refuse, as defined and regulated pursuant to the South Carolina Mining Act, S.C. Code Section 48-20-10 et seq., including processed mineral waste which will not have a significant adverse impact on the environment, is exempt from the requirements of this regulation.

5. This regulation does not apply to the remediation of petroleum contaminated soils.

6. This regulation does not apply to the land application of hazardous waste which must be in compliance with the South Carolina Hazardous Waste Management Regulations.

7. This regulation does not apply to solid waste contaminated with petroleum products, heavy metals, septage, or pesticides regulated by the "Federal Insecticide, Fungicide, Rodenticide Act".

8. This regulation does not apply to the beneficial reuse of solid wastes in processes other than land application, e.g., the addition of ash to concrete and use of solid waste for structural fill.

9. This regulation does not apply to wastes generated as a result of ongoing normal agricultural, silvicultural, and horticultural operations when application is on properties owned and/or operated by the generator.

10. This regulation does not apply to waste generated by a homeowner when the waste is land applied on the site where it is generated.

B. Definitions.

1. "Agricultural Laboratory" means a laboratory that performs a standard agricultural soil test, such as that performed by the Clemson Soil Test Laboratory for the purpose of recommending lime and plant nutrients needed or appropriate for good crop or forest production purposes based on Best Management Practices.

2. "Agricultural land" means any land managed for the production of food, animal feed, or fiber crops, including timber and wood products.

3. "Agronomic rate, silvicultural rate, and horticultural rate" is that application rate of solid waste which supplies the amount of one or more plant nutrients needed for good crop and forest growth or which will neutralize excess soil acidity; but the nutrient requirement is not exceeded to the extent that groundwater exceeds applicable South Carolina groundwater quality standards.

4. "Bark" means the outer covering of the woody stems, branches, roots, and the main trunks of trees and other woody plants.

5. "Certified Laboratory" means a laboratory that has been certified by the State Environmental Laboratory Certification Program to perform specific analyses. All analyses required by this Regulation to be performed by a Certified Laboratory must be done by the methodology outlined in the most current issue of the EPA Publication SW-846 "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods".

6. "Class I Solid Waste," for the purposes of this regulation, means those solid wastes which have the potential to add some nutrient and/or pH adjustment benefit to the soil and require permitting by the Department prior to land application of that waste, e.g., wood ash, coal ash, green liquor dregs, and slaker grit.

7. "Class II Solid Waste," for the purposes of this regulation, means those solid wastes which, due to lack of substantiating data needed to calculate agronomic rate or to document that the material is non-toxic to plants and wildlife normally associated with the crop ecosystem, require

issuance of a Department Research, Development, and Demonstration Permit pursuant to R.61-107.10.

8. "Class III Solid Waste," for the purposes of this regulation, means those solid wastes which have less potential to add nutrients to the soil or correct soil acidity than Class I wastes, and are considered to be innocuous with regard to effects on soil, plants and water resources when applied at approved rates. Prior to application, registration by the Department in lieu of permitting is required for Class III wastes, e.g., cotton mote waste, cotton gin trash, bark, woodyard waste, flume grit.

9. "Class IV Solid Waste," for the purposes of this regulation, means those solid wastes used for land reclamation and other projects when the application rate exceeds ten (10) dry tons per acre per year and scientific/technical data is submitted to ensure the proposed application rate will have no detrimental impact on the environment and public health, and is non-toxic to plants and wildlife normally associated with the crop ecosystem. Class IV solid wastes require permitting by the Department prior to application.

10. "Coal ash" means the residue remaining after combustion of coal and includes bottom ash, fly ash, boiler slag and flue gas desulfurization ("FGD") products.

11. "Commercial fertilizer," as defined in the South Carolina Fertilizer Law of 1954, S.C. Code Section 46-25-20, means any substance containing one or more recognized plant nutrients which are used for plant nutrient content and designed for use or claimed to have value in promoting plant growth, except unmanipulated animal and vegetable manures, marl, lime, limestone, and wood ashes.

12. "Cotton gin trash" means the residual material left as a result of ginning and cleaning cotton; it includes burs, stems, leaves, weed seed, waste cotton fiber, other plant material, and soil.

13. "Cotton mote waste" means the residual material remaining after processing of cotton mote and residue from cotton carding operations; it includes immature cotton fiber and many of the same materials found in cotton gin trash.

14. "Cumulative metal loading rate" means the maximum amount of an element which can be applied to an area of land.

15. "Department" means the South Carolina Department of Health and Environmental Control.

16. "Flume grit" means a mixture of tree bark, sand, soil, small twigs and leaves, and other debris that settles out of water used in a woodyard log flume.

17. "Generator" means any person who produces solid waste that is land applied.

18. "Green liquor dregs" means residues from the paper pulp-making process removed by sedimentation from green liquor clarification. The material is predominantly insoluble carbonates, oxides and sulfates of calcium, magnesium, aluminum and silicon.

19. "Horticultural" means land used for production of flowers, shrubs, fruits and ornamentals.

20. "Inorganic constituent" is one of the ninety-two (92) naturally occurring chemical elements or combination of those elements; generally, this excludes constituents which consist of carbon compounds other than carbonates.

21. "Land application" means the spreading of non-hazardous solid waste on the land surface and/or the mechanical incorporation of non-hazardous solid waste into the soil at agronomic or silvicultural rates.

22. "Land Reclamation" means the restoration of land for useful purposes and protection of the natural resources of the surrounding area by establishing on a continuous basis the vegetative cover, soil stability, water conditions, and the safety conditions of the area.

23. "Lime" means calcium carbonate or other calcium and magnesium compounds or mixtures which are alkaline in nature and used to neutralize excess soil acidity.

24. "Metal," for purposes of these regulation, means any of the eight (8) naturally occurring elements as listed in Section C.13., and which include arsenic, cadmium, copper, lead, mercury, nickel, selenium, and zinc.

25. "Open dumping" means any unpermitted solid waste disposal activity.

26. "Pasture" means land used for grazing livestock or forage crop production.

27. "Permit" means the process by which the Department can ensure cognizance of, as well as control over, the management of solid wastes.

28. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

29. "Representative sample and representative analysis," for the purposes of this regulation, mean that the chemical analyses of at least three samples (each sample being a composite of several subsamples) shall be used to calculate the amount of waste to be applied to a specific area for crop production purposes with a tolerance of ±25%, unless otherwise approved by the Department. That tolerance applies to whichever constituent or characteristic, such as alkalinity, metal concentration, or nitrogen content, that limits or establishes the application rate.

30. "Silvicultural" means land used for growing trees, i.e., forestry.

31. "Slaker grit" means the unburned residues and particulate, predominantly carbonates, oxides and sulfates of calcium, magnesium and sodium removed from the causticizing process that recycles green liquor to white liquor for making paper pulp.

32. "Solid waste," for the purposes of this regulation, means any garbage, refuse, or other discarded material from industrial, commercial, mining, agricultural, silvicultural, and horticultural operations and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, 42 USCA 2011 et seq. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural, silvicultural, and horticultural operations, or refuse as defined and regulated pursuant to the South Carolina Mining Act, S.C. Code Section 48-20-10, et seq., including processed mineral waste, which will not have a significant adverse impact on the environment.

33. "Soluble salts" means the amount of chemical constituents in non-hazardous solid waste which are readily soluble in water as estimated by electrical conductivity.

34. "Surface water body," for the purposes of this regulation, means any body of water on the land's surface which holds visible water for greater than six (6) consecutive months, excluding drainage ditches, sedimentation ponds and other man-made operational features on the site.

35. "Total alkalinity" means a measure of the ability of a substance to neutralize acidity and is expressed as the calcium carbonate equivalent.

36. "Wood ash" means the residue derived from the combustion of wood, wood waste, bark or other plant tissue or products, including both bottom ash, fly ash and their mixtures.

37. "Woodyard wastes" means non-contaminated residues from woodyard operations, which may include bark, portions of tree limbs and logs, sand or soil, sawdust and wood chips.

C. General Provisions. The land application of all solid wastes, i.e., Classes I, II, III & IV shall be in accordance with the requirements established in this section unless otherwise stated.

1. Open dumping of solid waste is prohibited. Land application shall only be approved on land being managed for agricultural, silvicultural, or horticultural production and land reclamation projects.

2. Solid waste shall not be land applied except in accordance with the requirements established in this regulation.

3. The Department may impose more stringent requirements based on scientific and/or technical data than those established in this regulation or may issue variances on a case-by-case or site-specific basis when necessary to protect human health and/or the environment from unintended consequences associated with site characteristics or unusual characteristics of a specific solid waste.

4. The land application of solid waste shall adhere to all Federal, State and local zoning, land use and other applicable ordinances, regulations and laws.

5. If at any time the Department obtains quantitative data indicating that land application of solid waste poses an actual or potential threat to public health or the environment, or to threatened or endangered species, upon notification by the Department, the generator, applicator, and

landowner shall cease activities, evaluate the extent of the problem, and implement a corrective action program approved by the Department.

6. All vehicles used to transport solid waste for the purpose of land application shall be constructed and maintained so as to minimize dropping, sifting, blowing or other escapement of solid waste from the vehicle and shall be maintained and operated in accordance with all local, State, and Federal regulations.

7. Solid waste shall not be applied to flooded, ponded, frozen or snow-covered grounds.

8. Unless part of a normal or ongoing agricultural, silvicultural or horticultural operation, exempted by 33 USC 1345 of the Clean Water Act, land application of solid waste shall be in compliance with the U.S. Army Corps of Engineers and the U.S. Environmental Protection Agency requirements concerning wetlands.

9. For all wastes with the exception of Class III (i.e., cotton gin trash, cotton mote waste, bark, flume grit, etc.) a twelve (12) inch separation from the water table and the solid waste application zone shall be maintained during the actual application period. For Classes II and IV, the presence of the water table shall be determined based on interpretation of the data from a minimum of three (3) hand auger borings at least three (3) inches in diameter to a depth of two (2) feet. These holes shall be bored at the lowest point in the proposed application area and at two (2) other points in the proposed application area. The borings shall be covered and allowed to stand for twenty-four (24) hours. The water level in the borings shall be reported to the Department with the permit request.

10. The waste generator of Classes I and III shall ensure that the boundary of application shall not extend closer than the buffers outlined below. Variances may be requested and granted on a case-by-case basis upon submittal of written documentation that the variance will not cause an environmental or public health concern. (The buffer requirements for Classes II and IV are outlined in Sections E. and G. of this regulation.)

a. Fifty (50) feet of any property line. When the property borders a paved public two-lane road, the application shall not extend closer than fifty (50) feet from the center of the road;

b. One hundred (100) feet of any residence;

c. Five hundred (500) feet of any school, day-care center, hospital or recreational park area;

d. One hundred (100) feet of any surface water body; and,

e. One hundred (100) feet of drinking water wells.

11. The land application of solid waste shall be conducted in a manner to:

a. Inhibit the harborage of flies, rodents, and other vectors;

b. Prevent conditions for transmission of diseases to man and/or animals;

c. Minimize runoff, prevent water pollution and prevent the escape of the solid waste to waters of the State; and,

d. Minimize objectionable odors, dust, unsightliness, and aesthetically objectionable conditions, and prevent the accumulation of materials in an untidy and unsafe manner so as to become a fire, human health, environmental, and/or safety hazard.

12. Analyses of Class I, II and IV solid wastes required by this regulation for any parameter shall be analyzed by a laboratory certified for those parameters by the State Environmental Laboratory Certification Program unless otherwise noted in the regulation.

13. Solid wastes shall not be land applied when cumulative lifetime loads for heavy metals exceed the limits outlined below.

CUMULATIVE LIFETIME LOADING RATES

Metal	lb/ac	kg/ha
arsenic	37	41
cadmium	35	39
copper	1370	1500
lead	274	300
mercury	15	17
nickel	383	420
selenium	91	100
zinc	2550	2800

The Department may delete the requirement for any of the analyses for metals listed above if it can be demonstrated that a metal(s) is not expected to be contained in or derived from the waste to be land applied in concentrations and amounts that would cause environmental pollution or deterioration of soil quality. Likewise, the Department may require analysis of additional parameter(s) if it is demonstrated that a metal is expected to be contained in or derived from the waste to be land applied at a level that could present environmental and health problems at the proposed rate of application.

14. If other wastes are subsequently applied to the proposed location, documentation to include soil analyses performed by a Certified Laboratory shall be submitted to the Department with the annual report to show that the cumulative metal loads have not been exceeded.

15. The generator shall notify the Department prior to any changes in fuel source, process operations, or other changes that may alter the chemical characteristics of the waste.

16. The temporary storage of Class I and Class II solid wastes at the application site shall be limited to the amount designated for use at that location, and shall comply with the criteria outlined below if storage exceeds seven (7) days. (Temporary storage requirements for Class III and Class IV are outlined in Sections F. and G. respectively in this regulation.)

a. Temporary storage at the application site shall not exceed ninety (90) days;

b. Earthen dikes, berms or other suitable barriers shall be constructed around the perimeter of the storage area to minimize off-site movement of the waste materials;

c. Monitoring wells around the perimeter of the storage area may be required on a case-by-case basis upon written notification from the Department based on consideration of the type of waste, the amount of solid waste to be stored, topography of the land, and the potential impact to groundwater, etc. Any analyses required shall be performed by a Certified Laboratory;

d. Unless otherwise approved by the Department, materials to be stored for longer than thirty (30) days shall be covered with an impermeable barrier; and,

e. Temporary storage locations shall be reclaimed within one (1) year of construction by re-establishing the original groundline, incorporating into the soil any small amounts of residual materials by disking or plowing and revegetating the area for soil stabilization.

17. Solid waste being land applied shall be spread uniformly over the entire acreage approved for receipt of the waste at the rate approved for application. This is not intended to preclude banding or other commonly accepted methods routinely used for application of materials to soil for crop and silvicultural production purposes.

18. For a solid waste not specifically addressed in this regulation, a request and application for a permit to land apply the said waste shall be submitted to the Department. For the purposes of this regulation, the Department will classify solid waste for land application into the following four (4) categories:

a. Class I. Those solid wastes which require permitting by the Department prior to land application of that waste, e.g., wood ash, coal ash, green liquor dregs, and slaker grit.

b. Class II. Those solid wastes which, due to lack of substantiating data needed to calculate agronomic rate or to document that the material is non-toxic to plants, require issuance of a Department Research, Development, and Demonstration Permit pursuant to R.61-107.10.

c. Class III. Those solid wastes which require the generator to register the solid waste to be applied with the Department prior to any application, and subsequent notification to the Department prior to each application in lieu of permitting, e.g., cotton mote waste, cotton gin trash, bark, woodyard waste, flume grit.

d. Class IV. Those solid wastes used in land reclamation and other projects when the application rate exceeds ten (10) dry tons per acre per year and scientific/technical data is submitted to document the proposed application rate will have no detrimental impact on the environment and public health, and is non-toxic to plants and wildlife normally associated with the crop ecosystem. Class IV solid wastes require permitting by the Department prior to application.

19. The Department may reclassify waste from one class to another based on sound scientific data.

D. Class I Solid Waste for Land Application (e.g., coal ash, wood ash, green liquor dregs, slaker grit.)

1. The generator of the Class I solid waste shall obtain a permit from the Department for the land application of the specific waste(s) at proposed location(s) prior to commencing land application operations.

2. A permit for land application of a Class I solid waste shall be reviewed by the Department on an annual basis.

3. A request for a Department permit for the land application of a Class I solid waste shall include, but not be limited to, the following:

a. A completed permit application on a form provided by the Department;

b. A county map(s) showing the location of the proposed application site(s);

c. A chemical analysis (representative analysis) of the waste material to be land applied. This chemical analysis shall be conducted on samples collected within the last three (3) months and include the parameters listed below. This sample shall be a representative sample of the waste material to be applied. New representative samples shall be analyzed if there are changes in fuel source, process operations, or other changes which would alter the chemical characteristics of the waste. The frequency of sampling and the number of sample analyses needed to establish a representative analysis will vary according to the uniformity and consistency of the waste. At a minimum, the determination of representative analysis shall be reassessed each year but shall be sufficiently frequent and extensive so as to comply with Section B.29 of this regulation, the definition for "representative sample and representative analysis".

(1) The following parameters shall be analyzed by a South Carolina Certified Laboratory certified for these parameters:

(a) Total alkalinity;

(b) Concentrations of the following metals:

arsenic	cadmium
copper	lead
mercury	nickel
selenium	zinc

(c) Total Keldjahl nitrogen, nitrate-nitrogen, and ammonium-nitrogen;

(2) The following parameters shall be analyzed by an Agricultural Laboratory:

(a) Electrical conductivity of a saturated extract; and,

(b) Soluble boron, sodium, and sulfate;

d. A soil test from each proposed application site performed by an Agricultural Laboratory for agricultural purposes shall be submitted to the Department unless specifically exempted in the Department permit. The soil sample(s) shall be representative of the field(s) to which the waste will be applied. The soil sample shall be collected subsequent to the most recent application of fertilizer, lime, and other material which would alter the soil test results but no more than six (6) months prior to submittal of the data. This analysis shall include a recommendation for lime and plant nutrients needed or appropriate for good crop or forest production purposes based on Best Management Practices (BMPs) and the parameters listed below. (BMPs are available from the State Extension Service, various governmental agencies involved in management of agricultural, silvicultural or horticultural lands, Certified Crop Advisers, registered foresters, soil scientists, and agronomists.)

(1) pH;

(2) Lime requirement; and,

(3) Available phosphorus and potassium.

e. An application plan detailing:

(1) Rates to be applied at each location, expressed on an areal application basis;

(2) Cropping plan and proposed schedule for each application;

(3) Application method and safeguards to limit soil loss; and,

(4) Equipment to be used for uniform application.

4. To add additional application sites to the permit, the generator shall request a permit modification prior to application. The information listed below shall be submitted to the Department for approval. A variance of Item 4.b. and 4.c. below may be requested once a compliance history is established. Variances will be based on past compliance history, the consistency of the waste stream, the consistency of the soils, the consistency of crops, and submittal of scientific data to document that the application program will have no adverse impact on the environment and public health, and is non-toxic to plants and wildlife normally associated within the crop ecosystem.

a. A county map(s) showing the location of each proposed application site;

b. A soil test from each application site as outlined in Section D.3.d. above; and,

c. An application plan as outlined in Section D.3.e. above.

5. Class I Application Rates:

a. Unless otherwise approved by the Department, application rates for Class I solid wastes shall not exceed ten (10) dry tons per acre per year on cultivated crop or forest lands or five (5) dry tons per acre per year on pasture land in which the waste is not incorporated into the soil surface layer unless otherwise limited to a lower rate by soil test recommendation, agronomic rate, or metal loading. For example, nitrogen, boron, sodium, or soluble salts content and alkalinity may limit application rate to less than ten dry tons per acre per year; and,

b. Requests for application rates exceeding the limits outlined above will be reviewed on a case- and site-specific basis. Such projects may be considered if accompanied by appropriate soil and crop monitoring data for purposes of establishing relationships between soil physical characteristics and solid waste application rates, or relationships between long term, repeated applications and mobility or plant availability of elemental constituents of the solid waste or chemical processes in soil. Monitoring data obtained from such projects shall be assembled into a technical report and submitted to the Department. Requests for changes in application plans or locations shall be submitted in writing to the Department for review, consideration, and approval.

6. The following potential rate limiting factors shall establish the amount of waste that may be land applied. The application of waste shall not cause the soil pH to significantly fall below or rise above the range indicated. In addition, the application of waste shall not add more than the indicated amount of soluble sulfate, sodium, or boron. Nutrient limits are those recommended by the Clemson Cooperative Extension Service.

FACTOR	CONSTITUENT	LIMIT
pH (soil)		The application of waste shall not cause the soil pH to significantly fall below or rise above the range of 5.0 to 7.0.
Soluble Salts:		
	boron	4 lbs/acre; readily soluble boron as determined by hot water extraction
	sulfate	300 lbs/acre
	sodium	Less than 15% of base saturation of soil
Plant Nutrients:		Agronomic crops - consult Circular 476, Cooperative Extension Service, Clemson University, Clemson, 1982. The recommendations for nitrogen, phosphorus, and potassium are provided with agricultural soil tests. In addition, recommendations may be obtained from the local County Extension Office, a Certified Crop Adviser, an agronomist or soil scientist, or the Faculty of Soils at Clemson University.

FACTOR	CONSTITUENT	LIMIT
		Silvicultural sites - recommendation for nitrogen and other nutrients may be obtained from the Forest Resources Department at Clemson University, Area County Extension Agents for Forestry, or professional foresters with training in nutrient management.
Metals		As specified in Section C.13 of this regulation.

7. Unless otherwise approved by the Department, Class I solid waste may be applied to the same location more frequently than once each year as long as the total amount applied in any 12-month period does not exceed ten (10) dry tons per acre, if one of the factors cited above relating to agronomic rate or metal loading does not otherwise limit the loading rate.

8. No less than twenty-four (24) hours prior to land application of a Class I solid waste at an approved location, the generator shall notify the Department's EQC District Office and provide the following information:

a. The location to receive the application;

b. An estimate of the volume of waste to be land applied during the project;

c. The anticipated date to begin application activities; and,

d. The anticipated duration of the application activities.

9. Monitoring Requirements for Class I Solid Waste.

a. Solid Waste. Annually, or more frequently if necessary to document the waste concentration within a tolerance of ±25%, a new chemical analysis of a representative sample of the solid waste shall be submitted to the Department with the annual report. If there are substantive changes in fuel source, process operations, or other changes which would alter the chemical characteristics of the waste, additional sampling shall be required at that time. This analysis shall include the parameters listed in Section D.3.c.(1) of this regulation performed by a Certified Laboratory and those parameters listed in Section D.3.c.(2) performed by an Agricultural Laboratory.

b. Soil Analyses. Prior to a subsequent application of the solid waste, soil samples shall be analyzed by a Certified Laboratory for whichever constituent(s) or parameter(s) limited the previous application. The soil sample from pastures shall be taken from the surface 2-3 inches. Samples from cultivated fields and forested landscapes shall be taken from the surface 6 inches. If nitrogen was the limiting constituent, the soil sample shall be taken to a depth of 4 feet and divided into five subsamples (0-6, 6-12, 12-24, 24-36, and 36-48 inches) for analysis of ammonium-nitrogen and nitrate-nitrogen.

10. Reporting Requirements. Generators of Class I solid waste that is land applied shall maintain and report the information as outlined below.

a. The generator shall submit to the Department the following information in the form of an annual report for the period of July 1 through June 30. This report shall be submitted to the Department on or before August 15th and shall include:

(1) Any chemical analyses of the wastes performed during the reporting period subsequent to the original data submitted with the permit application request;

(2) Soil analyses for all locations that received an application of solid waste subsequent to the application of the amount of waste approved for the initial 12-month period, pursuant to Section D.9.b. above; and,

(3) The total amount of solid waste in tons land applied during the reporting period; and,

b. The generator shall maintain on site the following application site information and shall submit to the Department upon request:

(1) Location of the site(s) that received solid waste applications during the reporting period;

(2) Amount of solid waste applied to each site;

(3) Number of acres treated at each site;

(4) Date of application(s) at each site; and,

(5) The crop being grown on the application site.

E. Class II Solid Waste for Land Application.

1. The Department may issue a Research, Development, and Demonstration Permit (RD&D Permit) in accordance with Regulation 61-107.10 for the land application of Class II solid waste. RD&D Permits will be issued for the purpose of gathering soil and crop information when documentation and data are unavailable to ensure that:

a. Land application of a particular solid waste will have no detrimental impact to the environment or public health; and,

b. Application rates that exceed 10 tons per acre per year on cultivated or forest land and 5 tons per acre per year on pasture land will have no detrimental impact to the environment or public health.

2. Land application of Class II solid waste will be considered by the Department on a case-and site-specific basis.

3. Unless otherwise defined in the Department permit, the boundary of a Class II solid waste application shall not extend closer than:

a. One hundred (100) feet of any property line. Variances may be requested and granted on a case-by-case basis upon submittal of written consent from the adjacent landowner(s).

b. One hundred (100) feet of any residence;

c. Five hundred (500) feet of any school, day-care center, hospital or recreational park area;

d. One hundred (100) feet of any surface water body; and,

e. One hundred (100) feet of drinking water wells.

4. Class II solid waste applications shall address the following:

a. Relationships between soil physical characteristics and the solid waste application rates; or,

b. Relationships between long term, repeated applications and mobility or plant availability of elemental constituents of the solid waste or chemical processes in soil.

5. Monitoring data obtained from Class II applications shall be submitted to the Department in the form of a technical report concerning the effectiveness and the environmental effect of the application. This report will be reviewed by the Department and an approved independent scientist(s) prior to determining the acceptability of the solid waste for land application and/or the proposed application rate. If the research and demonstration project is successful, the Department may classify the waste as either a Class I, Class III or a Class IV waste for the purposes of this regulation.

6. No less than seventy-two (72) hours prior to land application of a Class II solid waste at an approved location, the generator shall call the Department's EQC District Office and provide the following information:

a. The location to receive the application;

b. An estimate of the volume of waste to be land applied during the project;

c. The anticipated duration of the application activities; and,

d. An implementation schedule.

F. Class III Solid Waste for Land Application (e.g., cotton mote waste, cotton gin trash, bark, woodyard waste, flume grit.)

1. Prior to land application of a Class III solid waste, the generator shall submit a request to the Department for registration of a specific solid waste. Registration in lieu of permitting is required for land application of Class III solid wastes. This submittal shall include a qualitative description of the waste and brief explanation of why the waste is considered to be innocuous with regard to effects on soil and water resources.

2. Registration for Class III solid waste shall be renewed with the Department every five (5) years.

3. A brief report summarizing the experiences of those who operate the land application sites as to their degree of satisfaction with the practice shall be submitted to the Department every five (5) years from the date of registration with a request for renewal of registration.

4. Land application of Class III solid wastes shall not exceed ten (10) dry tons per acre per year without written authorization from the Department.

5. The land application of all Class III solid wastes shall be in accordance with the requirements in Section C. of this regulation.

6. No less than twenty-four (24) hours prior to land application of any permitted or registered solid waste at an approved location, the generator shall call the Department's Environmental Quality Control District Office and provide the following information:

a. The location to receive the application;

b. An estimate of the volume of waste to be land applied during the project;

c. The anticipated date to begin application activities; and,

d. The anticipated duration of the application activities.

7. Temporary Storage.

a. The temporary storage of a registered Class III solid waste at the application site prior to application shall not exceed six (6) months. Appropriate measures shall be taken to prevent fires and to control mosquitoes and rodents in order to protect the public health and welfare, and to prevent public health nuisances associated with the waste being temporarily stored; and,

b. Temporary stockpile volumes shall be limited to the amount designated for use at that location.

G. Class IV Solid Waste for Land Application/Reclamation. Class IV solid wastes are those solid wastes used for land reclamation and other projects when the application rate exceeds ten (10) dry tons per acre per year and scientific/technical data is submitted to document that the proposed application rate will have no detrimental impact on the environment and public health, and is non-toxic to plants and wildlife normally associated with the crop ecosystem. Solid wastes used in land reclamation and other projects when the application rate is less than ten (10) dry tons per acre per year shall be classified as either Class I or III, as appropriate.

1. The generator of the Class IV solid waste shall obtain a permit from the Department for the land application of the specific waste(s) at proposed location(s) prior to commencing land application/reclamation operations.

2. A permit for land application of a Class IV solid waste shall be reviewed by the Department on an annual basis.

3. A request for a Department permit for the land application of a Class IV solid waste shall include, but not be limited to, the following:

a. A completed permit application on a form provided by the Department;

b. A 7.5 minute quadrant map (U.S. Geological Survey topographic map, including the legend and name of the quadrant) with the proposed application site(s) identified;

c. A site plan on a scale of four (4) inches per mile for each application site. This map shall at a minimum identify the following:

(1) Location of surface water bodies, dry runs, wetlands, the location of the 100-year flood plain boundaries, and other applicable details regarding the general topography of the application site and immediately adjacent properties;

(2) Land use immediately adjacent to the boundaries of the proposed site to demonstrate compliance with buffer requirements including the location of all homes, schools, hospitals, recreational park areas, drinking water wells, and roads;

(3) Restricted or excluded areas; and,

(4) Proposed temporary storage area(s);

d. A Chemical analysis (representative analysis) of the waste material to be land applied. This chemical analysis shall be conducted on samples collected within the last three (3) months and include the parameters listed below. This sample shall be a representative sample of the waste

material to be applied. New representative samples shall be analyzed if there are changes in fuel source, process operations, or other changes that would alter the chemical characteristics of the waste. The frequency of sampling and the number of sample analyses needed to establish a representative analysis will vary according to the uniformity and consistency of the waste. At a minimum, the determination of representative analysis shall be reassessed each year but shall be sufficiently frequent and extensive so as to comply with Section B.29 of this regulation, the definition for "representative sample and representative analysis".

(1) The following parameters shall be analyzed by a South Carolina Certified Laboratory certified for these parameters:

(a) Total alkalinity;

(b) Concentrations of the following metals:

arsenic	cadmium
copper	lead
mercury	nickel
selenium	zinc

(c) Total Keldjahl nitrogen, nitrate-nitrogen, and ammonium-nitrogen;

(2) The following parameters shall be analyzed by an Agricultural Laboratory:

(a) Electrical conductivity of a saturated extract; and,

(b) Soluble boron, sodium, and sulfate;

e. A soil test from each proposed application site performed by an Agricultural Laboratory for agricultural purposes shall be submitted to the Department unless specifically exempted in the Department permit. The soil sample(s) shall be representative of the field(s) to which the waste will be applied. The soil sample shall be collected subsequent to the most recent application of fertilizer, lime, and other material which would alter the soil test results but no more than six (6) months prior to submittal of the data. This analysis shall include a recommendation for lime and plant nutrients needed or appropriate for good crop or forest production purposes based on Best Management Practices (BMPs) and the parameters listed below. (BMPs are available from the State Extension Service, various governmental agencies involved in management of agricultural, silvicultural or horticultural lands, Certified Crop Advisers, registered foresters, soil scientists, and agronomists.)

(1) pH;

(2) Lime requirement; and,

(3) Available phosphorus and potassium.

f. An application plan detailing:

(1) Rates to be applied at each location, expressed on an areal application basis;

(2) Cropping plan and proposed schedule for each application;

(3) Application method and safeguards to limit soil loss; and,

(4) Equipment to be used for uniform application.

4. To add additional application sites to the permit, the generator shall request a permit modification prior to application. The following information shall be submitted to the Department for approval:

a. A 7.5 quadrant map as outlined in Section G.3.b. above.

b. A site plan as outlined in Section G.3.c. above.

c. A soil test from each application site as outlined in Section G.3.e. above; and,

d. An application plan as outlined in Section G.3.f. above.

5. Unless otherwise defined in the Department permit, the boundary of a Class IV solid waste application shall not extend closer than:

a. One hundred (100) feet of any property line. Variances may be requested and granted on a case-by-case basis upon submittal of written consent from the adjacent landowner(s).

b. One hundred (100) feet of any residence;

c. Five hundred (500) feet of any school, day-care center, hospital or recreational park area;

d. One hundred (100) feet of any surface water body; and,

e. One hundred (100) feet of drinking water wells.

6. Class IV application rates will be reviewed on a case-and site-specific basis. Such projects will be considered if accompanied by appropriate soil and crop monitoring for purposes of establishing relationships between soil physical characteristics and solid waste application rates, or relationships between long term, repeated applications and mobility or plant availability of elemental constituents of the solid waste or chemical processes in soil. Monitoring data obtained from Class IV projects shall be assembled into a technical report and shall be submitted to the Department at the end of the project.

7. The following potential rate limiting factors shall establish the amount of waste that may be land applied. The application of waste shall not cause the soil pH to significantly fall below or rise above the range indicated. In addition, the application of waste shall not add more than the indicated amount of soluble sulfate, sodium, or boron. Nutrient limits are those recommended by the Clemson Cooperative Extension Service.

FACTOR	CONSTITUENT	LIMIT
pH (soil)		The application of waste shall not cause the soil pH to significantly fall below or rise above the range of 5.0 to 7.0.
Soluble Salts:		
	boron	4 lbs/acre; readily soluble boron as determined by hot water extraction
	sulfate	300 lbs/acre
	sodium	Less than 15% of base saturation of soil
Plant Nutrients:		Agronomic crops - consult Circular 476, Cooperative Extension Service, Clemson University, Clemson, 1982. The recommendations for nitrogen, phosphorus, and potassium are provided with agricultural soil tests. In addition, recommendations may be obtained from the local County Extension Office, a Certified Crop Adviser, an agronomist or soil scientist, or the Faculty of Soils at Clemson University. Silvicultural sites - recommendation for nitrogen and other nutrients may be obtained from the Forest Resources Department at Clemson University, Area County Extension Agents for Forestry, or professional foresters with training in nutrient management.
Metals		As specified in Section C.13 of this regulation.

8. Class IV solid waste may be applied to the same location more frequently than once each year as long as the total amount applied to any location:

a. Does not exceed the cumulative lifetime metal loading rate;

b. Does not exceed the annual application rate permitted by the Department; and,

c. Is non-toxic to plants and wildlife normally associated with the crop ecosystem.

9. Requests for changes in application plans or locations shall be submitted in writing to the Department for review, consideration, and approval.

10. The generator shall ensure that the Class IV solid waste is uniformly spread over the entire acreage and incorporated into the soil, e.g., that heavy equipment is available to properly spread and incorporate the waste.

11. No less than seventy-two (72) hours prior to land application of a Class IV solid waste at an approved location, the generator shall notify the Department's EQC District Office and provide the following information:

a. The location to receive the application;

b. An estimate of the volume of waste to be land applied during the project;

c. The anticipated date to begin application activities; and,

d. The anticipated duration of the application activities.

12. The temporary storage of Class IV solid wastes at the application site shall be limited to the amount designated for use at that location, and shall comply with the criteria outlined below if storage exceeds forty-eight (48) hours.

a. Temporary storage at the application site shall not exceed two (2) weeks;

b. Earthen dikes, berms or other suitable barriers shall be constructed around the perimeter of the storage area to minimize off-site movement of the waste materials;

c. Monitoring wells around the perimeter of the storage area may be required upon written notification from the Department on a case-by-case basis based on consideration of the type of waste, the amount of solid waste to be stored, topography of the land, and the potential impact to groundwater, etc. Any analyses required shall be performed by a Certified Laboratory; and,

d. Temporary storage locations shall be reclaimed within thirty (30) days of construction by re-establishing the original groundline, incorporating into the soil any small amounts of residual materials by disking or plowing and revegetating the area for soil stabilization.

13. Monitoring Requirements for Class IV Solid Waste.

a. Solid Waste. Annually, or more frequently if necessary to document the waste concentration within a tolerance of ±25%, a new chemical analysis of a representative sample of the solid waste shall be submitted to the Department with the annual report. If there are substantive changes in fuel source, process operations, or other changes which would alter the chemical characteristics of the waste, additional sampling shall be required at that time. This analysis shall include the parameters listed in Section G.3.d.(1) of this regulation performed by a Certified Laboratory and those parameters listed in Section G.3.d.(2) performed by an Agricultural Laboratory.

b. Soil Analyses. Prior to a subsequent application of the solid waste, soil samples shall be analyzed by a Certified Laboratory for whichever constituent(s) or parameter(s) limited the previous application. The soil sample from pastures shall be taken from the surface 2-3 inches. Samples from cultivated fields and forested landscapes shall be taken from the surface 6 inches. If nitrogen was the limiting constituent, the soil sample shall be taken to a depth of 4 feet and divided into five subsamples (0-6, 6-12, 12-24, 24-36, and 36-48 inches) for analysis of ammonium-nitrogen and nitrate-nitrogen.

14. Reporting Requirements. Generators of Class IV solid waste that is land applied shall submit to the Department and to the landowner, an annual report for the period of July 1 through June 30. This report shall be submitted to the Department on or before August 15th and shall include the information outlined below. This information shall be maintained by the generator for a period not less than ten (10) years.

a. Any chemical analyses of the wastes performed during the reporting period subsequent to the original data submitted with the permit application request;

b. Any soil analyses performed during the reporting period subsequent to the original data submitted with the permit application request;

c. Application Site Information. The following information shall be included in the annual report:

(1) Location of the site(s) that received solid waste applications during the reporting period;

(2) Amount of solid waste applied to each site;

(3) Number of acres treated at each site;

(4) Date of application(s) at each site; and,

(5) The crop(s) being grown on the application site(s).

H. Violations and Penalties. A violation of this regulation or any permit, order, or standard subjects the person to the issuance of a Department order or to civil enforcement action in accordance with S.C. Code Section 44-96-450. Willful violation of this regulation or any permit, order, or standard subjects the person to the issuance of a Department order or to criminal enforcement action in accordance with S.C. Code Section 44-96-450. Any person to whom an order is issued may appeal it as a contested case pursuant to R.61-72, Procedures for Contested Cases, and the S.C. Administrative Procedures Act, S.C. Code Section 1-23-310 et seq.

I. Severability. Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Added by State Register Volume 20, Issue No. 7, eff July 26, 1996.

61–107.17. Solid Waste Management: Demonstration-of-Need.

(Statutory Authority: 1976 Code Sections 44–96–10 et seq.)

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A. Applicability.

1. This regulation establishes the criteria for the demonstration-of-need for the construction of new and the expansion of existing commercial Class Two solid waste landfills, commercial Class Three solid waste landfills, commercial solid waste incinerators, and commercial solid waste processing facilities that process waste destined for disposal at Class Three solid waste landfills. Any solid waste management facility type listed herein that no longer has a valid permit to operate prior to the effective date of this regulation and attempts to reopen after the effective date of this regulation shall be considered a new facility and shall be required to demonstrate need pursuant to this regulation. Any existing facility that requests a change in classification or commercial status shall be considered a new facility and required to demonstrate need pursuant to this regulation. Commercial Class Three solid waste landfills permitted to accept only industrial waste that request approval to accept municipal solid waste shall be considered a new facility and required to demonstrate need pursuant to Sections C and D of this regulation.

2. This regulation does not apply to:

a. Class Two solid waste landfills, Class Three solid waste landfills, solid waste incinerators, or solid waste processing facilities that accept only waste generated in the course of normal operations on property under the same ownership or control as the solid waste management facility if the facility is classified as a non-commercial solid waste management facility. All other solid waste management facilities for the purpose of demonstrating need shall be considered commercial facilities;

b. Facilities that handle hazardous waste as defined by the Resource Conservation and Recovery Act (RCRA) and R.61–79, Hazardous Waste Management Regulations, and infectious waste as defined by R.61–105, Infectious Waste Management Regulations;

c. Air curtain incinerators that receive only wood waste and yard trash;

d. The processing of waste at the source of generation; and,

e. The processing of waste at permitted Class Three solid waste landfills destined for disposal at the landfill.

B. Definitions for the Purposes of this Regulation.

1. "Class Two solid waste landfills" means those landfills as described in Part IV, Section A of Regulation section 61–107.19. Solid Waste Management: Solid Waste Landfills and Structural Fill.

2. "Class Three solid waste landfills" means those landfills as described in Part V, Subpart A of Regulation section 61–107.19.

3. "Commercial solid waste management facility" means for the purposes of this regulation, all solid waste management facilities with the exception of non-commercial facilities.

4. "County or Regional Solid Waste Management Plan" means a solid waste management plan prepared, approved, and submitted by either a single county or a region, i.e., a group of counties, pursuant to the Solid Waste Policy and Management Act, S.C. Code Section 44–96–80 (1976, as amended).

5. "Consistency determination" means for the purposes of this regulation, a Department decision that a proposed solid waste project is or is not consistent with:

a. State and County/Region Solid Waste Management Plans;

b. Local zoning and land-use ordinances and regulations based on due consideration of written documentation from an appropriate local government official verifying that applicable local requirements have been met;

c. All other applicable local ordinances; and,

d. Buffer requirements pursuant to the appropriate Department regulation, e.g. Regulation sections 61–107.19, Part IV.B.1.a for Class Two solid waste landfills; 61–107.19, Part V, Subpart B.258.18.a for Class Three solid waste landfills; 61-107.12.E.8 for Solid Waste Incinerators; and 61-107.6.E.8 for Solid Waste Processors.

6. "Department" means the South Carolina Department of Health and Environmental Control.

7. "Disposal rate" means the total amount, either by tonnage or volume, of waste received at the solid waste disposal facility on a fiscal year (July 1 - June 30) basis.

8. "Expand" or "Expansion" means any increase in the permitted volumetric capacity of an existing solid waste management facility.

9. "Non-commercial solid waste management facility" means a facility that manages only solid waste that is generated in the course of normal operations on property under the same ownership or control as the solid waste management facility.

10. "Planning area" means the area around a solid waste management facility that is used for determining the need for new and expansions of existing facilities.

11. "Region" means a group of counties which is planning to or has prepared, approved, and submitted a regional solid waste management plan to the Department pursuant to S.C. Code Section 44–96–80 (1976, as amended).

12. "Solid waste" means any garbage, refuse, or sludge from a waste treatment plant, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining and agricultural operations, and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1964, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

13. "Solid waste incinerators" means any engineered device used in the process of controlled combustion of solid waste for the purpose of reducing the volume, and/or reducing or removing the hazardous potential of the waste charged by destroying combustible matter leaving the noncombustible

ashes, material and/or residue. For the purposes of this regulation, solid waste pyrolysis facilities, waste-to-energy facilities burning solid waste used for energy recovery, and air curtain incinerators that burn only wood waste and yard trash are not included in this definition.

14. "Solid waste management facilities" means Class Two solid waste landfills, Class Three solid waste landfills, solid waste incinerators, and solid waste processing facilities that process waste destined for disposal at Class Three solid waste landfills.

15. "State Solid Waste Management Plan" means the plan which the Department of Health and Environmental Control is required to submit to the General Assembly and to the Governor pursuant to S.C. Code Section 44–96–60 (1976, as amended).

16. "Solid waste processing facility" means those facilities as defined in Regulation section 61–107.6, Solid Waste Management: Solid Waste Processing Facilities.

C. Demonstration-of-Need Requirements.

1. No permit to construct a new or to expand the volume or capacity of an existing commercial Class Two solid waste landfill, Class Three solid waste landfill, solid waste incinerator, or solid waste processing facility that processes waste destined for disposal at a Class Three solid waste landfill shall be issued until a final demonstration-of-need and a consistency determination are approved by the Department. In determining whether there is a need for new or expanded solid waste management facilities listed in Section C.2, or in determining increases in annual disposal rates, the Department will consider only solid waste generated in jurisdictions subject to the provisions of a county or regional solid waste management plan pursuant to S.C. Code Section 44–96–80. Any increase in the disposal rate shall not require a demonstration-of-need as long as the requested increase in disposal rate is less than the maximum disposal rate as determined by Section D.3.

2. Need shall be demonstrated for the following commercial solid waste management facilities:

a. Class Two solid waste landfills;

b. Class Three solid waste landfills;

c. Solid waste incinerators; and,

d. Solid waste processing facilities that process waste destined for disposal at Class Three solid waste landfills.

3. Planning Area. The following planning areas shall be used by the Department for determining if the demonstration-of-need has been met for commercial facilities pursuant to this regulation:

Commercial Solid Waste Management Facility	Size of Planning Area Around Solid Waste Management Facility
Class Two solid waste landfills	20-mile radius
Class Three solid waste landfills	75-mile radius
Solid waste incinerators	75-mile radius
Solid waste processing facilities	75-mile radius

4. Requests for demonstration-of-need will be reviewed by the Department in the order in which they are received. If a request for demonstration-of-need is not accompanied by a request for a consistency determination pursuant to Section B.5 of this regulation, and need is demonstrated, the location for the proposed facility will be reserved for sixty (60) days. Failure to submit a consistency request within sixty (60) days of submittal of a demonstration-of-need request will result in termination of the reservation of the location for the proposed facility.

5. Demonstration-of-need determinations issued by the Department may be terminated, upon written notification by the Department, if either of the following occurs:

a. Failure to show evidence of diligent pursuit of the appropriate solid waste permit or any related necessary approval, including proof of property control, within one hundred twenty (120) days of the applicant's submittal of the demonstration-of-need request; or,

b. The Department denies the permit application.

6. Where, prior to the effective date of this regulation, the Department made determinations required under Part I.D.1.a. of South Carolina Regulation 61–107.19, such determinations shall remain applicable and become the agency's final determination subject to the appeal provision in

Section F of this regulation and any applicable public notice and application requirements. All demonstration of need determinations are subject to termination criteria outlined in Sections C.4 and C.5 of this regulation regardless of when the determination was made.

D. Demonstration-of-Need Application Process.

1. Prior to submitting a permit application to the Department for a new or expansion of an existing Class Two solid waste landfill, Class Three solid waste landfill, solid waste incinerator, or solid waste processing facility that processes waste destined for disposal at a Class Three solid waste landfill, the applicant shall submit to the Department a demonstration-of-need request that includes the following information:

a. The name of the facility. This name will be used in future correspondence to identify the facility;

b. Applicant contact information to include the following:

(1) Name of applicant;

(2) Address;

(3) Telephone number;

(4) Fax number; and,

(5) E-mail address (optional);

c. The geographical coordinates of the facility using the geographic center of the incinerator or processing facility as the reference point, or the geometric center of the landfill footprint as the reference point, as well as a brief description of the location. For expansions, the reference point shall be the center of the facility as assigned by the Department. Use either latitude/longitude coordinate system in degrees, minutes and seconds (preferred) or the Universal Transverse Mercator (UTM) coordinate system. Describe the method for determining coordinates;

d. The type facility, i.e., Class Two solid waste landfill, Class Three solid waste landfill, solid waste incinerator, or solid waste processing facility;

e. The annual disposal rate or throughput, as applicable, in tons/year (specify the desired annual tonnage within the applicable limits);

f. The name of the host county/region; and,

g. The applicant's signature.

2. In determining if there is a need for a new or expansion of an existing solid waste management facility, the Department will use the following criteria:

a. Where there are at least two (2) commercial solid waste management facilities of the same type within the planning area, no new capacity shall be allowed. Landfills in post-closure shall not be considered in determining need.

b. The Department reserves the right to review additional factors in determining need on a case-by-case basis.

3. In determining the maximum allowable yearly disposal rate for Class Three or Class Two solid waste landfills, the Department will use the following criteria:

a. Each new Class Three solid waste landfill permitted after the effective date of this regulation shall be initially allowed up to a maximum yearly disposal rate equal to the total amount of solid waste generated in the planning area for disposal in Class Three landfills as follows, unless otherwise provided in section C.6:

(1) 100 percent of the host county; and,

(2) 50 percent of each county, other than the host county, that falls wholly or partially within the 75-mile radius that does not have a Class Three landfill that accepts municipal solid waste located in that county.

(3) Solid waste generated in counties, other than the host county, that have at least one Class Three Landfill, is not counted in this calculation.

b. Each new Class Two solid waste landfill permitted after the effective date of this regulation shall be initially allowed up to a maximum yearly disposal rate equal to the total amount of solid

waste generated in the planning area for disposal in Class Two Landfills as follows, unless otherwise provided in section C.6:

(1) 100 percent of the host county; and,

(2) 30 percent of each county, other than the host county, that falls wholly or partially within the 20-mile planning radius.

c. An existing Class Three solid waste landfill operating within 20 percent of the permitted yearly disposal rate stated in the current permit, as documented in the most recently published S.C. Solid Waste Management Annual Report when the request is made, may submit a request for an increase in the permitted yearly disposal rate and will be allowed to increase the maximum yearly disposal rate based on the following:

(1) A Class Three landfill that has a permitted annual disposal rate greater than 30 percent of the total amount of waste generated in all jurisdictions subject to the provisions of a county or regional plan pursuant to S.C. Code Section 44–96–80 that is destined for disposal in Class Three Landfills shall not receive any increase in its yearly annual disposal rate;

(2) A Class Three Landfill that has a permitted annual disposal rate less than or equal to 30 percent pursuant to Section D.3.c(1) shall receive the lesser of either: (a) 150,000 tons or (b) the increase in waste generated by all jurisdictions that are subject to the provisions of a county or regional plan pursuant to S.C. Code Section 44–96–80 for disposal at Class Three Landfills, since the last increase in the permitted annual disposal rate at said landfill, as reported in the most recently published S.C. Solid Waste Management Annual Report when the request is made.

d. An existing Class Two solid waste landfill operating within 20 percent of the permitted yearly disposal rate stated in the current permit, as documented in the most recently published S.C. Solid Waste Management Annual Report when the request is made, shall be allowed to increase the maximum yearly disposal rate based on the following:

(1) The lesser of either: (a) 50,000 tons or (b) the increase in waste generated in the planning area for disposal at Class Two landfills, since the last increase in the permitted annual disposal rate for said landfill, as reported in the most recently published S.C. Solid Waste Management Annual Report when the request is made or,

(2) A variance to the permitted annual disposal rate may be granted for a specified term, corresponding to the need, in the event of an emergency or documented large project with a specified term, as determined solely by the Department. This temporary increase in annual disposal rate, if granted, is not considered by the Department when determining if a facility is within 20 percent of its permitted annual disposal rate.

e. In determining the amount of solid waste destined for disposal and solid waste generation amounts, the Department will use figures reflecting the previous fiscal year amount of solid waste as reported in the most recently published S.C. Solid Waste Management Annual Report, when the request is made, for the appropriate waste, (e.g. Class Two, Class Three, etc.). Annual disposal rates for facilities permitted prior to the effective date of this regulation shall not be reduced pursuant to Section D of this regulation.

4. The maximum allowable yearly throughput of a solid waste processing facility that processes waste destined for disposal at a Class Three solid waste landfill shall be equal to the total amount of solid waste destined for disposal that is generated in the host county and 50 percent of the waste generated in each county other than the host county, that falls wholly or partially within the 75-mile planning radius.

5. The yearly throughput for a solid waste incinerator shall be based on the manufacturer's design of the incinerator but shall not exceed 600 tons per day.

6. Variance in regard to demonstration of need. The Department shall grant a variance to the requirements of D.2 for Class Two and Class Three solid waste landfills according to the following conditions:

a. An operating Class Two or Class Three landfill shall receive a variance to construct a replacement Class Two or Class Three landfill at its permitted annual rate of disposal provided it meets all of the following conditions:

(1) For a Class Three landfill only, the primary business of the landfill since it began operation has been the disposal of "household waste" and "commercial waste" as defined in S.C. Regulation section 61–107.19.

(2) The landfill has a permit issuance date on or before the effective date of this Regulation.

(3) The landfill exhausts its permitted capacity at its current location (see 6.e below for timing).

(4) For the purpose of considering the location of a replacement facility under this section, the location for the replacement facility must be within the facility's existing planning area, provided that, if the planning area includes a portion of a county, the entire county will be considered to be part of the planning area. A Class Two or Class Three landfill, once replaced as provided for in Section D. 6.a., is no longer eligible to receive a variance for replacement under this section.

b. A Class Two or Class Three landfill shall receive a variance to expand the volume of an existing facility.

c. A facility receiving a variance under this section must meet the requirements of S.C. Regulation section 61–107.19 prior to receiving a permit.

d. No variance under this section will be granted to a facility that is under a unilateral administrative order issued by the Department until the issues associated with said order have been resolved.

e. An eligible facility shall apply to the Department for a variance to replace or expand the volume of an existing facility prior to exhausting: (1) its permitted capacity, or (2) the operational life of the facility. A facility shall not operate under an expansion variance and a replacement variance simultaneously, with the exception of a reasonable transition period as determined by the Department. A reasonable transition period is considered to be approximately one hundred eighty (180) calendar days.

7. The Department will advise the applicant and the host county or region in writing of its demonstration-of-need determination. Notice of the Department's demonstration-of-need determination for Class Two and Three landfills must be given in accordance with S.C. Regulation section 61–107.19.

E. Violations and Penalties.

A violation of this regulation or violation of any permit, order, or standard subjects the person to the issuance of a Department order, or a civil or criminal enforcement action in accordance with S.C. Code Section 44–96–450 (1976, as amended). In addition, the Department may impose reasonable civil penalties not to exceed ten thousand dollars ($10,000.00) for each day of violation of the provisions of this regulation, including violation of any order, permit or standard.

F. Appeals.

1. A Demonstration-of-need determination may be appealed at the time such determination is issued and may not be raised as part of an appeal of a decision on the permit.

2. A Department decision involving a demonstration-of-need may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

G. Severability.

Should any section, paragraph, sentence, word, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Added by State Register Volume 24, Issue No. 6, eff June 23, 2000. Amended by State Register Volume 33, Issue No. 6, eff June 26, 2009.

61–107.18. Solid Waste Management: Off-site Treatment of Contaminated Soil.

A. Applicability.

1. This regulation establishes minimum standards for the procedures, documentation, and other requirements which must be met for the proper site selection, design, operation, and closure of facilities treating contaminated soil and soil-like materials, here in after referred to as soil, which is not hazardous waste as defined by Resource Conservation and Recovery Act (RCRA), Public Law

94–580, and R.61–79, Hazardous Waste Management Regulations promulgated pursuant to the South Carolina Hazardous Waste Management Act, (SCHWMA), as amended, S.C. Code Ann. Section 44–56–10 et seq., and that has been excavated and is being treated off-site. Off-site treatment processes include, but are not limited to: biological, low-temperature thermal desorption, composting, prepared beds, bioreactors, soil slurry reactors, chemical oxidation, soil washing, incineration, and biopile technology. Other Department or other agency laws and regulations may apply to the treatment or handling of soil not addressed in this regulation and to other entities who might handle the soil before or after treatment.

2. This regulation is not applicable to on-site treatment of contaminated soil of any kind.

3. A research, development, and demonstration (RD&D) permit, pursuant to R. 61–107.10, Solid Waste Management: Research, Development, and Demonstration Permit Criteria, may be required for the treatment of soil based on the contaminant and the proposed treatment technology, and at the discretion of the Department.

B. Definitions As Used In This Regulation.

1. "Aerobic" means able to live, grow, or take place only when free oxygen is present.

2. "Biological treatment" means the degradation of contaminants of concern in soil by increasing the microbial activity through the aeration and/or addition of minerals, nutrients, and/or moisture.

3. "Biopile technology" means heaping contaminated soil into piles (or cells) and stimulating microbial activity within the soil through aeration and/or addition of minerals, nutrients, and/or moisture.

4. "Bioreactor" means a contained vessel in which biological treatment takes place, e.g., fermentor.

5. "BTEX" means the total chemical constituents benzene, toluene, ethyl benzene, and total xylenes.

6. "Chemical oxidation" means a chemical reaction that increases the oxygen content in a compound or a reaction in which an element or ion loses electrons, resulting in a more positive valence.

7. "Class I soil" means soil contaminated with one or more of the following contaminants: gasoline, jet fuels, diesel fuels, kerosene, distillate fuel oils (number one and number two fuel oils), and other contaminants as approved by the Department for this classification.

8. "Class II soil" means soil contaminated with one or more of the following contaminants: combination fuel oils (number three and number four fuel oils), residual fuel oils (number five and number six fuel oils), virgin lubricating oils, used oils, weathered oils, other petroleum based products not listed in Class I, and other contaminants as approved by the Department for this classification.

9. "Class III soil" means soil contaminated with any contaminant other than those listed under Class I or Class II.

10. "Composting" means treatment of contaminated soil by aerobic biodegradation of contaminants in an above ground, contained, or uncontained environment.

11. "Contaminated soil" means soil and soil-like material containing contaminants at a concentration that the Department has deemed poses a potential threat to human health and/or the environment and that does not constitute a hazardous waste, as defined by RCRA, the SCHWMA, and the Regulations promulgated pursuant thereto, as amended.

12. "Department" means the South Carolina Department of Health and Environmental Control.

13. "Existing facility" means those facilities in place and operating on the effective date of this regulation.

14. "Ex-situ" means the excavation of contaminated soil from its original location followed by treatment off-site.

15. "Facility" means all contiguous land, structures, other appurtenances and improvements on the land used for treating and storing waste. A facility may consist of several treatment, storage, or disposal operational units.

16. ''Generator'' means any person whose act or process produces or results in contaminated soil.

17. ''Incineration'' means an ex-situ technology that uses heating to volatilize and combust organic constituents.

18. ''In-situ'' means the treatment of contaminated soil on-site without excavation of the soil.

19. ''Leachate'' means a liquid that has passed through or emerged from contaminated soil and contains soluble, suspended, or miscible materials removed from such soil.

20. ''Low-Temperature Thermal Desorption'' (LTTD), also known as ''low-temperature thermal volatilization,'' ''thermal stripping,'' and ''soil roasting,'' means the ex-situ technology that uses heat to physically separate contaminants from excavated soil. Vaporized hydrocarbons may require treatment in a secondary treatment unit, such as an afterburner, prior to atmospheric discharge.

21. ''New facility'' means those treatment facilities not in place and operating on the effective date of this regulation.

22. ''Off-site'' means a location other than the property on which the contamination of the soil occurred and any contiguous property under the same ownership.

23. ''On-site'' means the property on which the contamination of the soil occurred and all contiguous property under the same ownership.

24. ''Open-dumping'' means any unpermitted solid waste disposal activity.

25. ''Owner/operator'' means the person who owns the land on which a solid waste management facility is located or the person who is responsible for the overall operation of the facility, or both.

25. ''PAH'' means polynuclear aromatic hydrocarbons

26. ''Person'' means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

27. ''Prepared beds'' means a contained area above ground where soil can be tilled or variously manipulated to increase biological treatment, i.e., contained land farming.

28. ''RD&D Permit'' means a research, development and demonstration permit issued pursuant to R.61–107.10.

29. ''Residence'' means any structure, all or part of which is designed or used for human habitation, that has received a final permit for electricity, permanent potable water supply, permanent sewage disposal, and a certificate of occupancy, if required by the local government.

30. ''Road base'' means that portion of road construction which is over-lain with a permanent impervious surface.

31. ''Shipment'' means all soil from the same release area.

32. ''Soil-like material'' means material, man-made or naturally occurring, that has good absorption capabilities and is used to absorb and bulk solid waste spills, e.g., kaolin clay, bentonite, kitty litter, sand, vermiculite.

33. ''Soil slurry reactor'' means biological or chemical treatment of soil by making a mixture with water and treating in a contained vessel.

34. ''Soil treatment facility'' means a facility that treats contaminated soil and soil-like material.

35. ''Soil venting,'' means a method to remove volatile and semi-volatile contaminants from soil. A positive or negative air pressure is applied either passively or actively to soil to remove vapors which are appropriately treated.

36. ''Soil washing'' means an ex-situ process to mechanically scrub soil to remove contaminants. Soft particles are separated from soil in an aqueous-based system. The wash water may be augmented with leaching agents, surfactants, pH adjustment or chelating agents.

37. ''TCLP'' means Toxicity Characteristic Leaching Procedure, a laboratory test used to determine if a substance is a hazardous waste due to leachability. The TCLP (Method 1311) is published in ''Test Methods for Evaluating Solid Waste, Physical/Chemical Methods,'' EPA Publication SW-846, as incorporated by reference in R.61–79.260.11.

38. ''TPH'' means total petroleum hydrocarbons.

39. "Treatment" means the off-site manipulation of contaminated soil in a confined and regulated environment to bring the soil into compliance with standards established in this regulation.

40. "Used Oil" means any oil that has been refined from crude oil or synthetic oil that has been used, and as a result of such use is contaminated by physical or chemical impurities.

41. "Virgin oil" means oil that has never been used or weathered.

42. "Waste profile sheet" means a form filled out by the waste generator outlining specific information regarding the generator, generator's site location, generating process information, and a full waste characterization. This includes describing the chemical and physical (solid, liquid, or gas) characteristics of the solid waste, a description of the waste including a list of the chemical contaminants in the waste, analytical testing certification, quantity, and container size for proper disposal. The generator shall submit the waste profile sheet to the treatment facility for approval prior to shipment of soil pursuant to this regulation.

43. "Weathered oil" means oil that has been exposed to leaching and low-level biodegradation or biotransformation and soil chemical reactions for extended periods of time, resulting in a contaminant chemical composition that is no longer virgin oil.

C. General Provisions.

1. The siting, design, construction, operation, and closure activities for facilities that treat contaminated soil shall conform to the standards set forth in this regulation, unless otherwise approved by the Department. Engineering plans, specifications, reports and other documents approved by the Department during the review process shall become enforceable documents upon issuance of a permit pursuant to this regulation. Facilities shall be constructed as approved and permitted.

2. Prior to the construction of a new soil treatment facility, a permit shall be obtained from the Department pursuant to this regulation. Prior to the modification of an existing soil treatment facility, as-built drawings of the existing facility which have current Department approval shall be submitted in addition to plans and specifications of proposed modifications to the facility. Any modification to the design/operation of a facility that would change the language of the permit shall receive prior Department approval.

3. Prior to operation of a new permitted soil treatment facility or a permitted modification to an existing facility, the facility shall be inspected by the Department and receive operational approval.

4. The Department reserves the right to require the soil treatment facility to acquire an RD&D permit pursuant to Regulation 61–107.10 for any process or compound for which the information provided is deemed insufficient to establish the efficacy of the proposed process to the Department's satisfaction. If, after the two (2) years expiration of the RD&D permit, the process is proved to be a viable method for treating soil, a permit pursuant to this regulation may be issued for the process. Petroleum and other compounds that have been shown to be highly degradable via the proposed treatment process will not generally require a RD&D permit. A permit requested pursuant to this regulation may be denied should the process not be determined to be acceptable to the Department's satisfaction.

5. No later than six (6) months from the effective date of this regulation, existing soil treatment facilities shall submit to the Department a permit application with supporting documents as outlined in Section D of this regulation.

6. Failure to begin construction of the treatment facility within twelve (12) months of the issuance of the Department permit shall render that permit invalid.

7. Upon reasonable cause to suspect that the treatment facility and/or treatment process poses a threat to human health or the environment, the Department, upon notification to the owner/operator, may require the owner/operator to investigate and, if appropriate, develop and implement a corrective action program approved by the Department.

8. Soil treatment facilities shall demonstrate consistency with the host Region/County Solid Waste Management Plan pursuant to Section D. of this regulation.

9. Open dumping of contaminated soil is prohibited.

10. Soil treatment facilities shall adhere to Federal and State rules and regulations and local zoning, land use and other applicable local ordinances and OSHA requirements.

11. Transfer of ownership.

a. The Department may, upon prior written request, transfer a permit to a new owner or operator of a soil treatment facility where no other change in the permit is necessary. The proposed new owner or operator of a permitted soil treatment facility shall, at least forty-five (45) days prior to the scheduled change in ownership or operating responsibility, provide to the Department:

(1) Documentation of the new owner's name and address;

(2) Documentation of the name and address of the party responsible for the operation and maintenance of the facility, if different from the owner;

(3) A written agreement signed by the current owner/operator and the proposed new owner/operator indicating the intent to change ownership or operating responsibility of the facility. The agreement shall contain a specific date for the transfer of permit responsibility;

(4) Documentation indicating that the facility shall be operated in accordance with the existing permit in effect at the time of transfer;

(5) Documentation of financial assurance as required in Section E. of this regulation. The previous owner/operator shall maintain financial assurance responsibilities until the new owner/operator can demonstrate satisfactory compliance with the financial assurance requirements outlined in this regulation; and,

(6) A disclosure statement as required in Section D. of this regulation.

b. Upon approval of all documents required by Item 11.a. above, the Department shall transfer the permit from the current owner/operator of the facility to the new owner/operator.

c. A request for a permit modification shall be submitted with the permit transfer request, if the facility will not be operated in accordance with the approved plans. The permit modification shall be in accordance with all provisions of this regulation.

d. The new owner shall submit legal documentation to the Department of the transfer of ownership of the facility within fifteen (15) days of the actual transfer.

12. All chemical and biological analyses required by this regulation for submittal to the Department shall be analyzed by a laboratory certified by the Department for that particular parameter.

13. All analytical methods used shall be appropriate for the parameters being quantified given the sample matrix (gasoline and diesel range organics at a minimum.) Quantification of total petroleum hydrocarbons shall employ appropriate extraction methods and include both short and long chain hydrocarbons.

14. Approval from the State Toxicologist shall be required when intergeneric (i.e., bioengineered) microorganisms or pathogenic (i.e., disease-causing) microorganisms are used in the proposed technology.

15. A maintenance plan shall be submitted that describes how each major component of the soil treatment facility and all associated equipment shall be maintained at the facility, and how the facility shall be operated in accordance with its intended use.

16. It is incumbent on the soil treatment facility to ensure that any soil-like material is compatible with the approved treatment process. Any contaminants in the soil-like material shall be treated to acceptable standards.

D. Administrative Review. All off-site soil treatment facilities shall request and obtain a Department permit pursuant to this regulation.

1. The first phase of the Department's review is the administrative review. All permit requests submitted to the Department shall include three (3) copies of the following documents for administrative review:

a. A letter from the host region/county of the soil treatment facility stating that the facility is consistent with the host region/county's solid waste management plan;

b. A letter of proof of proper zoning and land use from the county or city;

c. A letter from the Office of Ocean and Coastal Resources Management (OCRM) stating that the project is consistent with the South Carolina Coastal Zone Management Plan if the proposed

treatment facility is located in the coastal zone as defined by the OCRM or stating that the facility is exempt from this requirement because it is not located in that zone;

d. A letter from the Department's air program stating that the project is consistent with the goals of the South Carolina State Implementation Plan.

e. A disclosure statement, pursuant to S.C. Code Section 44–96–300, as amended. The Department may accept one disclosure statement for multiple facility permit applicants. Local governments and regions comprised of local governments are exempt from this requirement;

f. A cost estimate for complete closure of the facility. This estimate requires Department approval prior to the owner/operator establishing a financial assurance mechanism pursuant to Section E. of this regulation that shall ensure satisfactory closure of the facility;

g. A written request for any variances from the requirements of this regulation;

h. A completed permit application on a form provided by the Department, to include a brief description of the method of soil treatment;

i. Complete engineering plans and reports that are stamped by a South Carolina Licensed Professional Engineer in accordance with Section E. of this regulation; and,

j. A letter of approval from the State Toxicologist for the use of chemical and biological agents, if applicable.

2. When administratively complete, the Department will public notice the permit application and begin the technical review. Comments will be accepted throughout the technical review period.

E. Technical Review and Design Requirements. The Department's technical review of the permit application will involve the documents addressed in this section. All soil treatment facilities shall meet the criteria established in this section.

1. Siting Requirements.

a. Engineering Plans and Reports. The engineering plans and reports, pursuant to Section D.1.i. of this regulation, shall include the following documents:

(1) A site plan of the facility layout on a scale of not greater than two hundred (200) feet per inch clearly identifying conditions at the site. This plan shall at a minimum identify the following items:

(a) Identified on plan as "existing": property boundaries and all existing site conditions to be utilized in the operation of the soil treatment facility including, but not limited to, structures, access roads, on-site roads, parking areas, loading and unloading areas, soil storage areas, processing areas, fences, and gates; and

(b) Identified on plan as "proposed": all proposed site conditions that will be constructed including, but not limited to, structures, access roads, loading and unloading areas, soil storage areas, processing areas, fences, and gates; and,

(2) A location map that shows the location of all residences, schools, churches, day-care centers, hospitals, publicly owned recreational park areas, drinking water wells, monitoring wells, injection wells, roads, surface water bodies, dry runs, wetlands, the 100-year flood plain boundaries, and other applicable details regarding the general topography of the site and adjacent properties within one-fourth (¼) mile of the proposed site's property line.

b. Depending on conditions defined in Items E.1.a.(1)(a) and (b), and E.1.a.(2) above, the Department may require additional hydrogeological investigation prior to permit approval.

c. Site Standards. The site for a new soil treatment facility or expansion of an existing facility shall meet the standards outlined below, unless otherwise approved by the Department. Compliance with these standards shall be demonstrated in the engineering plans and reports referenced in Section E.1.a. of this regulation.

(1) A soil treatment facility located in a 100-year floodplain shall not restrict the flow of the 100-year flood as demonstrated on a 100-year flood plain map.

(2) A soil treatment facility shall be in compliance with the U.S. Army Corps of Engineers and the U. S. Environmental Protection Agency requirements concerning wetlands, where applicable.

(3) The soil treatment and storage area boundaries, as identified in the location map, shall not be located within:

(a) One hundred (100) feet of any property line;

(b) Two hundred (200) feet of any residence, school, church, day-care center, hospital or publicly owned recreational park area;

(c) Two hundred (200) feet of any surface water body which holds visible water for greater than six (6) consecutive months, excluding drainage ditches, sedimentation ponds and other operational features on the site; and,

(d) One hundred (100) feet of any drinking water well.

2. Facility Layout Requirements/Design Criteria.

a. Engineering Plans and Reports. The engineering plans and reports, pursuant to Section D.1.i. of this regulation, shall, at a minimum, include the following:

(1) All pertinent engineering drawings, on a scale no greater than one (1) foot per quarter inch, that identify and distinguish all existing and proposed construction of items (a) & (b) listed immediately below. Representative cross sections shall be used to show compliance with these requirements.

(a) The treatment process; and,

(b) The entire soil treatment facility, including, but not limited to, loading/unloading area(s), in-coming contaminated soil storage area(s), out-going treated soil storage area(s), soil processing area(s), impermeable floor, containment system(s), alarm system, fire fighting system, and leachate control system, if applicable.

(2) Technical details and specifications necessary to support the engineering drawings and operation plans for the facility including, but not limited to:

(a) A general operating plan including, but not limited to, a description of the methods of keeping all incoming shipments of contaminated soil segregated, the types and maximum quantity of contaminated soil to be accepted on a yearly basis, the storage areas for in-coming contaminated and out-going treated soil, the method(s) of preventing releases to the environment, and the measures taken to prevent unauthorized dumping and access.

(b) A plan for handling process waste water generated by the facility, if appropriate.

(c) A description of the treatment process. This detailed description shall, at a minimum, specify the methodology of the process to address how each of the following criteria impacts the process:

(i) Temperature(s)

(ii) Concentrations of contaminants

(iii) Microorganism activity

(iv) Nutrients—including oxygen

(v) Physical adjustments (mixing, tilling, etc.)

(vi) Moisture

(vii) pH adjustments

(viii) Soil characteristics

(ix) Concentrations of chemicals added

(x) Process by-product(s), and

(xi) Any other criteria applicable to the process to be used.

(d) A soil screening plan to ensure that the facility accepts only properly characterized soil that it is permitted to treat, and removes only the soil from the soil treatment facility that has been tested and meets the standards set forth in this plan. This portion of the plan shall, at a minimum, specify the following:

(i) The criteria from which determinations are made on whether to accept or reject contaminated soil;

(ii) The procedure and time frame that will be used to verify that waste profile sheets provided by the generator match all shipments of soil;

(iii) The procedure and time frame that will be taken if an incoming shipment of contaminated soil does not match the waste profile sheet provided by the generator including, but not limited to, a description of how the shipment will be managed and stored or removed based on the type waste;

(iv) The criteria used to determine whether the shipment of treated soil meets the standards for removal from the soil treatment facility;

(v) The procedure for the proper handling, storage, and removal of all treated soil; and,

(vi) Analytical procedures and protocols.

(e) Upon receipt of a petition, the Department may consider sampling reduction based on consistent demonstration of treatment results. The petition shall include technical justification and a proposed alternate sampling plan. Upon approval by the Department in writing, the facility's permit will be amended to reflect the change in sampling frequency and the new sampling plan may be implemented.

(f) A contingency plan that describes a technically and financially feasible course of action to be taken in response to contingencies during the operation of the facility. This plan shall set forth procedures to be employed during periods of non-operation, e.g., equipment breakdown which may require standby equipment, extension of operation hours, or diversion of shipments to other facilities. The plan shall be designed to minimize hazards to human health and the environment from fires, explosions, or any unplanned sudden or non-sudden release of potentially harmful constituents to air, soil or surface water.

(g) A detailed closure plan which shall identify the steps necessary to close the facility. It shall identify the components at the facility that will remain in-place and those that will be removed. The plan shall be amended whenever changes in operating plans or facility design effect the closure plan. The plan shall address the satisfactory maintenance, closure and post-closure care, monitoring and/or corrective action, if appropriate.

(h) A plan for training personnel to perform their duties in a way that ensures the facility's compliance with this regulation and their health and safety.

b. Design Standards. Unless otherwise approved by the Department, all soil treatment facilities shall be designed in accordance with the following standards:

(1) Access to the facility shall be controlled through the use of fences, gates, berms, natural barriers, or other means to prevent unauthorized dumping and access;

(2) Contaminated soil awaiting processing shall be completely contained from the outside environment and shall be:

(a) Placed only on an impermeable surface, e.g., sealed concrete;

(b) Stored in such a manner as to prevent releases to the environment; and,

(c) Covered with either a structure or an impermeable cover.

(3) The Department may require the process area to be covered and containment barriers installed based on the technology approved. During processing, soil shall be:

(a) Placed only on an impermeable surface, e.g., sealed concrete; and,

(b) Maintained in such a manner as to prevent releases to the environment.

c. Operation Standards.

(1) The facility shall be operated and maintained in a manner which will protect the established water quality standards of the surface and ground waters, and the air quality standards.

(2) Dust, odors, fire hazards, litter and vectors shall be effectively controlled so they do not constitute nuisances or hazards.

(3) Personnel Training. The personnel training program shall at a minimum:

(a) Identify positions that will require training and a knowledge of the procedures, equipment, and processes at the facility;

(b) Instruct facility personnel in how to perform their duties in a way that ensures the facility's compliance with this regulation, including the proper procedures for handling unauthorized solid waste;

(c) Instruct facility personnel in the proper responses to all emergencies and require employees to become familiar with the contingency plan, emergency and safety equipment, emergency procedures and emergency systems; and,

(d) Document employee training. This documentation shall be maintained at the facility for all employees. Documentation of training shall include the following:

(i) The job title for each position related to solid waste management at the facility and the name of the employee filling each position;

(ii) A written job description for each position including the requisite skill, education or other qualifications, and duties of employees assigned to each position;

(iii) A written description of the type and amount of both introductory and continuing training that will be given to each employee; and,

(iv) Records that document the training and/or job experience completed by each employee. Training records for each employee shall be maintained at the facility for a minimum of three (3) years for all current personnel.

(4) Soil containing non-compatible contaminants shall not be mixed during processing.

(5) Any contaminated soil received that is not acceptable for treatment, based on the facility's permit, shall be removed from the facility within ten (10) days of receipt in accordance with an approved contingency plan. Should the facility receive known or suspected hazardous wastes, a representative of the facility shall call the appropriate Department EQC District Office within twenty-four (24) hours of receipt.

(6) A waste profile sheet shall be provided with each soil shipment received by the soil treatment facility.

(7) Leachate and washwater from a soil treatment facility, including soil storage areas, shall not be allowed to drain or discharge into waters of the State unless an effluent disposal permit, i.e., National Pollutant Discharge Elimination System (NPDES), No Discharge (ND), or Underground Injection Permit, has been granted by the Department.

(8) Treated soil stored outside shall be managed in such a manner as to comply with S.C. Regulation 61–9, Water Pollution Control Permits and the NPDES General Permit issued pursuant to Regulation 61–9, as amended.

(9) A construction permit from the Department's air program shall be required for the storage or processing of any soil that may cause the release of any regulated air pollutant unless an exemption is granted pursuant to S.C. Regulation 61–62.1.II.A, Air Pollution Control Regulations and Standards.

(10) Treated soils for restricted use shall be stored on a covered, nonporous surface.

(11) Emergency Preparedness. In addition to requirements set forth in the contingency plan, all soil treatment facilities shall, at a minimum:

(a) Provide access to fire equipment and make provisions for availability of local fire-fighting services;

(b) Be equipped with a device, e.g., telephone or hand held two-way radio, at the scene of operations capable of summoning emergency assistance from local police departments, fire departments, and State or local emergency response teams;

(c) Be equipped with portable fire extinguishers and other fire control equipment; and,

(d) Ensure that facility personnel are trained to respond effectively to all emergencies, including different types of fires, by familiarizing them with the contingency plan, emergency and safety equipment, emergency procedures and emergency systems.

(12) Signs. Signs shall be posted and maintained in conspicuous places which:

(a) Identify the owner, operator, or a contact person and telephone number in case of emergencies and the hours during which the facility is open for business;

(b) Identify that the facility is a soil treatment facility; and,

(c) Identify the valid DHEC Solid Waste Permit Number for the soil treatment facility.

(13) Financial Assurance. Prior to accepting contaminated soil, soil treatment facilities shall fund a financial responsibility mechanism acceptable to the Department to ensure the satisfactory maintenance, closure and post-closure care. A final closure cost estimate, based on third party costs to complete closure by disposing of the maximum quantity of material at a facility, shall be calculated annually and adjusted annually, as necessary. Local governments are exempt from this requirement until such time as federal regulations require such local governments or regions to demonstrate financial responsibility for such facilities and the Department promulgates regulations addressing this issue.

F. Standards.

1. General Requirements. Soil shall be treated in accordance with the following criteria:

a. Soil shall be treated to levels that are protective of human health and the environment as approved by the Department. Treatment standards shall be based in part upon the intended use of the soil after the treatment process is complete. It is the responsibility of the permitted treatment facility to provide to the user of the treated soil written notice stating the treatment goals achieved and the end use of the soil as approved by the Department, including any restrictions on the use of the soil that are included in the facility's permit or in this regulation.

b. Contaminated soil treated under the purview of this regulation shall not be used to grow edible food crops nor to supplement soil used for the purpose of growing edible food crops. Other agricultural uses of soil treated under this regulation shall require approval from the Department prior to use.

c. Soil treated under the purview of this regulation shall not contain benzene in excess of 5 ppb after treatment unless it can be demonstrated that the end use of the treated soil will not impact groundwater such that it would exceed 5 ppb benzene or cause an adverse risk to human health as determined by the Department. Any soil treated to >5 ppb benzene shall be for restricted end use to be approved by the Department.

d. The type, composition, breakdown products and potential affect to human health and the environment shall be provided for all materials or microorganisms introduced into the soil for treatment purposes. In addition, the breakdown products for the microorganisms and contaminants being treated in the process shall be clearly defined.

e. The Department may require additional soil testing and/or alternate treatment activities, and/or soil removal for proper disposal, if the permittee is unable to demonstrate that the treatment process is effective, or the process has failed to perform to design standards. Additional testing and/or treatment may be required if constituents are present in the soils for which the permitted treatment process will not be effective, e.g., metals.

f. Based on the nature of the treatment process and the types of soil proposed for treatment at the facility, the Department may require additional environmental monitoring to be performed at the facility. Likewise, additional engineering provisions may be required by the Department to ensure protection of human health and the environment.

g. Contaminated soil shall be categorized into three classes, i.e., Class I, Class II, or Class III, based on the contaminants present in the soil. Treatment levels to be achieved for each class of soil differ.

h. Soil treated under the purview of this regulation shall be used in a manner which minimizes contact with the seasonal high water table.

i. When facilities co-mingle compatible soils prior to treatment, the end use of the treated co-mingled soil shall be limited to the most conservative end use as determined from the approved end uses identified for each of the co-mingled soils by permit.

2. Class I. Class I soil is soil contaminated with one or more of the following contaminants: gasoline, jet fuels, diesel fuels, kerosene, and distillate fuel oils (number one and number two fuel

oils.) Treatment levels for Class I contaminated soil shall depend on the planned end use of the soil after treatment processes are completed:

a. All Class I contaminated soil shall be analyzed for total petroleum hydrocarbons (TPH), and total benzene, toluene, ethyl benzene and xylene (BTEX).

b. Class I contaminated soil which is for restricted specific end uses as approved by the Department, e.g., as cover at municipal solid waste landfills, or in road base or similar types of construction, shall, unless otherwise approved by the Department, be treated to the following levels or below for TPH and BTEX:

TPH	BTEX (total)
200 ppm	20 ppm (with Benzene <5 ppb)

c. For all unrestricted end uses, Class I contaminated soil shall be treated to the following levels or below for TPH and BTEX:

TPH	BTEX (total)
10 ppm	1 ppm (with Benzene <5 ppb)

d. Alternate treatment levels may be specified by the Department based on the intended final use of the soil and the potential risk to human health and the environment.

e. The Department may require testing of incoming batches of contaminated soil and treated soil for additional parameters other than TPH and BTEX should there be reason to believe that other parameters of potential concern are present in the soil. Treatment levels for these additional parameters shall be determined by the Department on a case-by-case basis, taking end use into consideration and potential risk to human health and the environment.

3. Class II. Class II soil is soil contaminated with one or more of the following contaminants: combination fuel oils (number three and number four fuel oils), residual fuel oils (number five and number six fuel oils), virgin lubricating oils, weathered oils, and used oils that have not been mixed with other waste. Treatment levels for Class II contaminated soil shall depend on the planned end use of the soil after treatment processes are completed:

a. All Class II soil shall be analyzed for TPH, BTEX (total), and polynuclear aromatic hydrocarbons (PAH.)

b. Class II contaminated soil, including contaminated soil with polynuclear aromatic hydrocarbons (PAH) levels that exceed those levels listed in the current EPA approved Risk Based Concentrations (RBC) tables as determined by the Department, shall be restricted to specific end uses as approved by the Department, e.g., as cover at municipal solid waste landfills, or in road base or similar types of construction. Unless otherwise approved by the Department, this soil shall be treated to the following levels or below:

TPH	BTEX (total)	PAH
200 ppm	20 ppm (with Benzene <5 ppb)	≥ RBC values

c. For all unrestricted end uses, Class I contaminated soil shall be treated to the following levels or below:

TPH	BTEX (total)	PAH
10 ppm	1 ppm (with Benzene <5 ppb)	< RBC values

d. Soil contaminated with used oil and soil contaminated with weathered oil shall be considered as Class II.a. soil and shall be restricted to specific end use, as approved by the Department.

e. Alternate treatment levels may be specified by the Department based on the intended final use of the soil and the potential risk to human health and the environment.

f. The Department may require testing of incoming batches of contaminated soil and treated soil for additional parameters other than TPH, BTEX, and PAH should there be reason to believe that other parameters of potential concern are present in the soil. Treatment levels for these additional parameters shall be determined by the Department on a case-by-case basis, taking end use into consideration and potential risk to human health and the environment.

4. Class III. Class III soil is soil contaminated with any contaminant other than those listed under Classes I and II above.

a. Facilities applying for a Class III permit under this regulation shall submit for Department review, technical data that demonstrates that the proposed soil treatment technique can treat soil to concentration levels equal to or less than those levels listed in the current EPA approved Risk Based Concentrations (RBC) tables as determined by the Department. If the applicant fails to submit data, or the Department determines that the data submitted is insufficient, the facility shall obtain a Research, Development, and Demonstration (RD&D) permit as outlined in R.61–107.10. If the facility demonstrates to the Department under the RD&D permit that the soil treatment technique used is effective on each contaminant to be treated without the creation of harmful degradation products, the Department will issue the facility a Class III permit, pursuant to this regulation.

b. The permittee shall submit a list of contaminants to the Department for review and approval based on the chemical and physical nature of the Class III contaminated soil. Based on this information, the Department shall determine appropriate levels of treatment.

c. All Class III soil shall be analyzed for parameters approved by the Department.

d. The end use of Class III contaminated soil shall be approved by the Department prior to accepting the soil for treatment. Treatment levels for soil to be treated shall be determined by the Department on a case-by-case basis, and based on the intended end use. The Department will take potential risk to human health and the environment into consideration when determining appropriate treatment levels. These site specific determinations may be based on current EPA approved risk based concentrations (RBC) tables, toxicological review, scientifically defensible published data which are appropriate for use in developing permit limits and contaminant levels for which EPA has not developed national criteria or for which South Carolina has no standards. The Department will consider the site specific routes of potential exposure and the hydrogeological conditions for the potential to leach contaminants to the water table, and will use health and/or technical literature.

e. Those treatment processes which can be proved to the Department to effectively treat the contaminants in the Class III contaminated soil may be exempted from the requirements to obtain a RD&D permit under R.61–107.10 and may be permitted under this regulation. In all cases, the Department shall retain the authority to set treatment levels based on end use considerations to ensure treatment is protective of human health, surface water standards, and ground water standards.

5. Facilities may be permitted to treat only Class I soil, only Class II soil, only Class III soil, or a combination of any of these soil types. Any facility treating a combination of contaminated soil types that includes Class III soil type may be required to receive a permit under the authority of this regulation, and also a RD&D permit. Upon the two years expiration of the RD&D permit, if the process is proved to be a viable method for treating soil, the facility's existing permit issued under the authority of this regulation may be amended to include the treatment process proved viable under the RD&D permit.

G. Monitoring and Reporting Requirements.

1. Should the Department have evidence to suspect potential environmental and/or health problems associated with the treatment facility, monitoring (including groundwater, surface water, and air quality) may be required by the Department, as appropriate, and based on a case-by-case evaluation to ensure protection of the environment.

2. An annual report, on a form provided by, or acceptable to, the Department, shall be submitted to the Department by October 15 for the previous fiscal year (July 1 through June 30,) which includes, at a minimum, the following information:

a. The total quantity in tons of contaminated soil received at the facility for the previous fiscal year;

b. The total quantity in tons of treated soil transported off-site and the destination of this soil; and,

c. The county in South Carolina in which the contaminated soil originated, or the State if the soil originated outside South Carolina.

3. Analytical data showing that all treated soil met appropriate standards, pursuant to Section F. of this regulation, prior to removal from the facility, shall be maintained on-site for a minimum of five (5) years from the date the results are received from the laboratory. This data shall be generated by a laboratory certified by DHEC for the required parameters and in accordance with SW-846, Chapter 9. This data shall be made available to the Department upon request.

4. Documentation related to the acceptance, rejection, storage, operational data, and proper disposal of all contaminated soil received by the facility shall be maintained for a minimum of five (5) years, and made available to the Department upon request.

5. Upon implementation of the contingency plan, the owner or operator shall immediately notify the Department (using the 24-hour number 803–253–6488) and note, in the operating record and annual report, the following information:

a. The name, address and telephone number of the operator and the facility;

b. The date, time and type of incident (spill, fire, explosion, etc.); and,

c. The extent of physical damages to the operational part of the facility.

6. Upon request by the Department in response to a notification made in Item 5 of this Section, a written report shall be submitted to the Department that includes the following information:

a. An assessment of actual or potential hazards to human health or the environment, where this is applicable;

b. The procedures or equipment available to prevent a recurrence of the reported event; and,

c. Any long-term corrective action proposals. Upon Department review and approval, the corrective action proposal shall be implemented.

7. Records of all monitoring and reporting information, pursuant to these regulations, shall be maintained at the facility for a minimum of five (5) years from the sample or measurement date, unless otherwise specified by the Department. These reports shall be made available to Department personnel upon request.

H. Closure and Post-Closure Procedures. The following closure and post-closure procedures addressed in this section apply to all soil treatment facilities:

1. At least sixty (60) days prior to closure, the owner or operator shall submit to the Department written notice of intent to close and a proposed closure date;

2. Upon closing, the owner or operator shall immediately remove all treated soil, properly dispose of any waste associated with the treatment process, transport all contaminated soil to either another permitted soil treatment facility or permitted disposal facility, and post signs at the facility which state that the facility is no longer in operation;

3. Within thirty (30) days of final removal of all contaminated and treated soil, the owner or operator shall complete closure as outlined in the facility's approved closure plan and notify the Department;

4. After receiving notification that the facility closure is complete, the Department will conduct an inspection of the facility. If all procedures have been correctly completed, the Department will approve the closure in writing, at which time the Department permit shall be terminated; and,

5. If the Department's inspection reveals that closure, as outlined in the facility's approved closure plan, is incomplete, the owner or operator shall submit to the Department a post-closure care plan for Department approval to address the deficiencies noted by the Department. Post closure environmental monitoring and/or corrective action may be required. This post-closure care plan, if required, shall be submitted within thirty (30) days of the inspection, and shall include a time table.

I. Violations and Penalties. A violation of this regulation or any permit, order, or standard issued pursuant to or related to this regulation subjects the person to the issuance of a Department order or to civil enforcement action in accordance with S.C. Code Section 44–96–450, as amended, which may include civil penalties in accordance with the Solid Waste Policy and Management Act (SCPMA) and any amendments thereto. Willful violation of this regulation or any permit, order, or standard issued pursuant to or related to this regulation subjects the person to the issuance of a Department order which may also include civil penalties in accordance with the SCPMA, as amended, and may also result in a criminal enforcement action in accordance with S.C. Code Section 44–96–450, as amended. Any

person to whom an administrative order is issued may appeal it as a contested case pursuant to R.61–72, Procedures for Contested Cases, and the S.C. Administrative Procedures Act, S.C. Code Section 1–23–310 et seq., as amended.

J. Severability. Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Added by State Register Volume 25, Issue No. 5, Part 1, eff May 25, 2001.

61–107.19. SOLID WASTE. MANAGEMENT: SOLID WASTE LANDFILLS AND STRUCTURAL FILL.

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Part I. General Requirements.

A. Applicability.

1. This regulation establishes minimum standards for the site selection, design, operation, and closure of all solid waste landfills and structural fill areas. Disposal of waste under the purview of this regulation is based on the waste's chemical/physical properties and is not dependent upon the source of generation with the exception of municipal solid waste that shall be disposed in Class Three landfills. This regulation is divided into the following parts:

a. Part I outlines the general criteria that applies to one or more Parts of the regulation, e.g., the applicability for the regulation, waste characterization requirements for determining the type of landfill needed, definitions for the purposes of this regulation;

b. Part II outlines the Permit-by-rule requirements for structural fill activity using a limited waste stream;

c. Part III outlines the General Permitting requirements for Class One Landfills - using land-clearing debris, and yard trash to fill low areas, including permitted mining sites, for an aesthetic benefit or property enhancement;

d. Part IV outlines the requirements for Class Two Landfills - all landfills for the disposal of waste as outlined in Appendix I of this regulation, and similar waste, and wastes that test, pursuant to Section C of this Part, less than ten (10) times the maximum contaminant level (MCL) as published in R.61–58, State Primary Drinking Water Regulation current at the time of the permit application. When a waste not listed in Appendix I is approved by the Department for disposal, the landfill's permit will be modified to include the acceptability of the approved waste; and,

e. Part V outlines the requirements for Class Three Landfills that accept municipal solid waste, industrial solid waste, sewage sludge, nonhazardous municipal solid waste incinerator ash and other nonhazardous wastes.

2. This regulation replaces and simultaneously repeals Regulations: 61–107.11 Solid Waste Management: Construction, Demolition, and Land-clearing Debris Landfills; 61–107.13 Solid Waste Management: Municipal Solid Waste Incinerator Ash Landfills; 61–107.16 Solid Waste Management: Industrial Solid Waste Landfills; and 61–107.258 Solid Waste Management: Municipal Solid Waste Landfills. The Department will automatically convert as an administrative modification all existing landfill permits to the appropriate Part as outlined in this regulation.

3. A separate permit shall be required for each landfill even though there may be one or more different types of landfills located in different areas on the same site.

4. This regulation applies to all new and existing solid waste landfills and to all structural fill activities. All new solid waste landfills shall be in compliance with all requirements of this regulation prior to receipt of waste.

5. This regulation becomes effective upon publication as final in the State Register.

6. Existing permitted solid waste landfills shall comply with the following:

a. Existing permitted landfills operating on the effective date of this regulation are not subject to the location criteria outlined herein, but shall be subject to all other provisions of this regulation;

b. Within 180 days of the effective date of this regulation, existing permitted landfills that are not in compliance with required standards, shall submit to the Department a plan to bring the landfill into compliance with requirements of this regulation; and,

c. All landfills operating on the effective date of this regulation shall be in compliance with the requirements of this regulation within 18 months of the effective date of this regulation, unless additional time is allowed pursuant to requirements of this regulation.

7. Landfills for the disposal only of trees, stumps, wood chips, and yard trash when generation and disposal of such waste occurs on properties under the same ownership or control are exempt from the requirements of this regulation. Also, land-clearing debris generated from agricultural or silvicultural operations generated and disposed on site are not subject to the requirements of this regulation.

8. Open dumping is prohibited.

9. Use of Design Document, Plans, and Specifications.

a. The owner/operator of a solid waste landfill shall maintain copies of all Department approved plans and specifications for the landfill at a location readily accessible by landfill personnel and representatives of the Department during regular business hours; and,

b. All landfill operations shall be in accordance with this regulation and with all Department approved plans and specifications for the facility. Failure to operate in accordance with this regulation and/or the approved plans and permit may result in enforcement action by the Department.

10. All activities conducted under the purview of this regulation shall adhere to all Federal and State rules and regulations, and all local zoning, land use, and other applicable ordinances and laws;

B. Definitions for the Purposes of this Regulation.

1. "Active life" means the period of operation beginning with the initial receipt of solid waste and ending at completion of closure activities in accordance with this regulation.

2. "Active portion" means that part of a facility that has received or is receiving wastes and that has not been closed in accordance with this regulation.

3. "Administratively complete" means a determination by the Department that all elements of an application, as specified herein, have been received to include all required signatures and tender of the application fee, where required.

4. "Airport" means public-use airport open to the public without prior permission and without restrictions within the physical capacities of available facilities.

5. "Applicant" means an individual, corporation, partnership, business association, or government entity that applies for the issuance, transfer, or modification of a permit under this regulation.

6. "Aquifer" means a geological formation, group of formations, or portion of a formation, capable of yielding significant quantities of groundwater to wells or springs.

7. "Areas susceptible to mass movement" means those areas of influence (i.e., areas characterized as having an active or substantial possibility of mass movement) where the movement of earth material at, beneath, or adjacent to the landfill, because of natural or man-induced events, results in the downslope transport of soil and rock material by means of gravitational influence. Areas of mass movement include, but are not limited to, landslides, avalanches, debris slides and flows, soil fluction, block sliding, and rock fall.

8. "Ash" means the solid residue from the incineration of solid wastes.

9. "Beneficial fill" means filling to surrounding grade, low areas or depressions in the surface of the earth to include permitted mining sites for an aesthetic benefit.

10. "Bird hazard" means an increase in the likelihood of bird/aircraft collisions that may cause damage to the aircraft or injury to its occupants.

11. ''Bulk PCB Waste'' means waste derived from manufactured products containing PCBs in a non-liquid state, at any concentration where the concentration at the time of designation for disposal was ≥50 ppm PCBs. PCB bulk product waste does not include PCBs or PCB Items regulated for disposal under 40CFR761, the Toxic Substances Control Act (TSCA), Sections 761.60(a) through (c), Sec. 761.61, Sec. 761.63, or Sec. 761.64. PCB bulk product waste includes, but is not limited to:

(a) Non-liquid bulk wastes or debris from the demolition of buildings and other man-made structures manufactured, coated, or serviced with PCBs. PCB bulk product waste does not include debris from the demolition of buildings or other man-made structures that is contaminated by spills from regulated PCBs which have not been disposed of, decontaminated, or otherwise cleaned up in accordance with TSCA requirements, Sec. 761.61.

(b) PCB-containing wastes from the shredding of automobiles, household appliances, or industrial appliances.

(c) Plastics (such as plastic insulation from wire or cable; radio, television and computer casings; vehicle parts; or furniture laminates); preformed or molded rubber parts and components; applied dried paints, varnishes, waxes or other similar coatings or sealants; caulking; adhesives; paper; Galbestos; sound deadening or other types of insulation; and felt or fabric products such as gaskets.

(d) Fluorescent light ballasts containing PCBs in the potting material.

12. ''Closure'' means the discontinuance of operation by ceasing to accept, treat, store, or dispose of solid waste in a manner which minimizes the need for further maintenance and protects human health and the environment.

13. ''Commercial solid waste'' means all types of solid waste generated by stores, offices, restaurants, warehouses, and other nonmanufacturing activities, excluding residential and industrial wastes.

14. ''Construction'' means any physical modification to the site at which a potential or proposed solid waste management facility is to be located including, but not limited to, site preparation.

15. ''Contingency plan'' means a document acceptable to the Department setting out an organized, planned, and coordinated course of action to be followed at or by the facility in case of a fire, explosion, or other incident that could threaten human health and safety or the environment.

16. ''Cover'' means soil or other suitable material, or both, acceptable to the Department that is used to cover compacted solid waste in a land disposal site.

17. ''Department'' means the South Carolina Department of Health and Environmental Control.

18. ''Disclosure statement'' means a sworn statement or affirmation, the form and content of which shall be determined by the department and as required by SC Code Section 44–96–300.

19. ''Displacement'' means the relative movement of any two (2) sides of a fault measured in any direction.

20. ''Disposal'' means the discharge, deposition, injection, dumping, spilling, or placing of any solid waste into or on any land or water, so that the substance or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including groundwater.

21. ''Existing landfill'' means any landfill that is permitted to receive solid waste as of the effective date of this regulation.

22. ''Expand'' or ''Expansion'' means, for the purposes of this regulation, any increase in the permitted capacity of a solid waste disposal facility, or any increase in the total volume at a solid waste disposal facility.

23. ''Facility'' means all contiguous land, structures, other appurtenances and improvements on the land used for treating, storing, or disposing of solid waste. A facility may consist of several treatment, storage, or disposal operational units, including, but not limited to, one or more landfills, surface impoundments, or combination thereof.

24. ''Fault'' means a fracture or a zone of fractures in any material along which strata on one side have been displaced with respect to that on the other side.

25. ''Financial assurance mechanism'' means a mechanism designed to demonstrate that sufficient funds will be available to meet specific environmental protection needs of solid waste

management facilities. Available financial responsibility mechanisms include, but are not limited to insurance, trust funds, surety bonds, letters of credit, certificates of deposit, and financial tests as determined by the Department by regulation.

26. ''Flood plain'' means the lowland and relatively flat areas adjoining inland and coastal areas of the mainland and off-shore islands including, at a minimum, areas subject to a one percent or greater chance of flooding in any given year.

27. ''100-year flood'' means a flood that has a 1-percent or greater chance of recurring in any given year or a flood of a magnitude equaled or exceeded once in 100 years on the average over a significantly long period.

28. ''Footprint'' means the outer most edges of the waste disposal area.

29. ''Gas condensate'' means the liquid generated as a result of gas recovery process(es) at the landfill.

30. ''Generator'' means any person, by site, whose action or process produces solid waste, or whose action first causes a solid waste to become subject to regulation.

31. ''Groundwater'' means water beneath the land surface in the saturated zone.

32. ''Hazardous waste'' has the meaning provided in Section 44–56–20 of the South Carolina Hazardous Waste Management Act.

33. ''High water table'' means the highest water elevations measured at the uppermost aquifer.

34. ''Holocene'' means the most recent epoch of the Quaternary period, extending from the end of the Pleistocene Epoch to the present.

35. ''Household waste'' means any solid waste (including garbage, trash, and sanitary waste in septic tanks) derived from households (including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds, and day-use recreational areas).

36. ''Industrial waste'' means solid waste that results from industrial processes including, but not limited to, factories and treatment plants.

37. ''Karst terranes'' means areas where karst topography, with its characteristic surface and subterranean features, is developed as the result of dissolution of limestone, dolomite, or other soluble rock. Characteristic physiographic features present in karst terranes include, but are not limited to, sinkholes, sinking streams, caves, large springs, and blind valleys.

38. ''Landfill'' means a disposal facility or part of a facility where solid waste is placed in or on land, and which is not a land treatment facility, a surface impoundment, or an injection well.

39. ''Land-clearing debris'' means solid waste which is generated solely from land-clearing activities, but does not include solid waste from agricultural or silvicultural operations.

40. ''Lateral expansion'' means a horizontal expansion of the footprint of an existing landfill.

41. ''Leachate'' means the liquid that has percolated through or drained from solid waste or other man-emplaced materials and that contains soluble, partially soluble, or miscible components removed from such waste.

42. ''Lead-based paint'' means paint containing greater than 600 parts per million (ppm) total lead by weight, calculated as lead metal in the total nonvolatile content, i.e., >0.06%; or, when measured in situ with an X-ray Fluorescence Spectrum Analyzer (XRF), paint containing >0.7 mg/cm^2.

43. ''Liquid waste'' means any waste material that is determined to contain ''free liquids'' as defined by Method 9095B (Paint Filter Liquids Test), and as described in ''Test Methods for Evaluating Solid Wastes, Physical/Chemical Methods'' (EPA Pub. No. SW-846, as amended by EPA final updates).

44. ''Lithified earth material'' means all rock, including all naturally occurring and naturally formed aggregates or masses of minerals or small particles of older rock that formed by crystallization of magma or by induration of loose sediments. This term does not include man-made materials, such as fill, concrete, and asphalt, or unconsolidated earth materials, soil, or regolith lying at or near the earth's surface.

45. "Local government" means a county, any municipality located wholly or partly within the county, and any other political subdivision located wholly or partly within the county when such political subdivision provides solid waste management services.

46. "Lower explosive limit" means the lowest percent by volume of a mixture of explosive gases in air that will propagate a flame at 25° C and atmospheric pressure.

47. "Maximum horizontal acceleration in lithified earth material" means the maximum expected horizontal acceleration depicted on a seismic hazard map, with a 90% or greater probability that the acceleration will not be exceeded in 250 years, or the maximum expected horizontal acceleration based on a site-specific seismic risk assessment.

48. "Modification" means changes to a solid waste landfill as follows:

a. "Minor modification" means a change that keeps the permit current with routine changes to the facility or its operations, or an administrative change; and,

b. "Major modification" means a change that substantially alters the facility or its operations, e.g., tonnage increase above 25%, any volumetric capacity increase, alternate designs that vary from the design prescribed in this regulation.

49. "Municipal solid waste" includes, but is not limited to, wastes that are durable goods, nondurable goods, containers and packaging, food scraps, and miscellaneous inorganic wastes from residential, commercial, institutional, and industrial sources including, but not limited to, appliances, automobile tires, newspapers, clothing, disposable tableware, office and classroom paper, wood pallets, and cafeteria wastes.

50. "Municipal solid waste incinerator" means any solid waste incinerator, publicly or privately owned, that receives household waste. Such incinerator may receive other types of solid waste such as commercial or industrial solid waste.

51. "On-site landfill" means landfills that accept only solid waste generated in the course of normal operations on property under the same ownership or control as the waste management facility.

52. "Open burning" means any fire or smoke-producing process which is not conducted in any boiler plant, furnace, high temperature processing unit, incinerator or flare, or in any other such equipment primarily designed for the combustion of fuel or waste material.

53. "Open dumping" means any unpermitted or unregistered solid waste disposal or land filling activity.

54. "Pay-in period" means the time frame allotted for making annual payments into a trust fund.

55. "Perennial stream" means a stream or reach of a stream that flows continuously throughout the year and whose upper surface generally stands lower than the water table in the region adjoining the stream.

56. "Permit" means the process by which the department can ensure cognizance of, as well as control over, the management of solid wastes.

57. "Permittee" means the person to whom the Department issued either a permit, an approval to operate under a General Permit, or a Permit-by-rule, pursuant to this regulation.

58. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

59. "Poor foundation conditions" means those areas where features exist which indicate that a natural or man-induced event may result in inadequate foundation support for the structural components of a landfill.

60. "Practical Quantitation Limit (PQL)" means the lowest concentration of an analyte that can be measured within specified limits of precision and accuracy during routine laboratory operating conditions.

61. "Putrescible wastes" means solid waste that contains organic matter capable of being decomposed by microorganisms and of such a character and proportion as to be capable of creating foul smelling odors and attracting or providing food for animals.

62. ''Qualified professional'' means a qualified South Carolina registered professional geologist or qualified South Carolina registered professional engineer. Under Part IV Section E and Part V Subpart E the qualified professional shall have sufficient training and experience in groundwater hydrology and related fields, including groundwater monitoring, contaminant fate and transport, and corrective-action.

63. ''Recharge area'' for a particular aquifer is defined as areas where water enters the aquifer through downward migration. Principal examples include: outcrop areas of a particular aquifer where the potentiometric head within the unit decreases with depth; and, in the subsurface, where the potentiometric head relationship and leakage factors across any confining unit allow for downward flow into other aquifer systems.

64. ''Region'' means a group of counties in South Carolina that is planning to or has prepared, approved, and submitted a regional Solid Waste Management Plan to the Department pursuant to S.C. Code Section 44–96–80.

65. ''Regulated hazardous waste'' means a solid waste that is a hazardous waste, as defined in R.61–79.261.3, Hazardous Waste Management Regulations, that is not excluded from regulation as a hazardous waste under R.61-79.261.4(b), or was not generated by a conditionally exempt small quantity generator as defined in R.61–79.261.5.

66. ''Regulatory threshold'' means promulgated levels that can not be equaled or exceeded.

67. ''Representative sample'' means a sample that statistically represents the population.

68. ''Responsible party'' means:

a. Any officer, corporation director, or senior management official of a corporation, partnership, or business association that is an applicant;

b. A management employee of a corporation, partnership, or business association that is an applicant who has overall responsibility for operations and financial management of the facility under consideration;

c. An individual, officer, corporation director, senior management official of a corporation, partnership, or business association under contract to the applicant to operate the facility under consideration; or,

d. An individual, corporation, partnership, or business association that holds, directly or indirectly, at least five percent (5%) equity or debt interest in the applicant. If any holder of five percent or more of the equity or debt of the applicant is not a natural person, the term means any officer, corporation director, or senior management official of the equity or debt holder who is empowered to make discretionary decisions with respect to the operation and financial management of the facility under consideration.

69. ''Run-off'' means any rainwater, leachate, or other liquid that drains over land from any part of a facility.

70. ''Run-on'' means any rainwater, leachate, or other liquid that drains over land onto any part of a facility.

71. ''Saturated zone'' means that part of the earth's crust in which all voids are filled with water.

72. ''Seismic impact zone'' means an area with a 10% or greater probability that the maximum horizontal acceleration in lithified earth material, expressed as a percentage of the earth's gravitational pull (g), will exceed 0.10g in 250 years.

73. ''Sludge'' means any solid, semi-solid, or liquid waste generated from a municipal, commercial, or industrial wastewater treatment plant, water supply treatment plant, or air pollution control facility exclusive of the treated effluent from a wastewater treatment plant.

74. ''Small business'' means a commercial retail service, industry entity, or nonprofit corporation, including its affiliates, that:

a. Is, if a commercial retail service or industry service, independently owned and operated; and,

b. Employs fewer than one hundred (100) full-time employees or has gross annual sales or program service revenues of less than five million dollars.

75. ''Sole source aquifer'' is defined as specified in the Federal Safe Drinking Water Act.

76. ''Solid waste'' means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations and from community activities. This term does not include solid or dissolved material in domestic sewage, recovered materials, or solid or dissolved materials in irrigation return flows or industrial discharges that are point sources subject to NPDES permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

77. ''Special Wastes'' means nonresidential or commercial solid wastes, other than regulated hazardous wastes, that are either difficult or dangerous to handle and require unusual management at Class Three landfills, including, but not limited to, those wastes contained in S.C. Code Section 44-96–390.(A).

78. ''Special Wastes Analysis and Implementation Plan'' means the procedures used to identify and manage special wastes at Class Three landfills, pursuant to SC Code Section 44–96–390.

79. ''State'' means the State of South Carolina.

80. ''Structural components'' means liners, leachate collection systems, final covers, run-on/run-off systems, and any other component used in the construction and operation of the landfill that is necessary for protection of human health and the environment.

81. ''Structural fill'' means landfilling for future beneficial use utilizing land-clearing debris, hardened concrete, hardened/cured asphalt, bricks, blocks, and other materials specified by the department by regulation, compacted and landfilled in a manner acceptable to the department, consistent with applicable engineering and construction standards and carried out as a part of normal activities associated with construction, demolition, and land-clearing operations; however, the materials utilized must not have been contaminated by hazardous constituents, petroleum products, or painted with lead-based paint. Structural fill may not provide a sound structural base for building purposes.

82. ''Structural integrity'' means the ability of a landfill to withstand physical forces exerted upon designed components, appurtenances, and containment structures (e.g., liners, dikes) of the landfill.

83. ''Surface water'' means lakes, bays, sounds, ponds, impounding reservoirs, springs, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Atlantic Ocean within territorial limits, and all other bodies of surface water, natural or artificial, inland or coastal, fresh or salt, public or private. (This does not include drainage ditches, sedimentation ponds and other operational features on the site.)

84. ''Unstable area'' means a location that is susceptible to natural or human-induced events or forces capable of impairing the integrity of some or all of the landfill structural components responsible for preventing releases from a landfill. Unstable areas can include poor foundation conditions, areas susceptible to mass movements, and Karst terranes.

85. ''Uppermost aquifer'' means the geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected with this aquifer within the facility's property boundary.

86. ''Vector'' means a carrier that is capable of transmitting a pathogen from one organism to another including, but not limited to, flies and other insects, rodents, birds, and vermin.

87. ''Vertical expansion'' means an expansion of an existing solid waste landfill above previously permitted elevations for the purposes of gaining additional capacity.

88. ''Washout'' means the carrying away of solid waste by waters of the one-hundred year base flood.

89. ''Wetlands'' means those areas that are defined in 40 Code of Federal Regulations (CFR) Section 232.2(r) or State law.

90. "Yard trash" means solid waste consisting solely of vegetative matter resulting from landscaping maintenance.

C. Waste Characterization.

1. Waste Characterization Report.

a. Determination of the proper landfill class for disposal of a waste stream is based on the chemical and physical properties of the waste and not on the source of generation of the waste. To determine the class of landfill required for proper disposal of a waste stream, the permittee shall submit to the Department a waste characterization report. The waste characterization report shall consist of a comprehensive analytical evaluation of the chemical and physical nature of each waste stream. Hazardous wastes as defined in R.61–79, Hazardous Waste Management Regulations shall not be disposed of in the landfills under the purview of this regulation. The wastes acceptable for disposal in a Class One landfill, and waste items listed in Appendix I are exempt from the waste characterization process outlined in this regulation. Class Three landfills shall adhere to their approved Special Waste Analysis and Implementation Plan (SWAIP), pursuant to S.C. Code Section 44–96–390 which shall be deemed to be in compliance with this Section.

b. The toxicity characteristic leaching procedure (TCLP) (USEPA method 1311) shall be used to obtain all extracts for the purpose of characterizing a waste stream proposed for disposal in a solid waste landfill.

c. The analytical results of the TCLP shall be compared to the MCLs in South Carolina R.61–58 State Primary Drinking Water Regulation to determine the appropriate class landfill in which the waste stream may be disposed. If no MCL exists for a parameter, then those drinking water risk-based concentrations recognized by EPA Region IV shall be used to determine the appropriate class landfill for the waste. For those parameters where no MCL or Region IV number exists, the Department, using input from the permittee, will develop an appropriate number for determining the landfill class for disposal of that waste stream.

d. Unless otherwise exempted in this regulation, all wastes shall be characterized in accordance with the following schedule:

(1) A minimum of every three years using certified knowledge of the process by which the waste stream was generated;

(2) At a minimum of every six years using analytical test data from the TCLP;

(3) According to a Department approved alternate schedule based on the variability or non-variability noted in previous sampling events or other factors that affect the predictability of waste characteristics;

(4) When the process or raw materials used in the process that generates the waste changes significantly enough to alter the chemical makeup or chemical ratios of the waste stream; and,

(5) When a new waste stream is proposed for disposal.

e. Waste streams not listed in Appendix I, that demonstrate properties similar to the waste listed on Appendix I, may be exempted from testing as determined by the Department on a case-by-case basis. Requests for an exemption from testing, along with technical rationale for the exemption, shall be submitted to the Department in writing.

f. The Department will provide current forms and guidance documents needed for the successful completion of the waste characterization process. All analytical results from the characterization process shall be submitted to the Department on these forms or in a format approved by the Department.

2. Waste Testing and Waste Stream Determination.

a. The permittee shall submit to the Department a comprehensive determination of the chemical and physical nature of each waste stream to be landfilled in accordance with the following sampling and analytical requirements:

(1) To ensure that representative samples are obtained, the sampler shall develop a sampling plan and employ all reasonable measures, such as sampling different sources of solid waste at different times, or conducting random sampling of a representative pile of the waste generated

from different sources at different times. All samples of waste shall be collected using procedures as described in EPA Publication SW-846.

(2) All analytical testing required by this regulation shall be performed by a laboratory certified by the Department for the appropriate methodologies, to both properly prepare and analyze for the required parameters. The current guidelines for applicable regulatory thresholds, practical quantitation limits, and required quality assurance data shall be obtained from the Department prior to the start of the characterization project. Analytical results shall be submitted to the Department within 60 days of the sample collection date.

(3) Mixing of individual wastes to be disposed of prior to testing is acceptable only if:

(a) The individual wastes are mixed prior to discharge in the normal production process of the generator or the individual wastes are generated by identical processes and identical raw materials; or,

(b) The mixing of individual non-hazardous wastes results in a waste in which leaching characteristics are no greater than the leaching characteristics of one or more of the individual wastes; and,

i. A demonstration is submitted to the Department for review and approval that details how a reduction in leaching occurs due to some factor other than dilution. The demonstration shall include, at a minimum:

aa. The concentration, determined in accordance with the requirements of this Section, for each parameter which undergoes a reduction in concentration. Concentrations of parameters shall be determined for each individual waste in the mixture and for each parameter as a result of the mixture;

bb. A listing and the ratio, by weight and volume, of the individual wastes which comprise the mixture;

cc. Calculations using the concentration and weight data required in paragraphs aa. and bb. above, which demonstrate quantitatively that the reduction in leaching characteristics is not solely due to dilution; and,

dd. An identification and explanation of the chemical reactions, including chemical equations, which cause the reduction.

ii. The individual non-hazardous wastes are mixed in the same ratios and in the same manner in which they will be mixed prior to disposal.

(4) For the purpose of obtaining an extract, which will be analyzed for any volatile organic compounds, a zero head space extraction apparatus, as specified in the TCLP, shall be used.

(5) Practical Quantitation Limits (PQLs) for the analytical methods shall be one order of magnitude below the required regulatory threshold for the particular landfill class desired for disposal. Slight deviations in minimum PQL may be granted, on a case-by-case basis, with proper application and technical justification to the Department.

b. For the initial characterization of solid waste to be disposed of in a solid waste landfill, a minimum of two (2) representative samples of the waste shall be collected and tested in accordance with the TCLP. TCLP testing of additional samples of the solid waste may be required by the Department, based on a high degree of variability in the concentration of a parameter at or near the maximum allowable concentration for a particular landfill class. The Department may allow, with prior approval, the testing for selected constituents based on the generators knowledge of the process.

c. The permittee shall notify and obtain approval from the Department prior to making any physical or chemical changes to the waste stream being disposed of in a solid waste landfill.

(1) Significant changes in the chemical or physical nature of the waste stream may require disposal of the waste stream in a different class of landfill.

(2) Significant changes to the chemical or physical nature of the waste stream may require modification of the environmental monitoring program.

d. Any person seeking to utilize a testing or analytical method other than the TCLP method described in Section C.1.b. above may request authorization to do so. To be successful, the

applicant shall demonstrate to the satisfaction of the Department that the proposed method is equal to or superior to the TCLP in terms of its sensitivity, accuracy, and precision (i.e., reproducibility). The request shall include, at a minimum:

(1) A full description of the proposed method, including all procedural steps and equipment used in the method;

(2) Description of the types of wastes or waste matrices for which the proposed method may be used;

(3) Comparative results obtained from using the proposed method with those obtained from using the TCLP;

(4) An assessment of any factors, which may interfere with, or limit the use of, the proposed method;

(5) A description of the quality control procedures necessary to ensure the sensitivity, accuracy, and precision of the proposed method; and,

(6) Any other information on the proposed method, which the Department may reasonably request to evaluate the proposed method.

e. The outcome of an alternate testing procedure as outlined in Section C.2.d. above may result in revision of the landfill class limits as defined in Part I, Section A.1. of this regulation to ensure equivalent protection of human health and the environment.

f. Solid waste streams that contain chemicals or chemical properties potentially harmful to human health and the environment, for which TCLP or other approved testing procedures as outlined in Section C.2.d. above is not sufficient, shall be classified on a case-by-case basis by the Department. The permit applicant may be required to perform alternate testing procedures as necessary to determine the potential adverse effects to human health and the environment.

g. A sampling and analysis plan for performing the activities outlined in Section C.2.a.-f. above shall be submitted to the Department for review and approval prior to sampling for waste characterization purposes.

h. If the waste characterization test results indicate that a landfill reclassification is necessary based on exceedance of the landfill classification level outlined in Part IV A.1., the Department may require additional sampling and testing to confirm or reject such indication. If exceedance of the landfill classification level outlined in Part IV A.1 is confirmed and the facility intends to continue to accept the waste stream in question, the Department will require the permittee to submit a permit application for appropriate modifications to the landfill. The required modifications shall insure that the facility meets the requirements of the new landfill classification.

3. Waste Characterization Report for Class Two Landfills.

a. Class Two landfills shall, prior to permit issuance, submit a waste characterization report that contains at a minimum, the following:

(1) A listing of each solid waste proposed for disposal in the facility;

(2) The solid waste sampling plan used to ensure that accurate and representative samples are collected in accordance with Section C.2.a. above;

(3) A detailed description of any mixing to be proposed as described in Section C.2.a. above, and any available information that is required by that section;

(4) All laboratory results and quality assurance/quality control documentation that fully characterizes each waste; and,

(5) The name, location, and contact person of each generator of solid waste to be disposed of at the facility.

b. Class Two landfills that accept ONLY those wastes specifically listed in Appendix I are exempt from the waste characterization report requirements.

c. Class Three landfills shall adhere to their approved Special Waste Analysis and Implementation Plan (SWAIP), pursuant to S.C. Code Section 44–96–390.

4. Compliance with the Department approved SWAIP will satisfy requirements of this section for Class Three landfills.

D. Permit Application Process.

1. Determination of Need and Consistency.

a. Prior to submittal of a permit application to the Department for a new or expanded Class Two or Class Three Landfill, the applicant shall provide documentation of property ownership (e.g., tax map or deed) or proof of property control (e.g., contract) and request the following determinations by the Department:

(1) That there is a need for the proposed landfill or landfill expansion pursuant to Regulation 61–107.17 and that the Department has determined the maximum yearly disposal rate pursuant to Regulation 61–107.17;

(2) That the proposed landfill or landfill expansion is consistent with the State and county/region solid waste management plans pursuant to S.C. Section 44-96-290(F);

(3) That the proposed landfill or landfill expansion is consistent with local zoning, land use, and any other applicable ordinances pursuant to S.C. Code Section 44-96-290(F);

(4) That the proposed landfill or landfill expansion meets the buffer requirements set forth in Part IV, B.1.a. of this Regulation for Class Two landfills and Part V, Subpart B.258.18.a. of this Regulation for class Three landfills;

b. Where, prior to the effective date of this regulation, the Department has made determinations required under Part I.D.1.a. of this regulation, such determinations shall remain applicable and become the agency's final determination under Part I.D.1, subject to the appeal provision in Part I.D.1.c and the subsequent public notice and application process.

c. A Department decision involving a determination listed herein, may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

2. Public Notification and Participation.

a. Notice of Intent to File a Permit Application.

(1) Within 15 days of notification from the Department that all requests for need and consistency determinations as outlined in Section D.1.a. above have been submitted to the Department for a new or expanding Class Two or Class Three Landfill, the applicant shall publish Notice of Intent to File a Permit Application in a newspaper of general circulation in the area of the proposed landfill project. The notice shall be published in the legal section of the paper for three consecutive days. This section does not apply to major permit modifications that are not expansions of an existing landfill.

(2) The notice shall contain at least the following:

(a) Name and address of the applicant;

(b) The location of the proposed landfill or landfill expansion to include the county, roads and crossroads;

(c) The town or community nearest to the proposed landfill or landfill expansion;

(d) The proposed size of the landfill or landfill expansion, i.e., footprint acreage;

(e) An explanation of the type(s) of waste that will be accepted;

(f) A statement that a request has been submitted to the Department for a determination that there is a need for the proposed landfill or landfill expansion pursuant to Regulation 61–107.17 and for a determination of the maximum yearly disposal rate pursuant to Regulation 61–107.17;

(g) A statement that a request has been submitted to the Department for a determination that the proposed landfill or landfill expansion is consistent with the State and county/region solid waste management plans pursuant to S.C. Section 44-96-290(F);

(h) A statement that a request has been submitted to the Department for a determination that the proposed landfill or landfill expansion is consistent with local zoning, land use, and any other applicable ordinances pursuant to S.C. Code Section 44-96-290(F);

(i) A statement that a request has been submitted to the Department for a determination that the proposed landfill or landfill expansion meets the buffer requirements set forth in Part

IV, B.1.a. of this Regulation for Class Two landfills and Part V, Subpart B.258.18.a. of this Regulation for Class Three landfills;

(j) Department locations (Central Office and appropriate Regional Office) where a copy of these documents can be viewed during normal working hours; and,

(k) The Department's address and contact name for submittal of inquiries and placement of name on the Department's mailing list for future decisions.

(3) No permit application may be accepted by the Department for filing unless accompanied by documentation from the newspaper that publication has been made.

(4) No later than the first date of publication in the newspaper, the applicant shall mail a copy of the Notice of Intent to File a Permit Application by certified mail, return receipt requested, to all adjoining landowners of the proposed landfill or landfill expansion.

b. Notice of Draft Determinations of Need and Consistency Under Section D.1.a. Above.

(1) For Class Two and Class Three landfills, the Department will publish a notice when the draft determinations are ready for review for all new or expanded landfills. This notice will be published in a newspaper of general circulation in the area of the proposed landfill and sent to affected persons who have asked to be notified. The notice will list locations where a copy of the draft determinations can be reviewed. The public will have a 30-day period to review the draft determinations and submit comments to the Department, pursuant to the Administrative Procedures Act, SC Code Section 1–23–10 et seq.

(2) Public Hearings for Draft Determinations.

(a) The Department will conduct a public hearing upon receipt of requests in writing by ten (10) persons or by a governmental subdivision or agency or by an association having not less than ten members.

(b) A request for a public hearing must be mailed (postmarked) to the Department during the 30 day comment period and shall be based on technical reasons relating to siting, design, or operation of the landfill. The Department will send a notice acknowledging receipt of a request for a public hearing to the applicant and to the person(s) requesting a hearing within 15 days following receipt of the request. The Department will publish a notice of the time, date, and location of the hearing.

(3) Notice of Department Determinations. After close of the public comment period on the draft determination and the public hearing, if held, the Department will issue a Department Decision. Notice of the Department Decision will be sent by certified mail, return receipt requested, to the applicant. Notice of the Department's decision will be sent by regular mail, unless certified mail is requested, to affected persons who have asked to be notified, to all persons who commented in writing to the Department, and to all persons who attended the public hearing, if held. However, if the Department determines that members of the same group or organization have submitted comments or a petition, the Department may only notify all group leaders and petition organizers by certified mail, return receipt requested. The Department will ask these leaders and organizers to notify members of their groups or any concerned citizens who signed the petitions. The Department will also publish notice of the Department Decision in a newspaper of general circulation in the area of the proposed activity. The Department's notice will include instructions on how to request a final review conference and the time frame for filing such a request.

c. Notice of Filing Permit Application.

(1) Notice of all applications submitted to the Department for the initial construction and major modifications of Class Two and Class Three landfills shall be published by the applicant once in a newspaper of general circulation in the area of the proposed landfill project. Notice for Class Two landfill application shall be published as provided in Part IV, Section H.3. Notice for new Class Three landfills that accept municipal solid waste shall be published as provided in S. C. Code Section 44–96–470 and Part V, Subpart H.3.a. of this regulation within 15 days of filing the permit application. Notice for all other new Class Three landfills shall be published as provided in Part V, Subpart H.3.b.

(2) All notices shall contain the following:

(a) Name and address of the applicant;

(b) The location of the proposed activity to include the county, roads and crossroads. (Class Three landfills shall provide a location map of the proposed site);

(c) The nature of the proposed activity;

(d) A description of the proposed site or a description of the proposed major modification;

(e) An explanation of the type(s) of waste that will be accepted;

(f) Department locations (Central Office and appropriate Regional Office) where a copy of the permit application or draft permit, as appropriate, can be viewed during normal working hours;

(g) The Department's address and contact name for submittal of comments and inquires;

(h) The approximate tonnage/year expected for disposal at the landfill; and,

(i) The proposed life of the landfill.

(3) The Department will send a notice of receipt of the permit application by regular mail to all adjoining landowners of the proposed landfill.

d. Public notification requirements for Class One landfills are defined in Part III, Section B.4.

e. Notice of Draft Permit. For Class Two and Class Three landfills, the Department will publish a notice when the draft permit is ready for review for all new landfills and for major modifications as determined by the Department. This notice will be published in a newspaper of general circulation in the area of the proposed landfill and will be sent to affected persons who have asked to be notified. The notice will list locations where a copy of the draft permit can be reviewed. The public will have a 30-day period to review the draft permit and submit comments to the Department, pursuant to the Administrative Procedures Act, SC Code Section 1–23–10 et seq.

f. Public Hearings for Draft Permits.

(1) The Department will conduct a public hearing upon receipt of requests in writing by ten (10) persons or by a governmental subdivision or agency or by an association having not less than ten members.

(2) A request for a public hearing must be mailed (postmarked) to the Department during the 30 day comment period and shall be based on technical reasons relating to siting, design, or operation of the landfill. The Department will send a notice acknowledging receipt of a request for a public hearing to the applicant and to the person(s) requesting a hearing within 15 days following receipt of the request. The Department will publish a notice of the time, date, and location of the hearing.

g. Notice of Department Decision on the Permit. After close of the public comment period on the draft permit and the public hearing, if held, the Department will issue a Department Decision. Notice of the Department Decision will be sent by certified mail, return receipt requested, to the applicant. Notice of the Department's decision will be sent by regular mail, unless certified mail is requested, to affected persons who have asked to be notified, to all persons who commented in writing to the Department, and to all persons who attended the public hearing, if held. However, if the Department determines that members of the same group or organization have submitted comments or a petition, the Department may only notify all group leaders and petition organizers by certified mail, return receipt requested. The Department will ask these leaders and organizers to notify members of their groups or any concerned citizens who signed the petitions. The Department will also publish notice of the Department Decision in a newspaper of general circulation in the area of the proposed activity. The Department's notice will include instructions on how to request a final review conference and the time frame for filing such a request.

E. Financial Assurance Criteria. The requirements of this Section apply to all: Class One landfills, except landfills owned and operated by local government or a region comprised of local governments, State or Federal government; Class Two landfills, except landfills owned and operated by local government or a region comprised of local governments, State or Federal government; and, Class Three landfills, except landfills owned and operated by State or Federal government entities whose debts and liabilities are the debts and liabilities of the State or the United States.

1. Financial Assurance for Closure.

a. The permittee shall have a detailed written estimate, in current dollars, of the cost of hiring a third party to close the largest area of the landfill ever requiring a final cover at any time during the active life in accordance with the closure plan. The permittee shall submit a copy of the estimate to the Department for review and approval.

(1) The cost estimate shall equal the cost of closing the largest area of the landfill ever requiring a final cover at any time during the active life when the extent and manner of its operation would make closure the most expensive, as indicated by its closure plan.

(2) During the active life of the landfill, the permittee shall annually adjust the closure cost estimate for inflation.

(3) The permittee shall increase the closure cost estimate and the amount of financial assurance provided if changes to the closure plan or landfill conditions increase the maximum cost of closure at any time during the remaining active life.

(4) The permittee may reduce the closure cost estimate and the amount of financial assurance provided for proper closure if the cost estimate exceeds the maximum cost of closure at any time during the remaining life of the landfill. The permittee shall submit justification for the reduction of the closure cost estimate and the amount of financial assurance to the Department for review and approval.

b. The permittee of each landfill shall establish financial assurance for closure of the landfill as required by this regulation using an allowable mechanism. The permittee shall provide continuous coverage for closure until released from financial assurance requirements, pursuant to this regulation.

2. Financial Assurance for Post-closure Care.

a. The permittee shall have a detailed written estimate, in current dollars, of the cost of hiring a third party to conduct post-closure care for the landfill in compliance with the applicable post-closure plan. The post-closure cost estimate used to demonstrate financial assurance shall account for the total costs of conducting post-closure care, including annual and periodic costs as described in the post-closure plan over the entire post-closure care period. The permittee shall submit a copy of the estimate to the Department for review and approval.

(1) The cost estimate for post-closure care shall be based on the most expensive costs of post-closure care during the post-closure care period.

(2) During the post-closure care period, the permittee shall annually adjust the post-closure cost estimate for inflation.

(3) The permittee shall increase the post-closure care cost estimate and the amount of financial assurance provided if changes in the post-closure plan or landfill conditions increase the maximum costs of post-closure care.

(4) The permittee may reduce the post-closure cost estimate and the amount of financial assurance provided if the cost estimate exceeds the maximum costs of post-closure care remaining over the post-closure care period. The permittee shall submit justification for the reduction of the post-closure cost estimate and the amount of financial assurance to the Department for review and approval.

b. The permittee of each landfill shall establish financial assurance for the costs of post-closure care as required by this regulation using an allowable mechanism. The permittee shall provide continuous coverage for post-closure care until released from financial assurance requirements for post-closure care.

3. Financial Assurance for Corrective Action.

a. A permittee of a landfill required to undertake a corrective action, pursuant to this regulation, shall have a detailed written estimate, in current dollars, of the cost of hiring a third party to perform the corrective action in accordance with the corrective action plan. The corrective action cost estimate shall account for the total costs of corrective action activities as described in the corrective action plan for the entire corrective action period. The permittee shall submit a copy of the estimate to the Department for review and approval.

(1) The permittee shall annually adjust the estimate for inflation until the corrective action program is completed, pursuant to this regulation.

(2) The permittee shall increase the corrective action cost estimate and the amount of financial assurance provided if changes in the corrective action program or landfill conditions increase the maximum costs of corrective action.

(3) The permittee may reduce the amount of the corrective action cost estimate and the amount of financial assurance provided in Section E.3.b. below, if the cost estimate exceeds the maximum remaining costs of corrective action. The permittee shall submit justification for the reduction of the corrective action cost estimate and the amount of financial assurance to the Department for review and approval.

b. The permittee of each landfill required to undertake a corrective action program, pursuant to this regulation, shall establish financial assurance for the most recent corrective action program using an allowable mechanism. The permittee shall provide continuous coverage for corrective action until released from financial assurance requirements for corrective action in accordance with this regulation.

4. Allowable Mechanisms. The mechanisms used to demonstrate financial assurance under this section shall ensure that the funds necessary to meet the costs of closure, post-closure care, and corrective action for known releases will be available whenever they are needed. Owners/operators shall choose from the options outlined herein. Payments made into the standby trust fund by the provider of the financial assurance pursuant to the Department instruction shall be transferred to the Trustee and are referred to as the Fund, together with all earnings and profits thereon, less any payments or distributions made by the Trustee. An originally signed duplicate of the standby trust agreement shall be submitted to the Department with documentation of the selected mechanism(s).

a. Trust Fund.

(1) A permittee may satisfy the requirements of this section by establishing a trust fund that conforms to the requirements of this regulation.

(a) The trustee shall be an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(b) The text of the trust agreement shall be provided by the Department.

(c) The original trust agreement signed by the permittee and the trustee shall be submitted to the Department for review and approval. The trust agreement shall be accompanied by:

i. Schedule A. This information shall be in a format approved by the Department, updated within 60 days of each change in cost estimate, and include, at a minimum, the following about the facility:

(aa) Permit number, if available;

(bb) Name of the permittee;

(cc) Address of the facility;

(dd) Current closure cost estimate; and,

(ee) Current post-closure cost estimate, if appropriate.

ii. Schedule B. This information shall be in a format approved by the Department and include, at a minimum:

(aa) The amount of funds or property used to initially establish the trust fund; and,

(bb) The account number in which the funds are being held.

iii. A Certificate of Acknowledgment for Solid Waste Management Facility Trust Fund Agreement in a format approved by the Department to include, at a minimum, the:

(aa) Name of the trustee; and,

(bb) Name of the permittee.

(d) The trust fund shall be irrevocable and can not be changed or recalled without written agreements from the Department.

(2) Payments into the trust fund for closure and post-closure care shall be made annually by the permittee for five years or over the remaining life of the landfill, whichever is shorter. This

period is referred to as the pay-in period. In the case of a trust fund for corrective action of known releases, the pay-in period shall consists of one-half (½) of the estimated length of the corrective action program.

(3) For a trust fund used to demonstrate financial assurance for closure and post-closure care, the first payment into the fund shall be at least equal to the current cost estimate for closure or post-closure care divided by the number of years in the pay-in period as defined in Section E.4.a.(2) above. The amount of subsequent payments shall be determined by the following formula:

$$\text{Next Payment} = \frac{CE-CV}{Y}$$

where CE is the current cost estimate for closure or post-closure care (updated for inflation or other changes), CV is the current value of the trust fund, and Y is the number of years remaining in the pay-in period.

(4) For a trust fund used to demonstrate financial assurance for corrective action, the first payment into the trust fund shall be at least equal to one-half of the current cost estimate for corrective action, except as provided in Section E.4.h., divided by the number of years in the corrective action pay-in period as defined in Section E.4.a.(2) above. The amount of subsequent payments shall be determined by the following formula:

$$\text{Next Payment} = \frac{RB-CV}{Y}$$

where RB is the most recent estimate of the required trust fund balance for corrective action (i.e., the total costs that will be incurred during the second half of the corrective action period), CV is the current value of the trust fund, and Y is the number of years remaining on the pay-in period.

(5) The initial payment into the trust fund shall be made before the initial receipt of waste in the case of closure and post-closure care, or no later than 120 days after the corrective action remedy has been selected.

(6) If the permittee establishes a trust fund after having used one or more alternate mechanisms, the initial payment into the trust fund shall be at least the amount that the fund would contain if the trust fund were established initially and annual payments made according to the applicable specifications.

(7) The permittee, or other person authorized to conduct closure, post-closure care, or corrective action activities may request reimbursement from the trustee for these expenditures. Requests for reimbursement shall be granted by the trustee only if sufficient funds are remaining in the trust fund to cover the most recent Department-approved cost estimate for closure, post-closure care, or corrective action, and if justification and documentation of the cost is placed in the operating record. The permittee shall notify the Department that the documentation of the justification for reimbursement has been placed in the operating record and that reimbursement has been received.

(8) The trust fund account shall contain, at a minimum, the amount of funds needed to complete final closure of the facility at any given time during the life of the facility. An annual statement shall be provided to the Department at least 30 days prior to the anniversary date of establishment of the fund that confirms the value of the trust fund account to include all payments made into the account and all reimbursements paid from the account during the previous year.

(9) The trust fund may be terminated by the permittee only if the permittee substitutes alternate acceptable financial assurance or if he is no longer required to demonstrate financial responsibility in accordance with this regulation.

b. Surety Bond Guaranteeing Payment or Performance.

(1) A permittee may demonstrate financial assurance for closure or post-closure care by obtaining a payment or performance surety bond which conforms to the requirements of this

regulation. A permittee may demonstrate financial assurance for corrective action by obtaining a performance bond which conforms to the requirements of this regulation. The bond shall be effective before the initial receipt of waste in the case of closure and post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with this regulation. The permittee shall submit a copy of the bond to the Department. The surety company issuing the bond shall, at a minimum, be among those listed as acceptable sureties on Federal bonds in Circular 570 of the U.S. Department of the Treasury. The text of the surety bond shall be provided by the Department.

(2) In addition to the surety bond, the permittee shall establish a standby trust fund, to receive payments using a trustee that has the authority to act as a trustee and that is regulated and examined by a Federal or State agency. The text of the standby trust shall be provided by the Department.

(3) The following documents shall be submitted to the Department:

(a) The original surety bond signed by the Surety and the permittee; and,

(b) The original standby trust agreement signed by the permittee and the trustee.

(4) The penal sum of the bond shall be in an amount at least equal to the current closure, post-closure care or corrective action cost estimate, whichever is applicable, except as provided in Section E.4.j.

(5) Under the terms of the bond, the surety shall become liable on the bond obligation when the permittee fails to perform as guaranteed by the bond.

(6) The permittee shall establish a standby trust fund. The standby trust fund shall meet the requirements for a trust fund as defined in Section E.4.a. except the requirements for initial payment and subsequent annual payments specified in Section E.4.a.(2) through (5) above.

(7) Payments made under the terms of the bond shall be deposited by the surety directly into the standby trust fund. Payments from the trust fund shall be approved by the trustee.

(8) Under the terms of the bond, the surety may cancel the bond by sending notice of cancellation by certified mail to the permittee and to the Department 120 days in advance of cancellation. If the surety cancels the bond, the permittee shall obtain alternate financial assurance as specified in this section.

(9) The permittee may cancel the bond only if alternate financial assurance is substituted as specified in this section or if the permittee is no longer required to demonstrate financial responsibility in accordance with this regulation.

c. Letter of Credit.

(1) A permittee may satisfy the requirements of this section by obtaining an irrevocable standby letter of credit which conforms to the requirements of this regulation. The letter of credit shall be effective before the initial receipt of waste in the case of closure and post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with this regulation. The issuing institution shall be an entity which has the authority to issue letters of credit and whose letter-of-credit operations are regulated and examined by a Federal or State agency. The text of the letter of credit shall be provided by the Department.

(2) The original letter of credit shall be submitted to the Department.

(3) The letter of credit shall be irrevocable and issued for a period of at least one (1) year in an amount at least equal to the current cost estimate for closure, post-closure care or corrective action, whichever is applicable, except as provided in Section E.4.a.. The letter of credit shall provide that the expiration date will be automatically extended for a period of at least one year unless the issuing institution has canceled the letter of credit by sending notice of cancellation by certified mail to the permittee and to the Department 120 days in advance of cancellation. If the letter of credit is canceled by the issuing institution, the permittee shall obtain alternate financial assurance.

(4) The permittee may cancel the letter of credit only if alternate financial assurance is substituted as specified in this section or if the permittee is no longer required to demonstrate financial responsibility in accordance with this regulation.

d. Insurance.

(1) A permittee may demonstrate financial assurance for closure and post-closure care by obtaining insurance that conforms to the requirements of this regulation. The insurance shall be effective before the initial receipt of waste in the case of closure and post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with the requirements of this regulation. At a minimum, the insurer shall be licensed to transact the business of insurance, or eligible to provide insurance as an excess or surplus lines insurer, in one or more States. The permittee shall submit a copy of the insurance policy to the Department for review and approval. Once approved, the permittee shall submit a copy of the effective insurance policy including all endorsements and attachments to the Department.

(2) The closure or post-closure care insurance policy shall guarantee that funds will be available to close the landfill whenever final closure occurs or to provide post-closure care for the landfill whenever the post-closure care period begins, whichever is applicable. The policy shall also guarantee that once closure or post-closure care begins, the insurer shall be responsible for the paying out of funds to the permittee or other person authorized to conduct closure or post-closure care, up to an amount equal to the face amount of the policy.

(3) The insurance policy shall be issued for a face amount at least equal to the current cost estimate for closure or post-closure care, whichever is applicable, except as provided in the section that addresses the use of multiple financial mechanisms. The term "face amount" means the total amount the insurer is obligated to pay under the policy. Actual payments by the insurer shall not change the face amount, although the insurer's future liability will be lowered by the amount of the payments.

(4) A permittee, or any other person authorized to conduct closure or post-closure care, may receive reimbursements for closure or post-closure expenditures, whichever is applicable. Requests for reimbursement shall be granted by the insurer only if the remaining value of the policy is sufficient to cover the remaining costs of closure or post-closure care, and if justification and documentation of the cost is submitted to and approved by the Department.

(5) Each policy shall contain a provision allowing assignment of the policy to a successor permittee. Such assignment may be conditional upon consent of the insurer, provided that such consent is not unreasonably refused.

(6) The insurance policy shall provide that the insurer may not cancel, terminate or fail to renew the policy except for failure to pay the premium. The automatic renewal of the policy shall, at a minimum, provide the insured with the option of renewal at the face amount of the expiring policy. If there is a failure to pay the premium, the insurer may cancel the policy by sending notice of cancellation by certified mail to the permittee and to the Department 120 days in advance of cancellation. If the insurer cancels the policy, the permittee shall obtain alternate financial assurance.

(7) For insurance policies providing coverage for post-closure care, the insurer shall annually increase the face amount of the policy beginning on the date that liability to make payments is initiated. Such increase shall be equivalent to the face amount of the policy, less any payments made, multiplied by an amount equivalent to 85% of the most recent investment rate or of the equivalent coupon-issue yield announced by the U.S. Treasury for 26-week Treasury securities.

(8) The permittee may cancel the insurance policy only if alternate acceptable financial assurance is substituted, or if the permittee is no longer required to demonstrate financial responsibility in accordance with this regulation.

e. Corporate Financial Test. A permittee that satisfies the requirements of this section may demonstrate financial assurance up to the amount specified below:

(1) Financial component.

(a) The permittee shall satisfy one of the following three conditions:

i. A current rating for its senior unsubordinated debt of AAA, AA, A, or BBB as issued by Standard and Poor's or Aaa, Aa, A or Baa as issued by Moody's; or,

ii. A ratio of less than 1.5 comparing total liabilities to net worth; or,

iii. A ratio of greater than 0.10 comparing the sum of net income plus depreciation, depletion and amortization, minus $10 million, to total liabilities.

(b) The tangible net worth of the permittee shall be greater than:

i. The sum of the current closure, post-closure care, corrective action cost estimates and any other environmental obligations, including guarantees, covered by a financial test plus $10 million, except as provided in paragraph E.4.e.(1)(b)ii. below.

ii. $10 million in net worth plus the amount of any guarantees that have not been recognized as liabilities on the financial statements provided all of the current closure, post-closure care, and corrective action costs and any other environmental obligations covered by a financial test are recognized as liabilities on the owner's or operator's audited financial statements, and subject to the approval of the Department.

(c) The Permittee shall have assets located in the United States amounting to at least the sum of current closure, post-closure care, corrective action cost estimates and any other environmental obligations covered by a financial test as described herein.

(2) Record keeping and reporting requirements.

(a) The permittee shall place the following items into the facility's operating record and submit a copy to the Department:

i. A letter signed by the permittee's chief financial officer that:

(aa) Lists all the current cost estimates covered by a financial test, including, but not limited to, cost estimates required for municipal solid waste management facilities under 40 CFR Part 258, cost estimates required for UIC facilities under 40 CFR part 144, if applicable, cost estimates required for petroleum underground storage tank facilities under 40 CFR part 280, if applicable, cost estimates required for PCB storage facilities under 40 CFR part 761, if applicable, and cost estimates required for hazardous waste treatment, storage, and disposal facilities under 40 CFR parts 264 and 265, if applicable; and,

(bb) Provides evidence demonstrating that the firm meets the conditions outlined above for either the current rating for its senior unsubordinated debt, or compliance with the ratio comparing total liabilities to net worth, or the ratio comparing net income to total liabilities as outlined in Section E.4.e.(1)(a) above, and the tangible net worth requirements in Section E.4.e.(1)(b) above and assets as outlined in Section E.4.e.(1)(c) above.

ii. A copy of the independent certified public accountant's unqualified opinion of the permittee's financial statements for the latest completed fiscal year. To be eligible to use the financial test, the owner's or operator's financial statements shall receive an unqualified opinion from the independent certified public accountant. An adverse opinion, disclaimer of opinion, or other qualified opinion will be cause for disallowance, with the potential exception for qualified opinions provided in the next sentence. The Department may evaluate qualified opinions on a case-by-case basis and allow use of the financial test in cases where the Department deems that the matters which form the basis for the qualification are insufficient to warrant disallowance of the test. If the Department does not allow use of the test, the permittee shall provide alternate financial assurance that meets the requirements of this section.

iii. If the chief financial officer's letter providing evidence of financial assurance includes financial data showing that the permittee satisfies either the ratio comparing total liabilities to net worth in Section E.4.e.(1)(a)ii. above, or the ratio comparing net income to total liabilities in Section E.4.e.(1)(a)iii. above that is different from data in the audited financial statements in the independent certified public accountant's financial statements for the latest complete fiscal year, referred to in Section E.4.e.(2)(a)ii. above, or any other audited financial statement or data filed with the SEC, then a special report from the permittee's independent certified public accountant to the permittee is required. The special report shall be based upon an agreed upon procedures engagement in accordance with professional auditing standards and shall describe the procedures performed in comparing the data in the chief financial officer's letter derived from the independently audited, year-end financial

statements for the latest fiscal year with the amounts in such financial statements, the findings of that comparison, and the reasons for any differences.

iv. If the chief financial officer's letter provides a demonstration that the firm has assured for environmental obligations as provided in paragraph E.4.e.(1)(b)ii. above, then the letter shall include a report from the independent certified public accountant that verifies that all of the environmental obligations covered by a financial test have been recognized as liabilities on the audited financial statements, how these obligations have been measured and reported, and that the tangible net worth of the firm is at least $10 million plus the amount of any guarantees provided.

(b) A permittee shall place all records and reports required by this section in the operating record and notify the Department that these items have been placed in the operating record before the initial receipt of waste for closure and post-closure care, and within 120 days after a corrective action remedy has been selected in accordance with this regulation.

(c) After all required records and reports have been placed in the operating record, the permittee shall annually update the information and place updated information in the operating record within 90 days following the close of the permittee's fiscal year. The Department may allow an additional 45 days for a permittee who can demonstrate that 90 days is insufficient time to acquire audited financial statements. The updated information shall encompass all required reports and records.

(d) The record keeping and reporting requirements are no longer applicable when the permittee:

i. Substitutes alternate financial assurance that is not subject to the Record keeping and reporting requirements; or,

ii. Is released from the requirements of providing financial assurance for closure, post-closure, and corrective action pursuant to this regulation.

(e) If the requirements of the financial component in Section E.4.e.(1) above are no longer met, within 120 days following the end of the facility's fiscal year, the permittee shall:

i. Obtain alternative financial assurance that meets the requirements of this section;

ii. Place the required submissions for that assurance in the operating record; and,

iii. Notify the Department that the permittee no longer meets the criteria of the financial test and that alternate assurance has been obtained.

(f) Based on a reasonable belief that the requirements of the financial component are no longer met, at any time the Department may require the submittal of reports of its financial condition in addition to or including current financial test documentation pursuant to this regulation. If the Department finds that the permittee no longer meets the requirements of the financial component, the permittee shall provide alternate financial assurance that meets the requirements of this regulation.

(3) Calculation of costs to be assured. When calculating the current cost estimates for closure, post-closure care, corrective action, or the sum of the combination of such costs to be covered, and any other environmental obligations assured by a financial test pursuant to this regulation, the permittee shall include cost estimates required for municipal solid waste management facilities under this part, as well as cost estimates required for the following environmental obligations, if it assures them through a financial test: obligations associated with UIC facilities under 40 CFR part 144, petroleum underground storage tank facilities under 40 CFR part 280, PCB storage facilities under 40 CFR part 761, and hazardous waste treatment, storage, and disposal facilities under 40 CFR parts 264 and 265.

f. Local Government Financial Test. A permittee that satisfies the requirements of Sections E.4.f.(1) through (3) may demonstrate financial assurance up to the amount specified in Section E.4.f.(4) below:

(1) Financial Component.

(a) The permittee shall satisfy one of the following two conditions:

i. If the permittee has outstanding, rated, general obligation bonds that are not secured by insurance, a letter of credit, or other collateral or guarantee, it shall have a current rating of Aaa, Aa, A, or Baa, as issued by Moody's, or AAA, AA, A, or BBB, as issued by Standard and Poor's on all such general obligation bonds; or,

ii. The permittee shall satisfy each of the following financial ratios based on the permittee's most recent audited annual financial statement:

(aa) A ratio of cash plus marketable securities to total expenditures greater than or equal to 0.05; and,

(bb) A ratio of annual debt service to total expenditures less than or equal to 0.20.

(b) The permittee shall prepare its financial statements in conformity with Generally Accepted Accounting Principles for governments and have its financial statements audited by an independent certified public accountant (or appropriate State agency).

(c) A local government is not eligible to assure its obligations under the local government financial test if it:

i. Is currently in default on any outstanding general obligation bonds; or,

ii. Has any outstanding general obligation bonds rated lower than Baa as issued by Moody's or BBB as issued by Standard and Poor's; or,

iii. Operated at a deficit equal to 5% or more of total annual revenue in each of the past two fiscal years; or,

iv. Receives an adverse opinion, disclaimer of opinion, or other qualified opinion from the independent certified public accountant (or appropriate State agency) auditing its financial statement as required in Section E.4.f.(1)(b) above. However, the Department may evaluate qualified opinions on a case-by-case basis and allow use of the financial test in cases where the Department deems the qualification insufficient to warrant disallowance of use of the test.

(d) The following terms used in this Paragraph are defined as follows:

i. "Deficit" equals total annual revenues minus total annual expenditures;

ii. "Total revenues" include revenues from all taxes and fees but does not include the proceeds from borrowing or asset sales, excluding revenue from funds managed by local government on behalf of a specific third party;

iii. "Total expenditures" include all expenditures excluding capital outlays and debt repayment;

iv. "Cash plus marketable securities" is all the cash plus marketable securities held by the local government on the last day of a fiscal year, excluding cash and marketable securities designated to satisfy past obligations such as pensions; and,

v. "Debt service" is the amount of principal and interest due on a loan in a given time period, typically the current year.

(2) Public Notice Component. The local government permittee shall place a reference to the closure and post-closure care costs assured through the financial test into its next comprehensive annual financial report (CAFR) after the effective date of this section or prior to the initial receipt of waste at the facility, whichever is later. Disclosure shall include the nature and source of closure and post-closure care requirements, the reported liability at the balance sheet date, the estimated total closure and post-closure care cost remaining to be recognized, the percentage of landfill capacity used to date, and the estimated landfill life in years. A reference to corrective action costs shall be placed in the CAFR not later than 120 days after the corrective action remedy has been selected in accordance with this regulation. For the first year the financial test is used to assure costs at a particular facility, the reference may instead be placed in the operating record until issuance of the next available CAFR if timing does not permit the reference to be incorporated into the most recently issued CAFR or budget. For closure and post-closure costs, conformance with Government Accounting Standards Board Statement 18 assures compliance with this public notice component.

(3) Record Keeping and Reporting Requirements.

(a) The local government permittee shall place the following items in the facility's operating record and submit a copy to the Department:

i. A letter signed by the local government's chief financial officer that:

(aa) Lists all the current cost estimates covered by a financial test as required;

(bb) Provides evidence and certifies that the local government meets the conditions of either the required rating for general obligation bonds or satisfies the required financial ratios pursuant to Section E.4.f.(1)(a) above, and financial statements and audits as required in Section E.4.f.(1)(b) above, and meets the criteria outlined in Section E.4.f.(1)(c) above regarding eligibility to assure its obligations; and,

(cc) Certifies that the local government meets the requirements established for public notification pursuant to Section E.4.f.(2) above, and the calculation of costs to be assured pursuant to Section E.4.f.(4) below;

ii. The local government's independently audited year-end financial statements for the latest fiscal year (except for local governments where audits are required every two years and where unaudited statements may be used in years when audits are not required), including the unqualified opinion of the auditor who shall be an independent, certified public accountant or an appropriate State agency that conducts equivalent comprehensive audits;

iii. A report to the local government from the local government's independent certified public accountant (CPA) or the appropriate State agency based on performing an agreed upon procedures engagement relative to the financial ratios required by Section E.4.f.(1)(a)ii. of this section, if applicable, and the requirements for financial statements pursuant to Section E.4.f.(1)(b), and assuring obligations outlined in Sections E.4.f.(1)(c)iii. and iv. The CPA or State agency's report should state the procedures performed and the CPA or State agency's findings; and,

iv. A copy of the comprehensive annual financial report (CAFR) used to comply with the public notice requirements in Section E.4.f.(2) above or certification that the requirements of General Accounting Standards Board Statement 18 have been met.

(b) The record keeping and reporting requirements outlined in Section E.4.f.(3)(a) above shall be placed in the facility operating record and a copy submitted to the Department:

i. In the case of closure and post-closure care, prior to the initial receipt of waste at the facility; or,

ii. In the case of corrective action, not later than 120 days after the corrective action remedy is selected in accordance with the requirements of this regulation.

(c) After the initial placement of the items in the facility's operating record, the local government permittee shall update the information and place the updated information in the operating record and submit a copy to the Department within 180 days following the close of the permittee's fiscal year.

(d) The local government permittee is no longer required to meet the record keeping and reporting requirements outlined in Section E.4.f.(3) above when:

i. The permittee substitutes alternate financial assurance as specified in this section; or,

ii. The permittee is released from the requirements of this section in accordance with this regulation.

(e) A local government shall satisfy the requirements of the financial test at the close of each fiscal year. If the local government permittee no longer meets the requirements of the local government financial test it shall, within 210 days following the close of the permittee's fiscal year, obtain alternative financial assurance that meets the requirements of this section, place the required submissions for that assurance in the operating record, and notify the Department that the permittee no longer meets the criteria of the financial test and that alternate assurance has been obtained.

(f) The Department, based on a reasonable belief that the local government permittee may no longer meet the requirements of the local government financial test, may require additional reports of financial condition from the local government at any time. If the

Department finds, on the basis of such reports or other information, that the permittee no longer meets the requirements of the local government financial test, the local government shall provide alternate financial assurance in accordance with this section.

(4) Calculation of Costs to be Assured. The portion of the closure, post-closure, and corrective action costs for which a permittee can assure under this Section is determined as follows:

(a) If the local government permittee does not assure other environmental obligations through a financial test, it may assure closure, post-closure, and corrective action costs that equal up to 43% of the local government's total annual revenue.

(b) If the local government assures other environmental obligations through a financial test, including those associated with UIC facilities under 40CFR144.62, petroleum underground storage tank facilities under 40CFR280, PCB storage facilities under 40CFR761, and hazardous waste treatment, storage, and disposal facilities under 40CFR264 and 265, it shall add those costs to the closure, post-closure, and corrective action costs it seeks to assure under this Item.

g. Local Government Guarantee. A permittee may demonstrate financial assurance for closure, post-closure, and corrective action, as required in this regulation, by obtaining a written guarantee provided by a local government. The guarantor shall meet the requirements of the Local Government Financial Test in Section E.4.f. above, and shall comply with the terms of a written guarantee.

(1) Terms of the Written Guarantee. The guarantee shall be effective before the initial receipt of waste, in the case of closure, post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with this regulation. The guarantee shall provide the following:

(a) If the permittee fails to perform closure, post-closure care, and/or corrective action of a facility covered by the guarantee, the guarantor shall:

i. Perform, or pay a third party to perform, closure, post-closure care, and/or corrective action as required; or,

ii. Establish a fully funded trust fund as specified in Section E.4.a. above in the name of the permittee.

(b) The guarantee shall remain in force unless the guarantor sends notice of cancellation by certified mail to the permittee and to the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the permittee and the Department, as evidenced by the return receipts.

(c) If a guarantee is canceled, the permittee shall, within 90 days following receipt of the cancellation notice by the permittee and the Department, obtain alternate financial assurance, place evidence of that alternate financial assurance in the facility operating record, and notify the Department. If the permittee fails to provide alternate financial assurance within the 90 day period, the guarantor shall provide that alternate assurance within 120 days following the guarantor's notice of cancellation, place evidence of the alternate assurance in the facility operating record, and notify the Department.

(2) Record Keeping and Reporting.

(a) The permittee shall place a certified copy of the guarantee along with the items required in Section E.4.f.(3) above, into the facility's operating record and submit a copy to the Department before the initial receipt of waste in the case of closure, and post-closure care, or no later than 120 days after the corrective action remedy has been selected in accordance with this regulation.

(b) The permittee is no longer required to maintain the records specified in Section E.4.g.(2) above for the guarantee when:

i. The permittee substitutes alternate financial assurance as specified in this section; or,

ii. The permittee is released from the requirements of this section pursuant to the requirements for proper closure, completion of the post-closure care period, or completion of the corrective action remedy.

(c) If a local government guarantor no longer meets the requirements of the Local Government Financial Test in Section E.4.f. above, the permittee shall, within 90 days, obtain alternative assurance, place evidence of the alternate assurance in the facility operating record, and notify the Department. If the permittee fails to obtain alternate financial assurance within that ninety (90) day period, the guarantor shall provide that alternate assurance within the next 30 days.

h. State Approved Mechanism. A permittee may satisfy the requirements of this section by obtaining any other mechanism that meets the criteria for the language of the mechanism as specified in Section E.4.k. below, and that is approved by the Department.

i. Certificates of Deposit.

(1) A permittee may demonstrate financial assurance, wholly or in part, by assigning all rights, title and interest of a Certificate of Deposit (Certificate) to the Department, conditioned so that the permittee shall comply with the closure, post-closure care, or corrective action plan filed for the site. The amount of the Certificate shall be in an amount at least equal to the current closure, post-closure care, or corrective action cost estimate, whichever is applicable, for the site for which the permit application has been filed or any part thereof not covered by other financial assurance mechanisms. The permittee shall maintain the Certificate until proper final closure, post-closure care, or corrective action is completed. The original assignment of the Certificate of deposit shall be submitted to the Department to prove that the Certificate has been obtained and meets the requirements of this section. The Certificate shall be in the sole name of the South Carolina Department of Health and Environmental Control and shall be issued by a financial institution that is insured by the Federal Deposit Insurance Corporation or Federal Savings and Loan Insurance Corporation. The Certificate may not have a maturity date of less than six (6) months. Those Certificates with a maturity date of less than one year shall provide for automatic renewal. In those instances where renewal is not automatic, the permittee shall renew or replace the instrument no less than 60 days before the maturity date.

(2) In addition to the certificate of deposit, the owners/operators shall establish a standby trust fund to receive payments using a trustee that has the authority to act as a trustee and that is regulated and examined by a Federal or State agency. The text of the standby trust fund shall be provided by the Department.

(3) The permittee shall be entitled to demand, receive, and recover the interest and income from the Certificate as it becomes due and payable as long as the market value of the Certificate plus any other mechanisms used continue to at least equal the amount of the estimated current closure, post-closure care, or corrective action cost.

(4) Whenever the approved closure or post-closure maintenance care cost estimates or corrective action cost estimate increases to an amount greater than the amount of the certificate of deposit, the permittee shall, within 60 days of the increase, cause the amount of the certificate of deposit to be increased to an amount at least equal to the new estimate or obtain other financial assurance pursuant to this regulation to cover the increase. Anytime the cost estimate decreases, the permittee may reduce the amount of the certificate of deposit to the new estimate following written approval by the Department. The permittee shall submit a certificate of deposit and assignment reflecting the new cost estimate within 60 days of the change in the cost estimate.

(5) The Department will return the original assignment and certificate of deposit, if applicable, to the issuing institution for termination when the permittee substitutes acceptable alternate financial assurance or if the permittee is no longer required to maintain financial assurance in accordance with this regulation.

j. Use of Multiple Financial Mechanisms. A permittee may demonstrate financial assurance for closure, post-closure, and corrective action, as required in this regulation by establishing more than one financial mechanism per facility except that mechanisms guaranteeing performance rather than payment, may not be combined with other instruments. The mechanisms shall be as specified in Sections E.4.a., b., c., d., e., f., g., h. and i., except that financial assurance for an amount at least equal to the current cost estimate for closure, post-closure care, and/or corrective action may be provided by a combination of mechanisms rather than a single mechanism.

k. The language of the mechanisms listed in Sections E.4. a., b., c., d., e., f., g., h. and i. of this section shall ensure that the instruments satisfy the following criteria:

(1) The financial assurance mechanisms shall ensure that the amount of funds assured is sufficient to cover the costs of closure, post-closure care, and corrective action for known releases when needed;

(2) The financial assurance mechanisms shall ensure that funds will be available in a timely fashion when needed;

(3) The financial assurance mechanisms shall be obtained by the permittee by the effective date of these requirements or prior to the initial receipt of solid waste, whichever is later, in the case of closure and post-closure care, and no later than 120 days after the corrective action remedy has been selected in accordance with the requirements of this regulation until the permittee is released from the financial assurance requirements pursuant to this regulation;

(4) The financial assurance mechanisms shall be legally valid, binding, and enforceable under State and Federal law.

5. Discounting. The Department may allow discounting of closure cost estimates, post-closure cost estimates, and/or corrective action costs up to the rate of return for essentially risk free investments, net of inflation, under the following conditions:

a. The Department determines that the cost estimates are complete and accurate and the permittee has submitted a statement from a S.C. Registered Professional Engineer so stating;

b. The Department finds the facility in compliance with applicable and appropriate permit conditions;

c. The Department determines that the closure date is certain and the permittee certifies that there are no foreseeable factors that will change the estimate of site life; and,

d. Discounted cost estimates shall be adjusted annually to reflect inflation and years of remaining life.

6. Incapacity of Permittee or Financial Institution.

a. A permittee shall notify the Department by certified mail within 10 days of the commencement of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming the permittee as debtor.

b. In the event of bankruptcy of the trustee or issuing institution, or a suspension or revocation of the authority of the trustee or institution, that issues a surety bond, letter of credit, certificate of deposit, or insurance policy pursuant to this regulation, the permittee shall be deemed in violation of the financial assurance requirements. The permittee shall establish with Department approval other financial assurance within 60 days of such event.

7. Default by Permittee.

a. The Department may take possession of a financial assurance fund if the permittee fails to:

(1) Complete closure or post-closure maintenance care in accordance with the Department approved facility plan;

(2) Complete corrective action; or,

(3) Renew or provide alternate acceptable financial assurance as required.

b. Prior to taking possession of a financial assurance funds, the Department shall:

(1) Issue a notice of violation or order alleging that the permittee has failed to perform closure or post-closure care in accordance with the closure or post-closure care plan or permit requirements; and,

(2) Provide the permittee seven days notice and an opportunity for a hearing.

F. Permit Applicant Requirements.

1. Disclosure. Prior to issuance of a Department permit for Classes One, Two, and Three landfills, a disclosure statement, pursuant to S.C. Code Section 44–96–300 and in a format approved by the Department, shall be submitted to the Department. The Department may accept one disclosure statement for multiple facility permit applicants. This requirement shall not apply if the applicant is a local government or a region comprised of local governments. The disclosure

statement shall contain the following information with regard to the applicant and his responsible parties:

a. The full name, business address, and social security number of all responsible parties;

b. A description of the experience and credentials, including any past or present permits or licenses for the collection, transportation, treatment, storage, or disposal of solid waste issued to or held by the applicant within the past five years;

c. A listing and explanation of all convictions by final judgment of a responsible party in a state or federal court, whether under appeal or not, of a crime of moral turpitude punishable by a fine of five thousand dollars ($5,000.00) or more or imprisonment for one year or more, or both, within five years immediately preceding the date of the submission of the permit application;

d. A listing and explanation of all convictions by final judgment of a responsible party in a state or federal court, whether under appeal or not, of a criminal or civil offense involving a violation of an environmental law punishable by a fine of five thousand dollars ($5,000.00) or more or imprisonment for one year or more, or both, in a state or federal court within five years of the date of submission of the permit application;

e. A listing and explanation of the instances in which a disposal facility permit held by the applicant was revoked by final judgment in a state or federal court, whether under appeal or not, within five years of the date of submission of the permit application;

f. A listing and explanation of all adjudications of the applicant for having been in contempt of any valid court order enforcing any federal environmental law or any state environmental law relative to the activity for which the permit is being sought, within five years of the date of submission of the permit application; and,

g. If a responsible party of an applicant is a chartered lending institution or a publicly held corporation reporting under the Federal Securities and Exchange Act of 1934 or a wholly-owned subsidiary of a publicly held corporation reporting under the Federal Securities and Exchange Act of 1934, the information required under S.C. Code Section 44-96-300(A)(6), such responsible party shall submit to the Dept. reports covering its structure and operations as required by the chartering body or the Federal Securities and Exchange Commission. The Department is authorized to require a responsible party to provide such additional information to the Department as is reasonably necessary to make the determinations provided for in S.C. Code Section 44–96–300.

2. Permittee Requirements.

a. The permittee is required to notify the Department by certified mail within 10 days of any of the following conditions:

(1) Commencing a voluntary or involuntary proceeding in bankruptcy, naming the permittee as debtor;

(2) The sale of the holder of the permit or approval;

(3) The sale of the permitted or approved facility; or,

(4) The dissolution of the holder of the permit or approval.

b. Transfer of Ownership.

(1) The Department may, upon written request, transfer a permit to a new permittee where no other change in the permit is necessary. The proposed new owner of a permitted landfill shall, prior to the scheduled change in ownership, submit to the Department:

(a) Documentation of the new owner's name and address.

(b) Documentation of the name and address of the party responsible for the operation and maintenance of the landfill, if different from the owner.

(c) A written agreement signed by both parties indicating the intent to change ownership or operating responsibility of the facility. The agreement shall contain:

i. A specific date for the transfer of permit responsibility; and,

ii. A statement that the new permittee will operate the landfill in accordance with the existing permit in effect at the time of transfer.

(d) Documentation of financial assurance as required in Part I, Section E. of this regulation. The previous owner shall maintain financial assurance responsibilities until the new owner can demonstrate satisfactory compliance with Part I, Section E. of this regulation.

(e) A Disclosure Statement for the new owner pursuant to Subsection F.1. above.

(2) Upon approval of all items required by Subsection F.2.b.(1) above, the Department shall transfer the permit from the original owner of the landfill to the new owner.

(3) A request for a permit modification shall be submitted with the transfer of ownership request, if the landfill will not be operated in accordance with the approved plans. The permit modification shall be in accordance with all provisions of this regulation.

(4) The new owner shall submit legal documentation of the transfer of ownership of the landfill within 15 days of the actual transfer.

G. Severability. Should any regulation, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

H. Violations and Penalties. A violation of this regulation or violation of any permit, order, or standard subjects the person to the issuance of a Department order, or a civil or criminal enforcement action in accordance with S.C. Code Section 44–96–450. In addition, the Department may impose reasonable civil penalties not to exceed ten thousand dollars ($10,000.00) for each day of violation of the provisions of this regulation, including violation of any order, permit or standard.

I. Appeals.

1. A Department decision involving the issuance, denial, renewal, suspension, revocation or request for a variance of a permit may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23. Any person to whom an order is issued may appeal it pursuant to applicable law.

2. Determinations of Need and Consistency pursuant to Part I, Section D.1. may be appealed at the time such determinations are issued and may not be raised as part of an appeal of a decision on the permit.

J. Variances. Any request for variances to these rules and regulations shall be directed in writing to, and will be considered by, the Department on an individual basis.

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Editor's Note
Republished in 2016 to correct a scrivener's error.

Part II. Permit-by-rule: Short Term Structural Fill.

A. General Provisions. Structural fill activities shall comply with the requirements in this Part.

1. Structural fill activity shall be deemed to have a permit for disposal of the items listed below when the site is registered with the Department, and designed, constructed and operated in compliance with the requirements in this Part. Written approval from the Department to operate under the Permit-by-rule shall be obtained prior to filling. Approval for structural fill areas may be issued per tract of land and no less than 500 feet from a present or former fill area on the same tract of land under the same ownership, unless otherwise approved by the Department.

2. Structural fill may not provide a sound structural base for building purposes.

3. Structural fill activity in rights-of-way directly related to road construction under contract with the S.C. Department of Transportation shall be exempt from this Part.

4. Department approved structural fill activity shall:

a. Have a proposed life of twelve (12) months or less;

b. Occupy one (1) acre in size or less;

c. Use only those items listed below that have not been contaminated by hazardous constituents listed in the S.C. Hazardous Waste Management Regulations 61–79.261 (e.g., pesticides), petroleum products, or painted with lead-based paint:

(1) Hardened concrete (may include rebar);

(2) Hardened asphaltic concrete;

(3) Bricks;

(4) Masonry blocks; and,

(5) Land-clearing debris; and,

d. Be consistent with the South Carolina Coastal Zone Management Plan if the fill area is located in the coastal zone as defined in SC Code Section 48-39-10.B.

5. Should the Department have sufficient reason to believe that environmental and/or health problems are associated with an area that contains structural fill material, monitoring (including groundwater, surface water, and air quality monitoring) may be required by the Department to ensure protection of the environment.

B. Permit-by-rule Registration Requirements.

1. Prior to engaging in structural fill activity, the landowner or landowner's agent shall receive written approval from the Department to operate under the Permit-by-rule for a specific site. "Agent" means one that acts for or as a representative of another. To request approval and register a site, a completed registration form provided by the Department and all information required by this Part shall be submitted to the Department. The Department will process the administratively complete registration and notify the owner/agent in writing if the site is approved for structural fill activity under the Permit-by-rule.

2. All required information submitted to the Department shall be complete and accurate. The landowner and agent shall sign the registration form and the following certification: "I certify under penalty of law that I have personally examined and am familiar with the information submitted in the attached document; and, I believe the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

3. To request approval to operate under the Permit-by-rule, three copies of the following documents shall be submitted to the Department:

a. A registration form provided by the Department;

b. A current county map showing the location of the proposed fill area;

c. Proof of ownership or control of the property;

d. Site information to include:

(1) A written description of the location of the area that will accept the fill material including road names/numbers;

(2) The source(s) supplying the fill material;

(3) The anticipated time frame for filling the area;

(4) The size of the area to be filled;

(5) The maximum volume the fill area will be capable of receiving; and,

(6) The latitude and longitude coordinates of the proposed fill area;

e. An explanation of how the waste will be compacted and the cover applied; and,

f. Other pertinent information as deemed appropriate by the Department.

C. Location Restrictions.

1. Buffers. The boundary of the fill area shall not be located within:

a. 100 feet of any property line. Variances may be requested and granted on a case-by-case basis upon submittal of written consent from the adjacent landowner(s);

b. 200 feet of any residence, school, day-care center, church, hospital and publicly owned recreational park area;

c. 200 feet of any surface water that holds visible water for greater than six consecutive months, excluding ditches, sedimentation ponds, and other operational features on the site;

d. 100 feet of any drinking water well. A greater buffer may be required for compliance with the Department's Bureau of Water requirements;

e. The right-of-way of underground or above ground utility equipment or structures, i.e., water lines, sewer lines, storm drains, telephone lines, electric lines, etc., without the written approval of the impacted utility; and,

f. 50 feet of any wetlands, unless the permittee has obtained the permits and/or authorizations required by all other state and federal laws and regulations for the impact of such wetlands.

2. Fill areas shall be adjacent to or have direct access to roads which are of all weather construction and capable of withstanding anticipated load limits.

D. Design Requirements for Structural Fill.

1. The fill area shall meet the following standards, unless otherwise approved in writing by the Department:

a. Fill areas located in the 100-year floodplain shall not restrict the flow of the 100-year flood;

b. The fill area shall be consistent with the South Carolina Coastal Zone Management Plan if the site is located in the coastal zone as defined in SC Code Section 48–39–10.B.;

c. Access to the structural fill area shall be controlled through the use of fences, gates, berms, natural barriers, or other means to prevent promiscuous dumping and unauthorized access; and,

d. Fill material shall not be placed in water. If the fill area becomes inundated with water, all water shall be removed before adding additional fill material.

2. Procedures shall be established for maintaining conditions that are unfavorable for the habitation and production of vectors.

E. Operating Criteria. The following operational requirements shall apply to all structural fill activity, unless otherwise approved in writing by the Department:

1. The fill area shall accept only those waste items listed below that have not been painted with lead-based paint, and have not been contaminated by hazardous constituents listed in the S.C. Hazardous Waste Management Regulations 61–79.261 (e.g., pesticides), or petroleum products, and that have been reduced in size to less than or equal to one (≤1) cubic yard pieces with no side exceeding three feet in length:

a. Hardened concrete (may include rebar);

b. Hardened asphaltic concrete;

c. Bricks;

d. Masonry blocks; and,

e. Land-clearing debris.

2. The fill area shall have an attendant on duty any time fill material is being received.

3. Unauthorized wastes shall be removed from the fill area to an approved facility within 48 hours of receipt.

4. The fill area shall be staked prior to receipt of fill material, and the stakes shall remain until the fill area is properly closed.

5. The unloading of fill material shall be restricted to the working face of the fill area.

6. The working face of the fill area shall be confined to as small an area as the equipment can safely and efficiently operate. The slope shall not exceed 33%.

7. The fill material shall be compacted and a cover consisting of a uniform layer of soil or other suitable material, or both, acceptable to the Department, no less than six 6 inches in depth shall be used to cover all exposed waste material at least every 30 days.

8. Open burning at fill areas shall be prohibited.

9. The fill area shall be maintained and operated in a manner that protects the established water quality standards of the surface waters and ground waters.

10. Dust, odors, fire hazards, litter and vectors shall be effectively controlled so they do not constitute nuisances or hazards.

F. Closure.

1. Within 12 months of the Department's issuance of approval to operate under the Permit-by-rule, the owner/agent of the filled area shall:

a. Apply a minimum two-foot thick final earth cover with at least a 1%, but not greater than 4% surface slope, graded to promote positive drainage. The side slope cover shall not exceed three horizontal feet to one vertical foot, i.e., a 3:1 slope;

b. Either:

(1) Begin construction of the foundation of a building project; or,

(2) Seed the finished surface of the filled area with native grasses or other suitable ground cover to establish and maintain into the second growing season a 75% or greater permanent vegetative cover with no substantial bare spots;

c. Using a form approved by the Department, record with the appropriate Register of Deeds a notation in the record of ownership of the property - or some other instrument which is normally examined during title search - that will in perpetuity notify any potential purchaser of the property that the land or a portion thereof has been structurally filled and list the specific items used for filling, e.g., clean brick; and,

d. Submit to the Department a copy of the document in which the notation required by Section F.1.c. above was placed.

2. Upon the Department's receipt of the document defined in Section F.1.c. above, the owner/agent's approval to fill under the Permit-by-rule for this site shall be terminated.

3. If the Department has sufficient reason to believe that there are environmental problems associated with the fill area, the owner/agent shall submit for Department review and approval, a corrective action plan and a schedule of compliance for implementing the plan.

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Editor's Note

Republished in 2016 to correct a scrivener's error.

Part III. Class One Landfills - General Permit for Disposal of Land-Clearing Debris and Yard Trash

A. General Permit.

1. The Department may issue a general permit for solid waste landfills used solely for the disposal of trees, stumps, wood chips, and yard trash that is generated from land-clearing activities, excluding agricultural and silvicultural operations when generation and disposal are on site. These landfills shall be limited to filling to grade, of low areas or depressions in the surface of the earth to include permitted mining sites for an aesthetic benefit or property enhancement. Beneficial fill does not provide a sound structural base for building purposes, but does provide an aesthetic benefit.

2. The general permit shall outline the following:

a. Submittal requirements;

b. Design criteria;

c. Operational criteria;

d. Monitoring, if applicable; and,

e. Closure and corrective action requirements, if applicable.

3. The general permit, pursuant to this Part, may be issued, modified, revoked and reissued, or terminated in accordance with applicable requirements of this regulation and subject to the terms and conditions in this regulation.

4. The Department shall publish a notice of any general permit issued, modified, revoked, or reissued.

B. General Provisions.

1. Landfills approved to operate under the General Permit shall be known as Class One landfills.

2. Class One landfills shall be consistent with the State and Region/County Solid Waste Management Plans, local zoning, land use and other applicable ordinances.

3. A Class One Landfill shall be covered under the State's general permit if it provides proper notification of intent to the Department as outlined in the general permit, and if constructed and operated in compliance with the requirements established by the permit and this regulation.

4. Prior to submittal to the Department of a written Notice of Intent, pursuant to Section C. below, the owners/operator seeking coverage under the general permit shall:

a. Publish a notice informing the public of the intent to operate under the General Permit. All notices shall be published once in a newspaper of general circulation in the area of the proposed landfill project and contain the following:

(1) Name and address of the applicant;

(2) The location of the proposed activity to include the county, roads and crossroads;

(3) The nature of the proposed activity;

(4) A description of the proposed site or a description of the proposed major modification;

(5) An explanation of the type(s) of waste that will be accepted;

(6) The Department's address and contact name for submittal of comments and inquires;

(7) The approximate tonnage/year expected for disposal at the landfill; and,

(8) The proposed life of the landfill.

b. Submit to the Department:

(1) A written Notice of Intent, pursuant to Section C. below, to be covered by the general permit on a form approved by the Department;

(2) An affidavit of publication in a newspaper for the public notice required in Section B.4.a. above;

(3) The names and addresses of the owners of real property as they appear on the county tax maps as contiguous landowners of the proposed permit area; and,

(4) A disclosure statement pursuant to Part I, Section F.1.

5. The Department will notify by certified mail, return receipt requested, all adjoining landowners of receipt of the Intent to Operate under the General Permit.

6. Written Department approval to operate under the General Permit shall be received prior to operation of a Class One landfill.

7. Upon a determination by the Department and written notification that the landfill poses an actual or potential threat to human health or the environment, the Department may require the permittee to implement corrective measures as appropriate.

8. A Class One Landfill's approval to operate under the general permit may be revoked for any of the following reasons:

a. The facility fails to comply with the conditions of the general permit or this regulation;

b. Circumstances have changed since the time of the requested approval to operate so that the permittee is no longer appropriately regulated under the general permit, or a temporary or permanent closure of the landfill is necessary; and,

c. Environmental and/or health problems associated with the landfill are detected by the Department.

9. When an individual solid waste landfill permit is issued to a permittee otherwise subject to the general permit, the applicability of the general permit to that landfill is automatically terminated on the effective date of the individual permit.

10. A landfill excluded from the general permit solely because it already has an individual landfill permit may request that the individual permit be revoked, and that the landfill be covered by the general permit. Upon revocation of the individual permit and approval of the Notice of Intent to operate under the general permit, the general permit shall apply to the landfill.

C. Notice of Intent.

1. Prior to landfilling land-clearing debris under the State's general permit, the permittee shall submit to the Department a Notice of Intent on a form approved by the Department. This Notice

shall be accompanied by all information required by the general permit. All required information shall be complete and accurate.

2. The Notice of Intent shall be signed by the landfill applicant. The landowner shall also sign the Notice of Intent, thereby giving authorization for the proposed landfilling activity on said property. Any changes in the written authorization submitted to the Department which occur after the issuance of the Department's approval to operate under the general permit shall be reported to the Department by submitting a copy of the new written authorization.

3. Any person signing a Notice of Intent to landfill under the general information shall also sign the following certification: I certify under penalty of law that I have personally examined and am familiar with the information submitted in the attached document; and, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

D. Record Keeping and Reporting Requirements. Landfills operating under the General Permit shall submit in a format approved by the Department an annual report for the fiscal year beginning on July 1, and ending on June 30. This report shall be submitted to the Department on or before September 1, and shall identify the actual weight in tons or volume in cubic yards of wastes received per month at the land-clearing debris and yard trash landfill. Any records required by this regulation shall be retained near the facility in an operating record, or in an alternative location approved by the Department for a period of no less than three years.

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Part IV. Class Two Landfills.

A. General Provisions.

1. Applicability. Part IV. establishes minimum criteria for all landfills used for the disposal of: waste as outlined in Appendix I of this regulation; other wastes not listed in Appendix I that demonstrate similar properties to the wastes listed and are approved by the Department on a case-by-case basis; or, wastes that test less than ten (<10) times the maximum contaminant level (MCL) as published in R.61–58, State Primary Drinking Water Regulation current at the time of submittal of the permit application. The testing criteria outlined in Part I., Section C. Waste Characterization shall be used when testing is required. Hereinafter, these landfills will be referred to as Class Two landfills.

2. The siting, design, construction, operation, and closure activities of Class Two landfills shall conform to the standards set forth in this Part as well as applicable requirements in Part I of this regulation.

3. Prior to the construction, operation, expansion or modification of a Class Two landfill, a permit shall be obtained from the Department.

4. Only those items listed in Appendix I of this regulation, approved Appendix I-type waste, and any items specifically listed on the facility's permit issued by the Department may be accepted for disposal at a Class Two landfill. These wastes shall not be contaminated with hazardous constituents listed in the S.C. Hazardous Waste Management Regulations 61–79.261 (e.g., pesticides), or petroleum products. When a waste not listed in Appendix I is approved by the Department for disposal, the landfill's permit will be modified to add the approved waste. A list of Appendix I-type waste will be available from the Department.

5. Class Two landfills shall be consistent with the State and the Region/County Solid Waste Management Plans, local zoning, land use and other applicable ordinances. On-site landfills are not required to demonstrate consistency with the State and Region/County Solid Waste Management Plans.

B. Location Restrictions.

1. Buffers. Unless otherwise approved by the Department, the site for a new landfill or expansion of an existing landfill shall meet the following standards:

a. The boundary of the fill area shall not be located within 1,000 feet of any residence, school, day-care center, church, hospital, or publicly owned recreational park area. The Department will

determine whether the new landfill or expansion of an existing landfill meets this requirement prior to the publication of the Notice of Intent to File a Permit Application pursuant to Part I, Section D.1 of this Regulation;

b. A landfill located in a 100-year floodplain shall demonstrate that engineering measures have been incorporated into the landfill design to ensure the landfill will not restrict the flow of the 100-year flood, reduce the temporary water storage capacity of the flood plain, minimize potential for floodwaters coming into contact with waste, or result in the washout of solid waste so as to pose a hazard to human health or the environment;

c. The landfill shall be in compliance with applicable requirements concerning wetlands imposed by the U.S. Army Corps of Engineers, the U.S. Environmental Protection Agency, and the Department;

d. Access to the landfill shall be controlled through the use of fences, gates, berms, natural barriers, or other means to prevent promiscuous dumping and unauthorized access;

e. The boundary of the fill area shall not be located within 100 feet of any property line. An exemption may be issued by the Department upon receipt of written approval from adjacent property owners;

f. The boundary of the fill area shall not be located within 200 feet of any surface water that holds visible water for greater than six consecutive months, excluding drainage ditches, sedimentation ponds and other operational features on the site;

g. The boundary of the fill area shall not be located within 100 feet of any drinking water well. A greater buffer may be required for compliance with the Department's Bureau of Water requirements;

h. Waste material shall not be placed on or within any property rights-of-way or 50 feet of underground or above ground utility equipment or structures, i.e., water lines, sewer lines, storm drains, telephone lines, electric lines, natural gas lines, etc., without the written approval of the impacted utility.

2. Airport Safety. These requirements apply to all Class Two landfills permitted/approved for disposal of animal carcasses.

a. Owners/operators of all Class Two landfills located within 10,000 feet of any runway end used by turbojet aircraft or within 5,000 feet of any airport runway end used by only piston-type aircraft shall demonstrate that the units are designed and operated so that the Class Two landfill does not pose a bird hazard to aircraft.

b. Owners/operators proposing to site new Class Two landfills and lateral expansions located within a five mile radius of any airport runway end used by turbojet or piston-type aircraft shall notify the affected airport and the Federal Aviation Administration (FAA).

C. Operation Criteria for Class Two Landfills.

1. Owners/operators of all Class Two landfills shall implement a program at the facility for detecting and preventing the disposal of regulated hazardous wastes as defined in R.61–79 Hazardous Waste Management Regulations, Part 261, polychlorinated biphenyls (PCB) wastes as defined in Resource Conservation and Recovery Act (RCRA), Part 761, and wastes not specifically allowed by the permit. This program shall include, at a minimum:

a. Inspections of all incoming loads when deposited and prior to compaction unless the permittee takes other steps to ensure that incoming loads do not contain regulated hazardous wastes, PCB wastes, or wastes not specifically allowed by the permit;

b. Records of unacceptable waste to include waste quantity and description and generator information;

c. Training of facility personnel to recognize wastes not specifically allowed by the permit, regulated hazardous waste and PCB wastes; and,

d. Notification of the Department within 72 hours if the operator suspects that a regulated hazardous waste or PCB waste has been discovered at the facility.

2. The Class Two landfill shall, prior to receipt of any waste materials that are not specifically listed in the permit application, submit for Department approval a characterization of the waste

materials to determine the suitability for disposal in the landfill unless the Department grants an exemption for like materials.

3. Unless otherwise approved by the Department:

a. Unauthorized wastes shall be removed from the working face prior to cover or at the end of the working day, whichever occurs fist, and placed into an appropriate container; and,

b. Unauthorized waste shall be removed from the site for proper disposal no less than every 30 days unless otherwise approved by the Department. Putrescible waste shall be removed from the working face, placed in a container, and removed from the site within 72-hours of receipt. The Department may require more frequent removal based on the nature or quantity of other unacceptable waste.

4. The unloading of solid waste intended for disposal in the landfill shall be restricted to the working face of the landfill. Unloading of the waste adjacent to the working face within the permitted boundaries of the landfill may be allowed for the purpose of screening the waste stream.

5. The working face of the landfill shall be confined to as small an area as the equipment can safely and efficiently operate. The slope shall not exceed 33%.

6. Solid waste shall be spread in uniform layers to the extent practical and compacted to its smallest practical volume.

7. A uniform compacted layer of clean earth cover or other suitable cover material acceptable to the Department, no less than six (6) inches in depth shall be placed over all exposed waste material at least every 30 days, unless otherwise approved by the Department. The frequency of cover may be increased or decreased as determined by the Department. More frequent cover may be required by the Department based on the nature of the disposed materials and daily disposal rate in order to address landfill gas generation, odor, leachate formation or any environmental safety and health problems.

8. Open burning at landfills is prohibited.

9. The site shall be maintained and operated in a manner that protects the established water quality standards of the surface waters and ground waters.

10. Dust, odors, fire hazards, litter and vectors shall be effectively controlled so they do not constitute nuisances or hazards.

11. The landfill shall have an attendant on duty at all times the facility is open.

12. Sign Requirements. Signs shall be posted and maintained at the main entrance that:

a. Identify the owner, operator, or a contact person and telephone number in case of emergencies and the normal hours during which the landfill is open to receive waste;

b. State the types of waste that the landfill is permitted to receive; and,

c. Identify the valid SCDHEC Facility Identification Number.

13. Class Two landfills shall install and maintain scales capable of accurately determining the weight of incoming waste streams. Landfills that receive less than 10,000 tons/year are exempt from this requirements.

14. On-site landfills are exempt from Sections 11. 12. and 13. above.

15. Prior to accepting any materials containing asbestos for disposal at the landfill, the operator shall include in its landfill records a copy of the Permission for Disposal letter from the Department. The landfill shall retain these letters for a period of not less than three years and shall make them available to the Department upon request, if applicable.

16. Reporting Requirements.

a. Contingency Plan. Upon implementation of a contingency plan, the Department shall be notified immediately by telephone of actions taken. Written confirmation shall be sent to the Department within 72 hours.

b. Groundwater Monitoring. Reporting requirements as outlined in Subpart E. below.

c. Landfill Operation.

(1) Landfills, with the exception of on-site landfills, shall maintain daily records of:

(a) The actual weight in tons of waste received; and,

(b) The particular grid location of the area currently being used for disposal of solid waste.

(2) Landfills shall submit in a format approved by the Department an annual report for the fiscal year beginning on July 1 and ending on June 30. This report shall be submitted to the Department on or before September 1, and shall include the information outlined below:

(a) The actual weight in tons of wastes received per month;

(b) The county of origin of the waste; and,

(c) A description of the capacity of the landfill used in the previous fiscal year and the remaining permitted capacity. A yearly survey conducted by a S.C. certified land surveyor or engineer may be required by the Department on a case-by-case basis.

d. Any records required by this regulation for Class Two landfills shall be retained near the facility in an operating record, or in an alternative location approved by the Department, for a period of no less than three years.

17. Access to fire equipment and firefighting services shall be provided.

18. Procedures shall be established for maintaining conditions that are unfavorable for the habitation and production of insects, rodents and other pests.

19. A groundwater monitoring system shall be installed in accordance with Section E. below.

20. The landfill shall be adjacent to or have direct access to roads that are of all-weather construction and capable of withstanding anticipated load limits.

21. A gas monitoring system shall be designed and installed as required on a case-by-case basis to ensure that gas generated at the landfill will not create a hazard to health, safety, or property.

D. Design Criteria for Class Two Landfills.

1. The estimated deflected (or settled) bottom elevation of the landfill base grade shall be a minimum of two feet above the seasonal high water table elevation as it exists prior to the construction of the disposal area. The seasonal high water table shall be determined by interpretation of a minimum of 12 months data obtained from a representative number of monitoring wells approved by the Department. In cases where there is insufficient information to support the seasonal high water table elevation determination, additional separation may be required by the Department. The Department will inspect the landfill prior to the initial placement of waste in the landfill.

2. Drainage control requirements.

a. The disposal area shall be graded with a minimum of a 1% slope so as to divert and minimize run-off into the disposal area of the landfill, to prevent erosion and ponding within the disposal area, and to drain water from the surface of the landfill.

b. Prior to accepting waste, the owners/operators shall design, construct, and subsequently maintain:

(1) A run-on control system to prevent flow onto the active portion of the landfill during peak discharge from a 24-hour, 25-year storm; and,

(2) A run-off control system from the active portion of the landfill to collect and control at least the water volume resulting from a 24-hour, 25-year storm.

c. An appropriate permit from the Department may be required prior to the discharge of any storm waters to surface waters.

E. Groundwater Monitoring and Corrective Action.

1. General Groundwater Monitoring Requirements.

a. All submittals made to the Department in compliance with this Section shall be signed and stamped by a qualified professional.

b. All Class Two landfills shall implement a groundwater monitoring program as follows:

(1) New Class Two landfills, or lateral expansions of existing Class Two landfills shall submit a groundwater monitoring plan to monitor the entire landfill that meets the requirements of this Section as part of the permit application; and,

(2) Existing Class Two landfills shall, within 180 days of the effective date of this regulation, submit to the Department either a groundwater detection monitoring plan that meets the requirements of this Section, or written notification that the landfill plans to cease accepting waste within one year or less from the effective date of this regulation. Within 180 days of the Department's approval of the groundwater detection monitoring plan, the monitoring system shall be installed at the landfill. Facilities that cease accepting waste within one year of the effective date of this regulation are exempt from the groundwater monitoring requirements outlined herein. Landfills meeting this exemption shall submit a closure plan to the Department within 180 days of the effective date of this regulation. Additional time may be allowed for the installation of the groundwater monitoring system with prior approval from the Department;

(3) Existing Class Two landfills which have been performing groundwater monitoring prior to the requirements of this regulation shall within 90 days of the effective date submit to the Department certification by a qualified professional that the existing groundwater monitoring program meets the intent of this regulation. Any changes necessary to the existing groundwater monitoring system to ensure compliance with this regulation should be discussed in the certification letter.

c. A groundwater monitoring system shall consist of a sufficient number of wells installed at appropriate locations and depths to yield representative groundwater samples from the uppermost aquifer that can determine if contamination has occurred due to a release from the landfill. There shall be a minimum of one well up-gradient and three wells down-gradient of the disposal unit. These wells shall:

(1) Represent the quality of background groundwater that has not been affected by the landfill; and,

(2) Represent the quality of groundwater passing from beneath the waste disposal area footprint. The downgradient monitoring system shall be installed as close as practical to the actual disposal area but no further than 150 feet from the actual disposal area unless previously installed with Department approval, and shall ensure detection of any groundwater contamination in the uppermost aquifer.

d. The number, spacing, and depths of the wells in the monitoring network shall be determined based upon site-specific technical information that shall include thorough characterization of:

(1) Aquifer thickness, groundwater flow rate, groundwater flow direction including seasonal and temporal fluctuations in groundwater flow; and,

(2) Saturated and unsaturated geologic units and fill materials overlying the uppermost aquifer, materials comprising the uppermost aquifer, and materials comprising the confining unit defining the lower boundary of the uppermost aquifer, including, but not limited to: thicknesses, stratigraphy, lithology, hydraulic conductivities, porosities and effective porosities.

e. Monitoring wells shall be approved by the Department prior to installation and shall be constructed, at a minimum, to the standards established in the South Carolina Well Standards, R.61–71.H.

(1) The permittee shall maintain an operating record that contains documentation of the design, installation, development, and abandonment of any monitoring wells, piezometers and other measurement, sampling, and analytical devices; and,

(2) The monitoring wells, piezometers, and other measurement, sampling, and analytical devices must be maintained and operated so that they perform to design specifications throughout the life of the monitoring program.

(3) All monitoring wells, piezometers or other environmental sampling locations shall be located by a South Carolina Certified Land Surveyor. For wells, the elevation of the ground surface and the elevation of the top of the well casing shall also be determined to the nearest 0.01 ft above mean sea level.

f. Routine groundwater monitoring shall continue while the facility is performing detection monitoring, assessment or remediation activities.

g. The groundwater monitoring program shall include consistent sampling and analysis procedures that are designed to ensure monitoring results that provide an accurate representation of groundwater quality. A laboratory certified by South Carolina under R.61–81 State Environmental Laboratory Certification Program for the sample preparations and analysis methods employed shall conduct all groundwater analysis required by this regulation.

(1) The permittee shall submit to the Department for review and approval, a sampling and analysis plan outlining procedures and protocols to be used at the facility. The plan shall include procedures and techniques for:

(a) Sample collection;

(b) Sample preservation and shipment;

(c) Analytical procedures;

(d) Chain of custody control; and,

(e) Quality assurance and quality control.

(2) The groundwater monitoring program shall include approved sampling and analytical methods that are appropriate for groundwater sampling and that accurately measure the constituents in groundwater samples. Analytical methods chosen shall have a practical quantitation limit (PQL) that is less than the Maximum Concentration Level (MCL) for those constituents that have a MCL as established by the State Primary Drinking Water Regulation R.61–58. Groundwater samples required by this regulation shall not be field-filtered prior to laboratory analysis.

(3) Groundwater potentiometric elevations shall be measured and recorded for each well prior to initiating sampling procedures each time groundwater is sampled. Groundwater elevations in wells must be measured on the same day to avoid temporal variations in groundwater elevations that could preclude an accurate determination of groundwater flow rate and direction. The permittee must determine the potentiometric surface of each aquifer unit comprising the uppermost aquifer and report the rate and direction of groundwater flow each time groundwater is sampled.

(4) The results and supporting documentation, e.g., field data sheets, laboratory quality assurance /quality control testing, for all groundwater sample analysis taken during detection monitoring shall be submitted to the Department in accordance with the reporting requirements in this Subpart.

h. The permittee shall submit to the Department on or before the anniversary date of issuance of the permit, an annual report for the previous year containing the results of the requirements of this Section. The annual report shall contain the following:

(1) A summary of all analytical testing performed at the site during the previous year, and any applicable data concerning sampling and analysis of monitoring wells at the site;

(2) A determination of the technical sufficiency of the monitoring well network in detecting a release from the facility;

(3) A determination of groundwater elevations, groundwater flow directions and groundwater flow rates as specified in Section E.1.g.(3) above. Groundwater flow directions shall be based upon interpretation of a potentiometric map prepared utilizing the groundwater elevations measured at the site; and,

(4) Recommendations for any changes to the groundwater monitoring system, or any necessary actions to be performed at the site to ensure compliance with the groundwater monitoring requirements.

2. Groundwater Detection Monitoring Requirements.

a. Groundwater detection monitoring is required at Class Two solid waste landfills. The detection monitoring program shall include at a minimum, monitoring for the constituents listed in Appendix III.

(1) The Department may require additional groundwater monitoring parameters for routine monitoring based on the chemical and physical nature of the waste stream received by the landfill.

(2) The Department may delete specific monitoring parameters for a Class Two solid waste landfill if it can be shown that the constituent(s) are not reasonably expected to be contained in or derived from the waste contained in the unit. The deletion of specific constituents will be based on the permittee's knowledge of each waste stream disposed of in the facility and the operational controls of the facility.

b. For Class Two solid waste landfills, the detection monitoring frequency for all constituents required by this subpart shall be at least semiannual during the active life of the facility (including closure) and annual during the post-closure period. At least one sample from each well (background and downgradient) shall be collected and analyzed during each sampling event.

c. For Class Two solid waste landfills, the Department may approve an appropriate alternate frequency for repeated sampling and analysis for the constituents listed in Appendix III during the active life (including closure) and the post-closure care period to ensure protection of human health and the environment. The alternative frequency during the active life (including closure) shall be no less than the frequency specified in Section E.2.b. above. The alternative frequency shall be based on consideration of the following factors:

(1) Lithology of the aquifer and unsaturated zone;

(2) Hydraulic conductivity of the aquifer and unsaturated zone;

(3) Groundwater flow rates;

(4) Minimum distance between upgradient edge of the Class Two solid waste landfill footprint and downgradient monitoring well screen (minimum distance of travel); and

(5) Resource value of the aquifer.

d. During semiannual groundwater sampling, the two sampling events shall be scheduled approximately six (6) months apart. The submittal of data for one of the sampling events shall meet annual report requirements outlined in E.1.h.. For the other semiannual sampling event, the analytical data only shall be submitted to the Department. In all cases, the groundwater analytical results shall be submitted to the Department within 60 days of sample collection. In cases where the Department has approved an alternate sampling frequency, the Department will approve an appropriate schedule for submittal of groundwater data.

e. If the permittee determines that groundwater concentrations are above the PQL but below the MCL for any constituent listed in Appendix III, at any monitoring well (unless the constituent is being addressed by Section E.3. below) the permittee shall:

(1) Place a notice in the operating record showing which constituents have shown an exceedance above the PQL; and,

(2) Provide a notification of the results to the Department in the next regularly scheduled report and provide a discussion on the cause of this result.

f. If the permittee determines that groundwater concentrations are above the MCL, for any constituent listed in Appendix III at any monitoring well, the permittee shall:

(1) Notify the Department within 14 days of receiving the analytical results;

(2) Resample the monitoring well(s) in question for the constituents(s) in question to determine the validity of the data within 30 days of receiving the analytical results, unless the Department approves an alternate frequency. If the permittee chooses not to resample, then the initial exceedance(s) of the MCL shall be considered valid;

(3) Within 14 days of receiving the results of validation sampling required by Section E.2.f.(2) above, place a notice in the operating record and notify the Department of the results of the resampling;

(4) If resampling does not validate that the results are above applicable levels, return to routine detection monitoring; or,

(5) If resampling does validate the initial exceedance of the MCL, then establish an assessment monitoring program meeting the requirements of Section E.3. within 90 days of receiving the results of validation sampling required by Section E.2.f.(2), except as provided for in Section E.2.g. below.

g. The permittee may demonstrate that a source other than the Class Two landfill caused the contamination or that the concentration resulted from an error in sampling, analysis, or natural variation in groundwater quality. A report documenting this demonstration shall be placed in the operating record after being signed and stamped by a qualified professional and approved by the Department. If a successful demonstration is made and documented, the permittee may continue detection monitoring as specified in this Section. If, after 90 days of completing Section E.2.f.(2) above, a successful demonstration is not made, the permittee shall initiate an assessment monitoring program as required in Section E.3.

3. Assessment of Groundwater Impact.

a. Assessment monitoring is required whenever a release has been detected and validated, in accordance with Section E.2.f. above for any constituent listed in Appendix III, unless a successful demonstration has been made in accordance with Section E.2.g. above.

b. Within 90 days of validating an exceedance as outlined in E.2.f.(2), the permittee shall sample all groundwater monitoring wells identified as impacted for all constituents listed in Appendix V. Any additional constituents detected during this sampling shall be added to the assessment program.

c. The permittee shall establish a groundwater protection standard for each constituent detected in the groundwater. The groundwater protection standard shall be:

(a) For constituents for which a MCL has been promulgated under South Carolina R.61–58, State Primary Drinking Water Regulations, the MCL for that constituent;

(b) For constituents for which MCLs have not been promulgated, the drinking water risk-based number recognized by EPA Region IV; or,

(c) For constituents for which the background level is higher than the MCL identified under Section E.3.b.(3)(a) above or risk-based concentration identified under Section E.3.b.(3)(b) above, as applicable, the background concentration.

(d) For any parameter for which a groundwater protection standard cannot be established per E.3.c.(a), (b), or (c) above, the Department, using input from the permittee, will develop an appropriate groundwater protection standard. In establishing this groundwater protection standard, the Department may consider the following provided these criteria meet the intent of the South Carolina Water Classifications and Standards R.61–68:

(1) Multiple contaminants in the groundwater;

(2) Exposure threats to sensitive environmental receptors; and,

(3) Other site-specific exposure or potential exposure to groundwater.

d. The permittee shall submit to the Department for review and approval a groundwater quality assessment plan for characterizing the nature and extent of the release within 90 days of receiving the results of the sampling outlined in Section E.3.b. above. The groundwater quality assessment plan shall:

(a) Ensure that the nature and extent of the release is fully characterized by installing additional monitoring wells, as necessary;

(b) Install at least one additional monitoring well at the facility boundary in the direction of contaminant migration and sample this well in accordance with this section;

(c) In cases where contamination is present at the property boundary, take reasonable measures to gain access for offsite sampling;

(d) Notify all persons who own the land or reside on the land that directly overlies any part of the plume of contamination if contaminants have migrated off-site if indicated by sampling of wells in accordance with this section; and,

(e) Contain a detailed schedule for the implementation and completion of the provisions of the plan.

e. Upon completion of assessment activities outlined in this section, the permittee shall initiate an assessment of corrective measures as required by Section E.4.a. below within 90 days.

f. Based upon the outcome of the assessment outlined in this section, the Department may add additional monitoring wells, additional constituents, or additional sampling frequency to the routine detection monitoring program, required by Section E.2.above.

4. Groundwater Remediation.

a. Upon completion of the groundwater quality assessment, the permittee shall evaluate potential corrective actions to address groundwater quality. Based on the outcome of this evaluation, the permittee shall select a remedial action strategy and submit a remedial action plan to be approved by the Department. The remedial action plan shall contain a schedule for the initiation and completion of remedial activities.

b. The remedial action plan shall:

(1) Be protective of human health and the environment;

(2) Attain the groundwater protection standard as specified pursuant to Section E.3.b.(3) above;

(3) Control the source(s) of releases so as to reduce or eliminate, to the maximum extent practicable, further releases of constituents into the environment that may pose a threat to human health or the environment;

(4) Consider the long- and short-term effectiveness and protectiveness of the potential remedy(s), along with the degree of certainty that the remedy will prove successful based on consideration of the following:

(a) Magnitude of reduction of existing risks;

(b) Magnitude of residual risks in terms of likelihood of further releases due to waste remaining following implementation of a remedy;

(c) The type and degree of long-term management required, including monitoring, operation, and maintenance;

(d) Short-term risks that might be posed to the community, workers, or the environment during implementation of such a remedy, including potential threats to human health and the environment associated with excavation, transportation, and redisposal or containment;

(e) Time until full protection is achieved;

(f) Potential for exposure of humans and environmental receptors to remaining wastes, considering the potential threat to human health and the environment associated with excavation, transportation, redisposal, or containment;

(g) Long-term reliability of the engineering and institutional controls; and,

(h) Potential need for replacement of the remedy.

(5) Consider the effectiveness of the remedy in controlling the source to reduce further releases based on the extent to which containment practices will reduce further releases; and,

(6) Contain monitoring considerations to prove the effectiveness of the selected remedial action, which may be in addition to those constituents contained in the detection monitoring program.

c. The Department may determine that remediation of a release of a constituent from a Class Two landfill is not necessary if the permittee satisfactorily demonstrates to the Department that:

(1) The groundwater is additionally contaminated by substances that have originated from a source other than the Class Two solid waste landfill and those substances are present in concentrations such that cleanup of the release from the Class Two solid waste landfill would provide no significant reduction in risk to actual or potential receptors; or,

(2) The constituent(s) is present in groundwater that:

(a) Does not currently meet the definition of an underground source of drinking water per South Carolina Water Classifications and Standards R.61–68; and,

(b) Is not hydraulically connected with waters to which the constituents are migrating or are likely to migrate in a concentration(s) that would exceed the groundwater protection standards established under Section E.3.c. above; or,

(3) Remediation of the release(s) is technically impracticable; or,

(4) Remediation results in unacceptable cross-media impacts.

d. A determination by the Department pursuant to Section E.4.c.above shall not affect the authority of the Department to require the permittee to undertake source control measures or other measures that may be necessary to eliminate or minimize further releases to the groundwater, to prevent exposure to the groundwater, or to remediate the groundwater to concentrations that are technically practicable and significantly reduce threats to human health or the environment.

e. During the course of implementing the corrective action, the permittee may be required to take any interim measures necessary to ensure the protection of human health and the environment. Interim measures should, to the greatest extent practicable, be consistent with the objectives of and contribute to the performance of any remedy that may be required pursuant to this section. A permittee in determining whether interim measures are necessary shall consider the following factors:

(1) Time required to develop and implement a final remedy;

(2) Actual or potential exposure of nearby populations or environmental receptors to hazardous constituents;

(3) Actual or potential contamination of drinking water supplies or sensitive ecosystems;

(4) Further degradation of the groundwater that may occur if remedial action is not initiated expeditiously;

(5) Weather conditions that may cause hazardous constituents to migrate or be released;

(6) Risks of fire or explosion, or potential for exposure to hazardous constituents as a result of an accident or failure of a container or handling system; and,

(7) Other situations that may pose threats to human health and the environment.

f. If the permittee determines that compliance with requirements of this section cannot be practically achieved with any currently available methods, the permittee shall:

(1) Obtain certification of a qualified professional and approval by the Department, that compliance with requirements under Section E.4. cannot be practically achieved with any currently available methods;

(2) Implement alternate measures to control exposure of humans or the environment to residual contamination, as necessary to protect human health and the environment; and,

(3) Implement alternate measures for control of the sources of contamination, or for removal or decontamination of equipment, units, devices, or structures that are:

(a) Technically practicable; and,

(b) Consistent with the overall objective of the remedy.

g. Upon completion of the remedy, the permittee shall submit to the Department a certification signed by a qualified professional stating that the remedy has been completed in compliance with the requirements of Section E.4.

h. Upon the Department's approval of the certification required in Section E.4.g. above, the Class Two landfill shall return to detection monitoring as outlined in Section E.2. of this Part.

F. Closure and Post-Closure Care.

1. Closure. The termination of disposal operations at a Class Two landfill, whether the entire landfill site or a portion thereof, shall be in compliance with the following requirements.

a. Within one month following the last receipt of solid waste at a site or a part of the site, the application of final cover shall begin. A two foot thick final earth cover is required with at least a 3% but not greater than 5% surface slope, graded to promote positive drainage. The side slope cover shall not exceed three horizontal feet to one vertical foot, i.e., a 3:1 slope. Alternate final cover designs may be submitted for Department review and approval. Unless otherwise approved by the Department, the application of final cover shall be completed within six months of the last receipt of solid waste at the facility. The integrity of the final cover shall be maintained.

b. Testing for certification of cap closure by a South Carolina certified professional engineer shall be done at a rate of four thickness tests per acre as defined by best engineering and construction practices.

c. The storm water conveyance system for the landfill shall be designed to ensure that the system is capable of handling a 24-hour, 25-year storm event during the active life and post-closure period of the landfill.

d. The finished surface of the disposal area shall be seeded with native grasses or other suitable ground cover within 15 days of the completion of that portion of the landfill.

e. Within 15 days of closure of the entire landfill, the permittee shall post signs at the landfill that state the facility is no longer in operation. On-site landfills are exempt from this requirement.

f. Upon closure of the entire or a portion of the landfill and within 30 days of grading and seeding, pursuant to Section F.1.d. above, a professional engineer licensed in the State of South Carolina shall submit to the Department certification that the landfill has been properly closed in accordance with requirements outlined in this Part and the facility's permit. Upon receipt of certification of closure, the Department will schedule an inspection of the facility. Upon issuance of the Department's final closure approval, the Department's permit for this facility shall be modified to incorporate post-closure activities.

g. Within 30 days of the Department's issuance of final closure approval, the owner shall:

(1) Using a form approved by the Department, record with the appropriate Register of Deeds a notation in the record of ownership of the property - or some other instrument that is normally examined during title search - that will in perpetuity notify any potential purchaser of the property, that the land or a portion thereof, was used for the disposal of solid waste. This notation shall define the final boundaries of the waste disposal area including the latitude and longitude, and identify the type, location, and quantity of solid waste disposed of on the property; and,

(2) Submit to the Department:

(a) A plat showing the final boundaries of the waste disposal area of the closed landfill; and,

(b) A copy of the document in which the notation required by Section F.1.g.(1) above has been placed.

2. Post-closure Care Requirements.

a. Following closure of each Class Two landfill, the permittee shall conduct post-closure care. Post-closure care shall be conducted for a minimum of 20 years, except as provided under Subsection b.2.below, and consist of at least the following:

(1) Maintaining the integrity and effectiveness of any final cover, including making repairs to the cover as necessary to correct the effects of settlement, subsidence, erosion, or other events, and preventing run-on and run-off from eroding or otherwise damaging the final cover. A 75% or greater vegetative ground cover with no substantial bare spots shall be established and maintained throughout the post-closure period; and,

(2) Monitoring the groundwater in accordance with the requirements of Section E of this Part and maintaining the groundwater monitoring system. Groundwater monitoring data shall be submitted to the Department during the post-closure care period within 60 days of sample collection.

b. The length of the post-closure care period may be:

(1) Increased by the Department if the Department determines that the lengthened period is necessary to protect human health and the environment or the facility has groundwater impacts remaining at the end of the post-closure period;

(2) Decreased by the Department if the permittee can provide technical rationale that the decreased post-closure care period is sufficient to protect human health and the environment.

c. The permittee of all Class Two landfills shall prepare a written post-closure plan that includes, at a minimum, the following information:

(1) A description of the monitoring and maintenance activities required in Item 2.a.. above for each Class Two landfill;

(2) Name, address, and telephone number of the person or office to contact about the facility during the post-closure period; and,

(3) A description of the planned uses of the property during the post-closure period. Post-closure use of the property shall not disturb the integrity of the final cover, or any other components of the containment system, or the function of the monitoring systems unless necessary to comply with the requirements of this regulation. The Department may approve any other disturbance of the containment system if the permittee demonstrates that disturbance of the final cover, or other component of the containment system, including any removal of waste, will not increase the potential threat to human health or the environment.

d. Prior to permit issuance, the permittee shall submit to the Department a post-closure plan for review and approval. The post-closure plan shall be updated if any changes occur at the facility which require a deviation from the approved post-closure plan.

e. Following completion of the post-closure care period for each Class Two landfill, the permittee shall submit to the Department certification, signed by a South Carolina registered professional engineer other than the design engineer, verifying that post-closure care has been completed in accordance with the post-closure plan.

G. Financial Assurance Criteria. (See Part I, Section E. of this regulation.)

H. Permit Application Requirements. Prior to the construction, operation, expansion or modification of a Class Two landfill, a permit shall be obtained from the Department.

1. Prior to submitting a permit application to the Department, the applicant shall satisfactorily complete the following:

a. Determination of Need. The applicant shall submit to the Department a request pursuant to Regulation 61–107.17 for determining need of a proposed landfill or landfill expansion, if applicable.

b. Consistency Determination. The applicant shall submit to the Department a request for a determination of consistency with items listed below.

(1) State and County/Region Solid Waste Management Plans. The permit applicant shall demonstrate consistency with the State Solid Waste Management Plan in effect at the time of the request for a determination of consistency. The permit applicant shall demonstrate consistency with the county/region plan in effect at the time of the request for a determination of consistency. Class Two landfills managing solid waste generated solely in the course of normal operation on property under the same ownership or control as the Class Two landfill are not required to demonstrate consistency with the State and host County/Region Solid Waste Management Plans;

(2) Local zoning and land-use ordinances. Documentation demonstrating consistency with local zoning and land-use plans, e.g., zoning map, land-use map, and applicable part of the zoning ordinance shall be submitted to the Department; and,

(3) All other applicable local ordinances. Supporting documentation to include a copy of the ordinance shall be submitted to the Department.

(4) Buffer Requirement. The applicant shall demonstrate that it meets the buffer requirement set forth in Part IV, Section B.1.a. of this Regulation at the time of submittal of the demonstration.

c. If the Department's final determination of need is terminated, pursuant to R.61–107.17, all other determinations under Section H.1.a. and b. above will also be void.

2. Administrative Review. Upon satisfactory completion of Section H.1. above, the applicant shall submit to the Department a complete permit application. The applicant shall submit to the Department three copies of the following documents:

a. A completed permit application on a form provided by the Department;

b. A cost estimate for hiring a third party to close the sum of all active areas of the landfill requiring a final cover at any time during the operating life when the extent and manner of its

operation would make closure the most expensive, as indicated in the closure plan. This estimate shall be sufficient to ensure satisfactory closure and post-closure maintenance of the landfill and requires Department approval prior to the permittee establishing a financial assurance mechanism pursuant to Part I, Section E. of this regulation;

c. A Disclosure Statement pursuant to Part I, Section F.1;

d. Complete engineering plans, drawings and reports in accordance with Section H.4 below, that are stamped by a Professional Engineer duly licensed to practice in the State of South Carolina; and,

e. The names and addresses of the owners of real property as they appear on the county tax maps as contiguous landowners of the proposed permit area.

f. Tonnage Limit. The applicant shall submit to the Department a request for a determination of a maximum annual tonnage limit.

(1) Prior to the issuance of a permit for a new or expanded commercial Class Two landfill, the Department will approve a maximum annual tonnage limit based on the facility's design capacity, operational capacity, the expected operational life, and the planning area as determined by R.61–107.17, SWM: Demonstration-of-Need; provided, however, that the maximum annual tonnage limit must not exceed the maximum yearly disposal rate pursuant to R. 61–107.17.

(2) Prior to issuance of a permit for a new or expanded noncommercial Class Two landfill, the Department will approve a maximum annual tonnage limit based on the facility's design capacity, operational capacity, and the expected operational life.

3. Public Notice. When the submittal is administratively complete, the Department will notify the applicant in writing. Within 15 days of receipt of notification from the Department, the applicant shall publish notice of the permit application pursuant to Part I, Section D.2. of this regulation, and submit an affidavit of publication of the public notice in the newspaper to the Department.

4. Technical Review. After determining that the permit application is administratively complete, the Department will conduct a Technical Review of the proposed project. The Department's technical review of the permit application will involve the following:

a. Engineering Drawings and Plans. All applications for new Class Two landfills and landfill expansions shall contain engineering drawings that set forth the proposed landfill location, property boundaries, adjacent land uses and construction details. All construction drawings shall be bound and rolled and shall contain the following:

(1) A vicinity plan or map that shows the area within one mile of the property boundaries of the landfill in terms of: the existing and proposed zoning and land uses within that area at the time of permit application; and, residences, public and private water supply wells, known aquifers, surface waters (with quality classifications), access roads, bridges, railroads, airports, historic sites, and other existing and proposed man-made or natural features relating to the facility. The plan shall be on a scale of not greater than 500 feet per inch, unless otherwise approved by the Department;

(2) A site plan on a scale of not greater than 200 feet per inch unless otherwise approved by the Department. This plan shall at a minimum identify the following:

(a) The landfill's property boundaries, as certified by an individual licensed to practice land surveying in the State of South Carolina; off-site and on-site utilities (such as, electric, gas, water, storm, and sanitary sewer systems), right-of-ways and easements; the names and addresses of abutting property owners; the location of soil borings, excavations, test pits, gas venting structures (if applicable), wells, piezometers, environmental and facility monitoring points and devices; benchmarks and permanent survey markers; on-site buildings and appurtenances, fences, gates, roads, parking areas, drainage culverts, and signs; the delineation of the total landfill area including planned staged development of the landfill's construction and operation, and the lateral limits of any previously filled areas; the location and identification of the sources of cover materials; and site topography with five feet minimum contour intervals; and, any other relevant information as necessary for proper operation.

The site plan drawings shall show wetlands, property lines, existing wells, water bodies, residences, schools, day-care centers, churches, hospitals, publicly owned recreational park areas and any building on adjoining property;

(b) Location of surface water, dry runs, wetlands, the location of the 100-year floodplain boundaries, and other applicable details regarding the general topography of the landfill site and adjacent properties within one-fourth (¼) mile of the disposal area;

(c) The area where unauthorized waste will be temporarily stored while it awaits removal for proper disposal; and,

(d) The area where recovered materials will be temporarily stored;

(3) Detailed plans of the landfill that clearly show in plan and cross-sectional views the following: the original, undeveloped site topography before excavation or placement of solid waste; the existing site topography, if different, including the location and approximate thickness and nature of any existing solid waste; plan view of the location of the seasonal high water table in relation to the bottom elevation of the proposed landfill; a cross sectional view of existing and final elevations, bottom elevation and deflected bottom elevation, and seasonal high water table; geologic units; known and interpolated bedrock elevations; the proposed limits of excavation and waste placement; other devices as needed to divert or collect surface water run-on or run-off; a plan and cross section view of fill progression for the life of the landfill; the final elevations and grades of the landfill; groundwater monitoring system; and, the building locations and appurtenances;

(4) Detailed plans of the sedimentation ponds. These plans shall clearly show in plan and cross sectional views the following: the existing site topography, the seasonal high water table, pond bottom elevation, permanent pool elevation, first flush elevation, maximum elevation for sedimentation clean-out, emergency spillway 100-yr storm elevation, riser pipe, antiseep collars, outlet protection, emergency spillway, dewatering riser, trash/antivortex rack, and sedimentation pond gauge legend.

b. Engineering Report. The engineering report shall contain a comprehensive description of the existing site conditions and an analysis of the proposed landfill. All engineering reports shall be bound. This report shall include, but is not limited to, the following:

(1) A current 7.5 minute quadrant map (U.S. Geological Survey topographic map, including the legend and name of the quadrant) which shows contour intervals not exceeding five feet with the location, i.e. footprint, of the proposed landfill indicated;

(2) Source and description of cover material to be used. If soil excavated during landfill construction is to be used as cover material, indicate the location of stockpiles during landfill operation;

(3) Frequency of covering;

(4) Depth of disposal area;

(5) Final contours of the finished landfill areas;

(6) Stabilization Plan. This plan shall:

(a) Identify and locate existing vegetation to be retained and proposed vegetation to be used for cover, soil stockpiles, and other purposes; and,

(b) Include a schedule for seeding or implementing other appropriate erosion control measures. Appropriate measures shall be taken to stabilize stockpiled soils within 30 days;

(7) Operating Plan. A general operating plan for the proposed landfill shall include the expected life of the landfill, the maximum volume of solid waste the landfill will be capable of receiving over the operational life of the landfill, and the maximum rate at which the landfill will receive that waste during the designed life of the landfill. This plan shall at a minimum address the following:

(a) Screening procedures defining the methods for inspecting and measuring incoming waste;

(b) Procedures for control of storm water drainage;

(c) Procedures for prevention of fires;

(d) Procedures for control of vectors;

(e) Procedures for odor control;

(f) Procedures for dust control;

(g) Procedures for ensuring that waste does not escape the landfill boundaries during flooding;

(h) Hours of operation;

(i) Procedures for excavating, earth moving, spreading, compacting and covering operations, including a list of equipment to be at the landfill for daily operation. This submittal shall also include:

i. A description of the site's preparation and fill progression for the life of the site in terms of method, depth, location and sequence;

ii. A method of elevation control for the operator including the location and description of the permanent surveying benchmark at the site; and,

iii. A fill progression discussion describing the placement and compacted thickness of cover;

(j) Description of stormwater diversion in areas of constructed cells that have not had waste placement;

(k) A contingency plan describing landfill operation in the event of fire, explosion, or other event that would threaten human health and safety of the environment, and equipment failure. Reserve equipment shall be available within 24 hours of equipment breakdown. The contingency plan shall also contain procedures for the proper removal and disposal of unauthorized waste; and,

(*l*) A list of items that are not listed in Appendix I but are similar in nature to Appendix I of this regulation that the permittee wishes to place in the landfill, the anticipated quantity and source of the waste. Upon Department review, items other than those listed in Appendix I, that are approved for landfilling, shall be listed on the permit for that facility. After issuance of the permit, other items may be approved for disposal at the landfill by modification of the permit by the Department. Only items that will cause no environmental harm as determined by the Department shall be approved for disposal;

(8) A groundwater monitoring and corrective action plan pursuant to Sections D. and E. of this Part;

(9) Detailed closure plan in accordance with Section I. of this Part, to include a description of the final cover and the methods and procedures to be used to install the cover. This plan shall also include the following: an estimate of the sum of all active areas of the landfill requiring a final cover at any time during the operating life of the facility; an estimate of the maximum inventory of wastes ever on site over the active life of the facility; a schedule for completing all activities; and, a site plan of the landfill showing the proposed final elevations. The plan may be amended at any time during the active life of the facility with Department approval. The plan shall be amended whenever changes in operating plans or facility design affect the closure plan, or whenever there is a change in the expected year of closure;

(10) Detailed post-closure plan in accordance with Section J. of this Part. This plan may address, but not be limited to, groundwater monitoring, landfill gas monitoring and maintenance of the integrity and effectiveness of the final cover including future use of the site.

c. South Carolina Coastal Zone Management Plan. The proposed landfill project shall be consistent with the South Carolina Coastal Zone Management Plan, if the landfill is located in the coastal zone as defined in accordance with the Coastal Zone Management Act.

I. Permit Conditions and Review.

1. Application forms for permits shall be provided by the Department and shall be submitted with sufficient detail to support a judgment that operation of the disposal system will not violate the laws and regulations of the State of South Carolina. The application shall be signed by the permittee of the landfill. The approved application and associated plans and drawings shall be an

enforceable part of the permit. Permits shall be effective for the design and operational life of the facility.

2. Prior to issuance of permits for major modifications, as determined by the Department, and for new construction, the Department will make the draft permit available for public review and comment pursuant to Part I, Section D of this regulation.

3. The Department shall review the permit at least once every five years. Upon notification from the Department, the landfill shall submit to the Department a topographic survey map of the site that shows the contours at the beginning and the end of the period since the last permit review.

4. If, upon review, the Department finds that material or substantial violations of the permit demonstrate the permittee's disregard for, or inability to comply with, applicable laws, regulations, or requirements, and would make continuation of the permit not in the best interest of human health and safety or the environment, the Department may, after a hearing, amend or revoke the permit as appropriate and necessary. When a permit is reviewed, the Department shall include additional limitations, standards, or conditions when the technical limitations, standards, or regulations on which the original permit was based have been changed by statute or amended by regulation.

5. The Department may amend or attach conditions to a permit when:

a. There is a significant change, as determined by the Department, in the manner and scope of operation which may require new or additional permit conditions or safeguards to protect human health and safety and the environment;

b. The investigation has shown the need for additional equipment, construction, procedures, and testing to ensure the protection of human health and safety and the environment; and,

c. The amendment is necessary to meet changes in applicable regulatory requirements.

6. Failure to begin construction within twelve (12) months of the issuance of the Department permit shall render that permit invalid unless granted a variance in writing by the Department.

J. Transfer of Ownership. The Department may, upon written request, transfer a permit to a new permittee where no other change in the permit is necessary pursuant to Part I, F.2.b. of this regulation.

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Part V. Class Three Landfills.

(Subsections A through F of this Part are codified to coincide with those Subparts in 40CFR258.)

Subpart A. General Provisions.

258.1. Purpose, Scope, and Applicability.

a. Part V. establishes minimum criteria for landfills that accept municipal solid waste, industrial solid waste, sewage sludge, nonhazardous municipal solid waste incinerator ash and other nonhazardous waste. Hereinafter, these landfills will be referred to as Class Three landfills. Class Three landfills shall adhere to their approved Special Waste Analysis and Implementation Plan (SWAIP), pursuant to S.C. Code Section 44–96–390.

b. This Part applies to owners and operators of new and existing Class Three landfills, except as otherwise specifically provided in this regulation.

c. No Class Three landfill shall be operated in the State of South Carolina without first obtaining a written permit from the South Carolina Department of Health and Environmental Control.

d. Class Three landfills failing to satisfy the criteria in this Part are considered open dumps for purposes of State solid waste management planning under RCRA.

e. Class Three landfills failing to satisfy the criteria in this Part constitute open dumps, which are prohibited under section 4005 of RCRA.

f. Class Three landfills containing sewage sludge and failing to satisfy the criteria in this Part violate sections 309 and 405(e) of the Clean Water Act.

g. Class Three landfills permitted prior to the effective date of this regulation to accept only industrial waste that test less than 30 times the MCL shall be exempted from the design criteria as outlined in Subpart D of this Part.

258.2. Definitions. See Part I., Section B. for definitions that apply to this regulation.

258.3. Considerations of other Federal Laws. The permittee of a Class Three landfill shall comply with any other applicable Federal rules, laws, regulations, or other requirements.

258.4. Research, Development, and Demonstration Permits.

a. When the leachate collection system is designed and constructed to maintain less than a 1 ft. depth of leachate on the liner, the Department may issue a research, development, and demonstration (RD and D) permit pursuant to R.61–107.10 for a Class Three Landfill for the use of innovative and new methods that vary from either or both of the following criteria:

(1) The run-on control systems in Section 258.26.a.(1); and,

(2) The liquids restrictions in Section 258.28.a., and Subpart H. Section 7.c. for specific permit requirements for leachate recirculation.

b. The Department may issue a research, development, and demonstration permit pursuant to R.61–107.10 for a Class Three Landfill to utilize innovative and new methods that vary from the final cover criteria of Section 258.60.a.(1), a.(2), and b.(1) when it can be demonstrated that the infiltration of liquid through the alternative cover system will not cause contamination of groundwater or surface water, or cause leachate depth on the liner to exceed 1 foot.

c. Any permit issued under this section shall include such terms and conditions at least as protective as the criteria for Class Three landfills to assure protection of human health and the environment. Such permits shall:

(1) Provide for the construction and operation of such facilities as necessary, for not longer than two years, unless renewed in writing by the Department;

(2) Provide that the landfill receive only those types and quantities of municipal solid waste and nonhazardous wastes that the Department deems appropriate for the purposes of determining the efficacy and performance capabilities of the technology or process;

(3) Include such requirements as necessary to protect human health and the environment, including such requirements as necessary for testing and providing information to the Department with respect to the operation of the facility;

(4) Require the permittee of a Class Three landfill permitted under this section to submit an annual report to the Department showing whether and to what extent the site is progressing in attaining project goals. The report will also include a summary of all monitoring and testing results, as well as any other operating information specified by the Department in the permit; and,

(5) Require compliance with all criteria in this part, except as permitted under this section.

d. The Department may order an immediate termination of all operations at the facility allowed under this section or other corrective measures at any time the Department determines that the overall goals of the project are not being attained, including protection of human health or the environment.

e. Any permit issued under this section shall not exceed two years and each renewal of a permit shall not exceed two years.

(1) The total term for a permit for a project including renewals may not exceed six years; and,

(2) When a permit renewal is requested, the applicant shall provide the Department with a detailed assessment of the project showing the status with respect to achieving project goals, a list of problems and status with respect to problem resolutions, and any other requirements that the Department determines necessary for permit renewal.

f. Upon expiration of the RD and D permit, if the innovative/new method is proved to be a viable method, the facility's existing landfill permit issued under the authority of this regulation may be amended to include the innovative/new method.

Subpart B. Location Restrictions.

258.10. Airport Safety.

a. Owners/operators of Class Three landfills that are located within 10,000 feet of any airport runway end used by turbojet aircraft or within 5,000 feet of any airport runway end used by only piston-type aircraft shall demonstrate that the units are designed and operated so that the Class Three landfill does not pose a bird hazard to aircraft.

b. Owners/operators proposing to site new Class Three Landfills and lateral expansions located within a five mile radius of any airport runway end used by turbojet or piston-type aircraft shall notify the affected airport and the Federal Aviation Administration (FAA).

c. The permittee shall place the demonstration required in a. above in the operating record and submit a copy to the Department.

d. See Part I, Section B. for definitions.

e. A new Class Three landfill that receives putrescible waste shall not be constructed or established after the effective date of this regulation within six (6) miles of a public airport that has received federal grant funds under 49 U.S.C. 47101 and is primarily served by general aviation aircraft and regularly scheduled flights of aircraft designed for sixty (60) passengers or more. The Federal Aviation Administration has issued guidance which includes criteria for determining when an airport is covered and has identified those airports meeting the criteria. Anyone considering construction or establishment of a new Class Three landfill within six (6) miles of a public airport should contact the Federal Aviation Administration. This requirement does not apply to:

(1) A new Class Three landfill if the S.C. Division of Aeronautics requests that the Administrator of the Federal Aviation Administration exempt the landfill from the application of this Item, and the Federal Aviation Administration Administrator determines that such exemption would have no adverse impact on aviation safety; or,

(2) Expansions, either vertical or lateral, of existing Class Three landfills constructed before the effective date of this regulation.

258.11. Floodplains.

a. Owners/operators of Class Three Landfills located in 100-year floodplains shall demonstrate that engineering measures have been incorporated into the landfill design to ensure the landfill will: not restrict the flow of the 100-year flood, reduce the temporary water storage capacity of the floodplain, minimize potential for floodwaters coming into contact with waste, or result in the washout of solid waste so as to pose a hazard to human health or the environment. The permittee shall place the demonstration in the operating record and submit a copy to the Department.

b. See Part I., Section B. for definitions that apply to this regulation.

258.12. Wetlands. All landfills shall be in compliance with the U.S. Army Corps of Engineers, the U.S. Environmental Protection Agency, and the Department's requirements concerning wetlands.

258.13. Fault Areas.

a. Class Three landfills shall not be located within 200 feet of a fault that has had displacement in Holocene time unless the permittee demonstrates to the Department that an alternative setback distance of less than 200 feet will prevent damage to the structural integrity of the Class Three landfill and will be protective of human health and the environment.

b. See Part I., Section B. for definitions that apply to this regulation.

258.14. Seismic Impact Zones.

a. Class Three landfills shall not be located in seismic impact zones, unless the permittee demonstrates to the Department that all containment structures, including liners, leachate collection systems, and surface water control systems, are designed to resist the maximum horizontal acceleration in lithified earth material for the site.

b. Definitions. See Part I., Section B. for definitions that apply to this regulation.

258.15. Unstable Areas.

a. Owners/operators of Class Three landfills located in an unstable area shall demonstrate that engineering measures have been incorporated into the landfill's design to ensure that the integrity of the structural components of the Class Three landfill will not be disrupted. The permittee shall place the demonstration in the operating record and notify the Department that it has been placed

in the operating record. The permittee shall consider the following factors, at a minimum, when determining whether an area is unstable:

(1) On-site or local soil conditions that may result in significant differential settling;

(2) On-site or local geologic or geomorphologic features; and,

(3) On-site or man-made features or events (both surface and subsurface).

b. See Part I., Section B. for definitions that apply to this regulation.

258.16. Reserved.

258.17. Hydrogeologic Considerations.

a. Class Three landfills shall be located in areas that can be demonstrated to have the characteristics listed below (258.17.a.(1), a.(2), a.(3), and a.(4)). The inability of a site to meet full compliance with these criteria may not necessarily make the site unsuitable, but the applicant has the burden to demonstrate to the satisfaction of the Department why variance from the criteria will not compromise protection to human health and the environment. If Department review finds the demonstration to be inadequate, the application may be denied. Upon notification from the Department that the site meets the requirements of this section, the applicant may submit a complete application to the Department. This approval shall not be valid after a period of twelve (12) months of the date of issuance if the complete application has not been submitted, unless granted a variance by the Department.

(1) The site shall not be located in an area where the hydrogeologic conditions allow the groundwater to migrate from shallow geologic units that have little potential as an underground source of drinking water, into deeper units. At the disposal area, any release to the uppermost aquifer would remain in the uppermost aquifer until discharge into the perennial stream nearest to the disposal area. The potentiometric head in the shallow portion of the uppermost aquifer shall be equal to or lower than the potentiometric head in the deeper portion of the uppermost aquifer (i.e., a lateral or an upward hydraulic gradient shall exist).

(2) The estimated deflected (or settled) bottom elevation of the landfill base grade shall be a minimum of three feet above the seasonal high water table elevation as it exists prior to the construction of the disposal area. The seasonal high water table shall be determined by interpretation of a minimum of 12 months data obtained from a representative number of monitoring wells approved by the Department. In cases where there is insufficient information to support the seasonal high water table elevation determination, additional separation may be required by the Department.

(3) A minimum 10 foot vertical separation of naturally occurring or engineered material shall be maintained between the base of the constructed liner and bedrock; provided, however, the nature of the material and sufficient separation exists to provide for installation and operation of an effective groundwater monitoring system. The nature of the material comprising this interval is subject to Department approval.

(4) The landfill shall not be located over an area where a stratum of limestone exhibiting secondary permeability with an average thickness of greater than five feet lies within 50 feet of the base of the landfill.

b. Class Three landfills are prohibited in areas where the permittee cannot demonstrate to the satisfaction of the Department that:

(1) The Class Three landfill is not located in a manner that would result in the destruction of a perennial stream, within 200 feet of a perennial stream, within that portion of a drainage basin included in a 2500 foot radius on the upstream side of a public drinking water supply intake, and within that portion of a drainage basin which is within 1000 feet of a lake, pond, or reservoir used as a source of public drinking water supply; and,

(2) The hydrogeologic properties of the site can be adequately characterized. The characterization shall include, but not be limited to, a detailed description of the geologic units below the site (including mineralogy, sedimentary structures, thickness, continuity, and structure), the hydraulic properties of each geologic unit (including secondary porosity and a discussion of variations noted across the site), hydraulic gradient, hydraulic conductivity, and direction and rate of groundwater flow within the uppermost aquifer system and all interconnected aquifers and confining units

using a groundwater flow net. In addition, the relationship between the units below the site to locally and regionally recognized geologic and hydrogeologic units shall be described.

c. Class Three landfills shall not be located over Class GA groundwater or over the recharge area for Class GA groundwater as designated by the Department, over a sole source aquifer, or over the recharge area for a sole source aquifer as designated by the Department.

d. All Class Three landfills shall demonstrate compliance with the groundwater monitoring requirements pursuant to Subpart E.

258.18. Buffer Zones. Class Three landfills shall meet the buffer zone requirements outlined below:

a. The boundary of the fill area shall not be located within 1,000 feet of any residence, day-care center, church, school, hospital or publicly owned recreational park area unless such features are included in the site design for a planned end use or otherwise approved by the Department. The Department will determine whether the proposed landfill or landfill expansion meets this requirement prior to publication of the Notice of Intent to File a Permit Application pursuant to Part I, Section D.1 of this Regulation;

b. The boundary of the fill area shall not be located within 200 feet of any property line not under control of the permittee. An exemption may be issued by the Department upon receipt of written approval from adjacent property owners;

c. The boundary of the fill area shall not be located within 200 feet of any surface water that holds visible water for greater than six consecutive months, excluding ditches, sediment ponds, and other operational features on the site;

d. The boundary of the fill area shall not be located within the distances designated below from any well used as a source of water for human consumption, that is in a hydrologic unit potentially affected by the landfill. Exemptions may be granted if the applicant can demonstrate to the satisfaction of the Department that the hydrologic conditions below the landfill provide protection to the aquifer in use.

(1) The boundary of the fill area shall not be located any closer than 500 feet from a well hydraulically upgradient of the landfill.

(2) The boundary of the fill area shall not be located any closer than 750 feet from a well hydraulically sidegradient of the landfill.

(3) The boundary of the fill area shall not be located any closer than 1000 feet from a well hydraulically downgradient of the landfill.

e. Waste material shall not be placed on or within any property rights-of-way or 50 feet of underground or above ground utility equipment or structures, i.e., water lines, sewer lines, storm drains, telephone lines, electric lines, natural gas lines, etc., without the written approval of the impacted utility.

Subpart C. Operating Criteria.

258.20. Procedures for Excluding the Receipt of Hazardous Waste and Special Waste.

a. Owners/operators of all Class Three landfills shall implement a program at the facility for detecting and preventing the disposal of regulated hazardous wastes as defined in the South Carolina Hazardous Waste Management Regulations R.61–79.261 and polychlorinated biphenyls (PCB) wastes as defined in Toxic Substances Control Act (TSCA), Part 761. This program shall be a part of the Special Waste Analysis and Implementation Plan (SWAIP) and shall include, at a minimum:

(1) Random daily inspections of no less than 10% of incoming loads unless the permittee takes other steps as outlined in the SWAIP to ensure that incoming loads do not contain regulated hazardous wastes, PCB wastes, or wastes not specifically allowed by the permit. Bulk PCB wastes may be allowed for disposal in a Class Three landfill based on a case-by-case determination by the Department;

(2) Records of unacceptable waste to include quantities and descriptions of waste, generator information, and how/where waste was properly disposed;

(3) Training of facility personnel to recognize regulated hazardous waste and PCB wastes; and,

(4) Notification of the Department within 72 hours of facility personnel becoming aware that a regulated hazardous waste or PCB waste may have been disposed of at the facility.

b. Definitions. See Part I., Section B. for definitions that apply to this regulation.

c. The owners/operators of all Class Three landfills shall implement a program at the facility for regulating the receipt of special wastes as described in SC Code Section 44–96–390.

258.21. Cover Material Requirements.

a. Except as provided in paragraph b. below, the owners/operators of all Class Three landfills shall cover solid waste with six (6) inches of earthen material at the end of each operating day, or at more frequent intervals if necessary, to control vectors, fires, odors, blowing litter, and scavenging. Special waste may require more frequent or additional cover.

b. Alternative materials of an alternative thickness (other than at least six (6) inches of earthen material) may be approved by the Department on a case-by-case basis if the permittee demonstrates that the alternative material and thickness control vectors, fires, odors, blowing litter, and scavenging without presenting a threat to human health and the environment.

c. The Class Three landfill shall have an adequate quantity of acceptable earth (or approved alternate) cover for routine operations. If the material does not originate on-site, the permit application shall indicate the calculated volume of material needed for cover, provide assurances that off-site quantities of cover material are available, the location of any earth stockpiles, and any provisions for saving topsoil for use as final cover. The earth cover material shall be easily workable and compactable, shall be free of large objects that would hinder compaction, and shall not contain organic matter conducive to the harborage and/or breeding of vectors or nuisance animals.

d. The Department may grant, with prior notice from the permittee, a temporary waiver not to exceed seven days from the requirements of paragraphs a. and b. above for emergency situations.

258.22. Disease Vector Control.

a. Owners/operators of all Class Three landfills shall prevent or control on-site populations of vectors using techniques appropriate for the protection of human health and the environment.

b. Definitions. See Part I., Section B. for definitions that apply to this regulation.

258.23. Explosive Gases Control.

a. Owners/operators of all Class Three landfills shall ensure that:

(1) The concentration of methane gas generated by the facility does not exceed 25% of the lower explosive limit for methane in facility structures (excluding gas control or recovery system components); and,

(2) The concentration of methane gas does not exceed the lower explosive limit for methane at the facility property boundary.

b. Owners/operators of all Class Three landfills shall implement a routine methane monitoring program to ensure that the standards in paragraph a. above are met.

(1) The type and frequency of monitoring shall be determined based on the following factors:

(a) Soil conditions;

(b) The hydrogeologic conditions surrounding the facility;

(c) The hydraulic conditions surrounding the facility; and,

(d) The location of facility structures and property boundaries.

(2) The minimum frequency of monitoring shall be quarterly.

c. If methane gas levels exceeding the limits specified in Section 258.23.a. above are detected, the permittee shall:

(1) Immediately take all necessary steps to ensure protection of human health and notify the Department;

(2) Within seven days of detection, place in the operating record and submit to the Department a copy of the methane gas levels detected and a description of the steps taken to protect human health; and,

(3) Within 30 days of detection, submit a methane remediation plan and construction details, signed and stamped by a South Carolina Licensed Professional Engineer, to the Department for approval; and,

(4) Within 30 days of plan approval, implement the Department approved remediation plan for the methane gas releases, place a copy of the plan in the operating record, and notify the Department that the plan has been implemented. The plan shall describe the nature and extent of the problem, the proposed remedy, and contain a schedule for compliance.

d. Definitions. See Part 1., Section B. for definitions that apply to this regulation.

258.24. Air Criteria.

a. Owners/operators of all Class Three landfills shall ensure that the landfills do not violate any applicable requirements developed in a State Implementation Plan (SIP) approved or promulgated by the Department pursuant to Section 110 or Section 111 of the Clean Air Act, as amended.

b. Open burning of solid waste, except for the infrequent burning of agricultural wastes, silvicultural wastes, landclearing debris, diseased trees, or debris from emergency clean-up operations, all of which require prior Department approval, is prohibited at all Class Three landfills.

258.25. Access Requirements.

a. Owners/operators of all Class Three landfills shall control public access and prevent unauthorized vehicular traffic and illegal dumping of wastes by using artificial barriers, natural barriers, or both, as appropriate to protect human health and the environment.

b. The landfill shall be adjacent to or have direct access to roads that are of all-weather construction and capable of withstanding anticipated load limits.

c. Salvaging and scavenging shall not be allowed at the working face of a Class Three landfill at any time.

258.26. Run-on/run-off Control Systems.

a. Owners/operators of all Class Three landfills shall design, construct, and maintain:

(1) A run-on control system to prevent flow onto the active portion of the landfill during the peak discharge from a 25-year storm; and,

(2) A run-off control system from the active portion of the landfill to collect and control at least the water volume resulting from a 24-hour, 25-year storm.

b. Run-off from the active portion of the landfill shall be handled in accordance with 258.27.a. below.

258.27. Surface Water Requirements.

a. Class Three landfills shall not:

(1) Cause a discharge of pollutants into waters of the United States, including wetlands, that violates any requirements of the Clean Water Act, including, but not limited to, Section 402 of the National Pollutant Discharge Elimination System (NPDES); and,

(2) Cause the discharge of a nonpoint source of pollution to waters of the United States, including wetlands, that violates any requirement of an area-wide or State-wide water quality management plan that has been approved in Section 208 or 319 of the Clean Water Act, as amended.

b. The permittee shall obtain an appropriate permit from the Department prior to the discharge of any storm waters to surface waters.

258.28. Liquids Restrictions.

a. Bulk or noncontainerized liquid waste may not be placed in Class Three landfills unless:

(1) The waste is household waste; or,

(2) The landfill has a Department Research, Development, and Demonstration Permit as outlined in Section 258.4 of this regulation.

b. Containers holding liquid waste may not be placed in a Class Three landfill unless:

(1) The container is a small container similar in size to that normally found in household waste;

(2) The container is designed to hold liquids for use other than storage; or,

(3) The waste is household waste.

c. For definitions, see Part I, Section B.

258.29. Record Keeping Requirements.

a. The permittee of a Class Three landfill shall record and retain near the facility in an operating record or in an alternative location approved by the Department for a period of no less than three years the following information as it becomes available:

(1) Any location restriction demonstration required in Subpart B of this Part;

(2) Inspection records, training procedures, and notification procedures required in Section 258.20. of Subpart C;

(3) Gas monitoring results and any remediation plans required by Section 258.23. of Subpart C;

(4) Any Class Three landfill design documentation for placement of leachate or gas condensate in the landfill as required in Section 258.28.a.(2) above;

(5) Any demonstration, certification, finding, monitoring, testing, or analytical data required by Subpart E;

(6) Closure and post-closure care plans, updates to the closure and post-closure care plans, and any monitoring, testing, or analytical data as required by Sections 258.60. and 258.61. of this Part;

(7) Any cost estimates and financial assurance documentation required by Part I., Section E. of this regulation; and,

(8) The results of any environmental monitoring or testing performed in accordance with this regulation or the operating permit for the facility.

b. All information contained in the operating record shall be furnished upon request to the Department or be made available at all reasonable times for inspection by the Department.

c. The permittee of a Class Three landfill shall record in an operating record, information concerning the source or type (e.g. residential route, commercial, industrial, transfer station identity, special); weight (tons); county and State of origin of each load of waste delivered to the facility. A summary of this information shall be submitted to the Department no later than September 1, of each year, for the previous fiscal year, on a form approved by the Department.

d. The Department can set alternative schedules for record keeping and notification requirements as specified in Sections 258.29.a. and b. above, except for the notification requirements in Sections 258.10.b. and 258.55.i.(1)(d).

258.30. Scale Installation. Each permittee of a Class Three landfill shall install and/or maintain scales capable of accurately determining the weight of incoming waste streams.

258.31. Equipment. The following equipment shall be required to ensure adequate operation of the Class Three landfill:

a. Equipment or adequate contractual arrangements for equipment sufficient for excavating, earth moving, spreading, dust suppression, compacting and covering operations;

b. Sufficient reserve equipment, or arrangements to provide alternate equipment within 24 hours following equipment breakdown; and,

c. Equipment to extinguish fires or arrangements to provide for fire protection.

258.32. Supervision and Inspection.

a. Supervision of the operation of the Class Three landfill shall be the responsibility of a qualified individual who has experience in the operation of a Class Three Landfill, and has completed operator training courses and is certified pursuant to R.61–107.14.

b. Routine inspection and evaluation of landfill operations will be made by a representative of the Department. A notice of any deficiencies, together with any recommendations for their correction, will be provided to the owner or local government responsible for the operation of the landfill.

258.33. Leachate Handling Agreement. Either a legal document (contract, local permit, etc.) certifying acceptance of leachate by the operator of a wastewater treatment facility for the discharge of leachate to that facility, or a state pollutant discharge elimination system permit shall be obtained prior to initial receipt of waste at the facility.

258.34. Leachate Control. The permittee of the Class Three landfill shall ensure that the leachate head above the liner system does not exceed one (1) foot, except for brief periods not to exceed one (1) week, due to circumstances beyond the immediate control of the permittee.

258.35. Testing of Municipal Solid Waste Incinerator Ash.

a. Ash residue disposed at a Class Three landfill shall be sampled and analyzed according to the current Environmental Protection Agency (EPA) acceptable methodology for determining the hazardous nature of the ash.

b. The required analysis of all ash shall be performed in accordance with the conditions of the solid waste incinerator permit where the ash is generated, and the Class Three landfill where the ash is disposed.

c. Prior to disposal, ash from each facility generating ash shall be tested, at a minimum semi-annually and when any changes occur to the waste streams being incinerated, to determine the hazardous or non-hazardous nature of the ash stream.

d. No ash determined to be hazardous waste shall be disposed at a Class Three landfill.

e. Records of all ash testing shall be maintained in the operating record of the Class Three landfill.

258.36. Sign Requirements. Signs shall be posted and maintained at the main entrance that:

a. Identify the owner, operator, or a contact person and telephone number in case of emergencies and the normal hours during which the landfill is open to receive waste;

b. State the types of waste that the landfill is permitted to receive; and,

c. Identify the valid SCDHEC Facility I.D. Number for the facility.

258.37. Litter Control. Wind borne waste shall be controlled at the Class Three landfill. The entire facility shall be policed as necessary to remove any accumulations of blown litter.

Subpart D. Design Criteria for Class Three Landfills.

258.40. Design Criteria.

a. Class Three landfills shall be constructed:

(1) In accordance with a design approved by the Department. The design shall ensure that the maximum contaminant level (MCL) as specified in the South Carolina State Primary Drinking Water Standards, R.61–68 will not be exceeded in the uppermost aquifer at the relevant point of compliance, as specified by the Department in Section 258.40.i. below; or,

(2) With a composite liner, as defined in Item b. below of this section and a leachate collection system that is designed and constructed to maintain less than a one (1) foot depth of leachate over the liner, except in sumps.

(3) Monofills that accept coal combustion byproducts that test greater than ten (>10) times the maximum contaminant level (MCL), may be constructed with a clay liner system consisting of a minimum of a two (2) foot layer of compacted soil with a hydraulic conductivity of no more than 1 x 10–7 cm/sec, and an appropriate leachate collection system. These facilities shall comply with all other requirements for a Class III landfill.

b. Liner. A composite liner system shall consist of two components: the upper component shall consist of a minimum 30-mil flexible membrane liner (FML); and, the lower component shall consist of at least a two foot layer of compacted soil with a hydraulic conductivity of no more than 1 x 10–7 cm/sec. FML components consisting of High Density Polyethylene (HDPE) shall be at least 60-mil thick. The FML component shall be installed in direct and uniform contact with the compacted soil component.

c. The leachate collection and removal system shall be designed and built to operate without clogging during the operational life of the site and post-closure maintenance period. The system shall be designed to allow for routine maintenance and cleaning of the system.

d. Filter layers shall be designed to prevent the migration of fine soil particles into a coarser grained material, and allow water or gases to freely enter a drainage medium (pipe or drainage blanket) without clogging.

e. The total thickness of the drainage and protective layers above the liner material shall be a minimum of two feet thick, and shall be composed of material with a minimum hydraulic conductivity of 1 x 10–4 cm/sec.

f. All material used in the leachate collection and removal system of the landfill shall be designed to ensure that the hydraulic leachate head on the liner system does not exceed one foot as a result of a 24-hour, 25-year storm event during the active life and post-closure care period of the landfill.

g. A foundation analysis shall be performed to determine the structural integrity of the subgrade to support the horizontal and vertical stresses and overlying facility components.

(1) The constructed landfill subgrade material shall consist of on-site soils or select fill with minimal organic material, as approved by the Department.

(2) The landfill subgrade shall be graded in accordance with the requirements of the approved engineering plans, reports and specifications. The material shall be sufficiently dry and structurally sound to ensure that the first lift and all succeeding lifts of soil placed over the landfill subgrade can adequately be compacted to the design requirements.

h. When approving a design that complies with the requirements of this Part, the Department shall consider at least the following factors:

(1) The hydrogeologic characteristics of the facility and surrounding land;

(2) The climatic factors of the area; and,

(3) The volume and physical and chemical characteristics of the leachate.

i. The relevant point of compliance specified by the Department shall be no more than 150 feet from the waste management unit boundary and shall be located on land owned by the owner of the Class Three landfill. In determining the relevant point of compliance, the Department shall consider at least the following factors:

(1) The hydrogeologic characteristics of the facility and surrounding land;

(2) The volume and physical and chemical characteristics of the leachate;

(3) The quantity, quality, and direction of flow of groundwater;

(4) The proximity and withdrawal rate of the groundwater users;

(5) The availability of alternative drinking water supplies;

(6) The existing quality of the groundwater, including other sources of contamination and their cumulative impacts on the groundwater and whether groundwater is currently used or reasonably expected to be used for drinking water;

(7) Public health, safety, and welfare effects; and,

(8) Practicable capability of the permittee.

j. One permanent survey benchmark of known elevation measured from a U.S. Geological Survey benchmark shall be established and maintained at the site. This benchmark shall be the reference point for establishing horizontal and vertical elevation control.

k. A minimum separation of three feet shall be maintained between the base of the constructed liner system and the high water table. Settlement of the landfill base grade shall be factored into the minimum separation requirement.

l. The soil component of the liner system shall conform with the following:

(1) The soil component of the liner system shall be placed on a slope of no less than 2% to promote positive drainage across the liner surface and at a maximum slope not greater than 33% to facilitate construction; and,

(2) Compaction shall be performed by properly controlling the moisture content, lift thickness and other necessary details to obtain satisfactory results.

m. The flexible membrane liner material shall demonstrate a chemical and physical resistance to waste placement or leachate generated by the landfill. Documentation shall be submitted to ensure chemical compatibility of the geomembrane liner material chosen, or in absence of the appropriate documentation, chemical compatibility testing shall be performed using a test method acceptable to

the Department. Flexible membrane liners shall be installed in accordance with the requirements of the approved engineering plans, report, specifications and manufacturer's recommendations.

n. All storm water ditches should have a minimum slope of 0.5% or a minimum permissible non-silting velocity of two feet per second. When it is not possible to achieve minimum slopes and/or velocities, alternative system design and maintenance, which ensures proper run-on and run-off control, may be approved by the Department.

o. For landfill expansions adjacent to existing Class Three landfills, the Department may approve encroachment upon the existing landfill's side slopes only if a leachate barrier system is designed and constructed to eliminate leachate migration into the existing landfill. The expansion area shall be constructed in compliance with all applicable sections of this regulation. The subsurface conditions of the underlying area shall be capable of supporting the expansion.

p. A construction certification report shall be submitted to the Department for approval after the completion of landfill construction by a S.C. licensed engineer other than the design engineer. This report shall include at a minimum, the information prepared in accordance with the application requirements. In addition, the construction certification report shall contain as-built drawings prepared and sealed by a land surveyor registered in South Carolina noting any deviations from the approved engineering plans. The construction certification report shall include a comprehensive narrative by the engineer. Upon approval of the construction certification report and a satisfactory Department inspection, the Department will grant approval for disposal of waste.

q. The Department may, on a case-by-case basis, approve other landfill designs, provided there is adequate information to demonstrate that the proposed design meets or exceeds the environmental and public health protection standards outlined in this regulation.

r. Class Three landfills shall have a minimum 1.7 factor safety against failure, where the soil conditions are complex and when available strength data does not provide a consistent, complete, or logical picture of the strength characteristics. Where the soil conditions are uniform and high quality strength data provides a consistent, complete, and logical picture of the strength characteristics, a minimum 1.2 factor safety against failure may be used. The determination of the maximum horizontal acceleration of the lithified earth material for the site shall be based on the seismic 250-year interval maps in U.S. Geological Survey Open-File Report 82–1033 [1]. The permittee shall place the demonstration in the operating record and submit a copy to the Department.

Subpart E. Groundwater Monitoring and Corrective Action

258.50. Applicability.

a. The requirements in this part apply to all Class Three landfills, except as provided in paragraph b. below.

b. Groundwater monitoring requirements in Sections 258.51. through 258.55. of this Part may be modified by the Department for a Class Three landfill if the permittee can demonstrate that there is no potential for migration of hazardous constituents from the Class Three landfill to the uppermost aquifer during the active life of the landfill and the post-closure care period. This demonstration shall be certified by a qualified professional and approved by the Department, and shall be based upon:

(1) Site-specific field collected measurements, sampling, and analysis of physical, chemical, and biological processes affecting contaminant fate and transport; and,

(2) Contaminant fate and transport predictions that maximize contaminant migration and consider impacts on human health and environment.

c. Class Three landfills shall be in compliance with the groundwater monitoring requirements specified in Sections 258.51.–258.55. before waste can be placed in the landfill.

d. Once established at a Class Three landfill, groundwater monitoring shall be conducted throughout the active life and post-closure care period of the landfill as specified in Section 258.61.

e. For the purposes of this Subpart, a qualified professional shall certify all submittals.

[1] Entitled "Probabilistic Estimates of Maximum Acceleration and Velocity in Rock in the Contiguous United States," (Algermissen and Perkins, 1982).

f. The Department may establish alternative schedules for demonstrating compliance with the various sections of this Subpart on a case-by-case basis, provided sufficient technical rationale is provided to the Department to justify the alternate compliance schedule.

258.51 Groundwater Monitoring Systems

a. A groundwater monitoring system shall be installed that consists of a sufficient number of wells, installed at appropriate locations and depths, to yield representative groundwater samples from the uppermost aquifer that:

(1) Represent the quality of background groundwater that has not been affected by leakage from a landfill. A determination of background quality may include sampling of wells that are not hydraulically upgradient of the waste management area where:

(a) Hydrogeologic conditions do not allow the permittee to determine what wells are hydraulically upgradient; or,

(b) Sampling at other wells will provide an indication of background groundwater quality that is as representative or more representative than that provided by the upgradient wells; and,

(2) Represent the quality of groundwater passing the relevant point of compliance approved by the Department in Section 258.40.i. The downgradient monitoring system shall be installed between the relevant point of compliance and the actual disposal area, and shall ensure detection of any groundwater contamination in the uppermost aquifer. When physical obstacles preclude installation of groundwater monitoring wells at the relevant point of compliance at existing landfills, the downgradient monitoring system shall be installed at the closest practicable distance hydraulically downgradient from the relevant point of compliance to ensure detection of groundwater contamination in the uppermost aquifer.

b. Reserved.

c. Monitoring wells shall be approved by the Department and constructed, at a minimum, to the standards established in the R.61–71.H., South Carolina Well Standards.

(1) The permittee shall submit to the Department and place in the operating record, documentation of the design, installation, development, and abandonment of any monitoring wells, piezometers and other measurement, sampling, and analytical devices; and,

(2) The monitoring wells, piezometers, and other measurement, sampling, and analytical devices shall be operated and maintained so that they perform to design specifications throughout the life of the monitoring program.

d. The number, spacing, and depths of monitoring systems shall be:

(1) Determined based upon site-specific technical information that shall include thorough characterization of:

(a) Aquifer thickness, groundwater flow rate, groundwater flow direction including seasonal and temporal fluctuations in groundwater flow, and the information required by Section 258.17.; and,

(b) Saturated and unsaturated geologic units and fill materials overlying the uppermost aquifer, materials comprising the uppermost aquifer, and materials comprising the confining unit defining the lower boundary of the uppermost aquifer; including, but not limited to: thicknesses, stratigraphy, lithology, hydraulic conductivities, porosities and effective porosities; and,

(2) Certified by a qualified professional and approved by the Department. Within 14 days of this certification, the permittee shall place the certification in the operating record and submit a copy to the Department.

258.52. Reserved.

258.53. Groundwater Sampling and Analysis Requirements.

a. The groundwater monitoring program shall include consistent sampling and analysis procedures that are designed to ensure monitoring results that provide an accurate representation of groundwater quality at the background and downgradient wells installed in compliance with Section 258.51.a. of this Part. The permittee shall submit to the Department for review and approval, the sampling and analysis procedures and protocols to be used at the facility. After approval by the

Department, documentation shall be placed in the operating record. The program shall include procedures and techniques for:

(1) Sample collection;

(2) Sample preservation and shipment;

(3) Analytical procedures;

(4) Chain of custody; and,

(5) Quality assurance and quality control.

b. The groundwater monitoring program shall include sampling and analytical methods that are appropriate for groundwater sampling and that accurately measure hazardous constituents and other monitoring parameters in groundwater samples. Detection limits for those parameters that have a Maximum Contaminant Level (MCL) that has been promulgated under South Carolina R.61–58, State Primary Drinking Water Regulations, shall be, at a minimum, below the established MCL. Detection levels shall be as low as practically possible, and at the practical quantitation level (PQL) for those constituents with no MCL. Groundwater samples shall not be field-filtered prior to laboratory analysis.

c. The sampling procedures and frequency shall be protective of human health and the environment.

d. Groundwater elevations shall be measured and recorded for each well prior to initiating sampling procedures each time groundwater is sampled. The permittee shall determine the rate and direction of groundwater flow each time groundwater is sampled. Groundwater elevations in wells that monitor the same waste management area shall be measured on the same day to avoid temporal variations in groundwater flow which could preclude an accurate determination of groundwater flow rate and direction.

e. The permittee shall establish background groundwater quality in a hydraulically upgradient or background well(s) for each of the metals or constituents required in the particular groundwater monitoring program that applies to the Class Three landfill, as determined in Section 258.54.a., or Section 258.55.a. Background groundwater quality may be established at wells that are not located hydraulically upgradient from the Class Three landfill if it meets the requirements of Section 258.51.a.(1). In order to establish background groundwater quality in a reasonable period of time, pursuant to Sections 258.53.i.(1) and 258.53.i.(2), the permittee shall collect and analyze a minimum of four (4) independent groundwater samples from each compliance well and each background well prior to the end of the first year of operation. The Department may, on a case-by-case basis, approve an alternate subset of wells to be sampled for the establishment of background groundwater quality. The alternate subset of wells shall consist of a minimum of four (4) wells, or the total number of wells monitoring the landfill, whichever is least, and shall include all background well(s). This sampling and analysis shall be accomplished in a manner consistent with the requirements of Section 258.53.f. Pursuant to Section 258.51.a.(1), the above samples shall represent the quality of background groundwater that has not been affected by leakage from a landfill.

f. The number of samples collected to establish groundwater quality data shall be consistent with the appropriate statistical procedures determined pursuant to paragraph g. below. The sampling procedures shall be those specified in Section 258.54.b. for detection monitoring, Sections 258.55.b. and d. for assessment monitoring, and Section 258.56.b. for corrective action.

g. The permittee shall specify in the operating record a statistical method to be used in evaluating groundwater monitoring data for each metal or other hazardous constituent requiring statistical analysis. The statistical test chosen shall be conducted for each parameter in each well, every time samples are collected. The following methods may be used:

(1) A parametric analysis of variance (ANOVA) followed by multiple comparisons procedures to identify statistically significant evidence of contamination. The method shall include estimation and testing of the contrasts between each compliance well's mean and the background mean levels for each constituent;

(2) An analysis of variance (ANOVA) based on ranks followed by multiple comparisons procedures to identify statistically significant evidence of contamination. The method shall include

estimation and testing of the contrasts between each compliance well's median and the background median levels for each constituent;

(3) A tolerance or prediction interval procedure in which an interval for each constituent is established from the distribution of the background data, and the level of each constituent in each compliance well is compared to the upper tolerance or prediction limit;

(4) A control chart approach that gives control limits for each constituent; or,

(5) Another statistical test method that meets the performance standards of Section 258.53.h. The permittee shall place a justification for this alternative in the operating record and obtain approval from the Department prior to the use of this alternative test. The justification shall demonstrate that the alternative method meets the performance standards of Section 258.53.h.

h. Any statistical method chosen according to paragraph g. above shall comply with the following performance standards, as appropriate:

(1) The statistical method used to evaluate groundwater monitoring data shall be appropriate for the distribution of chemical parameters or hazardous constituents. If the distribution of the chemical parameters or hazardous constituents are shown by the permittee to be inappropriate for a normal theory test, then the data shall be transformed or a distribution-free theory test used. If the distributions for the constituents differ, more than one statistical method may be needed;

(2) If an individual well comparison procedure is used to compare an individual compliance well constituent concentration with background constituent concentrations or a ground-water protection standard, the test shall be done at a Type I error level no less than 0.01 for each testing period. If a multiple comparisons procedure is used, the Type I experiment wise error rate for each testing period shall be no less than 0.05; however, the Type I error of no less than 0.01 for individual well comparisons shall be maintained. This performance standard does not apply to tolerance intervals, prediction intervals, or control charts;

(3) If a control chart approach is used to evaluate groundwater monitoring data, the specific type of control chart and its associated parameter values shall be protective of human health and the environment. The parameters shall be determined after considering the number of samples in the background data base, the data distribution, and the range of the concentration values for each constituent of concern;

(4) If a tolerance interval or a predictional interval is used to evaluate groundwater monitoring data, the levels of confidence, and for tolerance intervals, the percentage of the population that the interval contains, shall be protective of human health and the environment. These parameters shall be determined after considering the number of samples in the background data base, the data distribution, and the range of the concentration values for each constituent of concern;

(5) The statistical method shall account for data below the limit of detection with one or more statistical procedures that are protective of human health and the environment. Any practical quantitation limit (pql) that is used in the statistical method shall be the lowest concentration level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions that are available to the facility; and,

(6) If necessary, the statistical method shall include procedures to control or correct for seasonal and spatial variability as well as temporal correlation in the data.

i. The permittee shall determine whether or not there is a statistically significant increase over background values for each parameter or constituent required in the particular groundwater monitoring program that applies to the Class Three landfill, as determined in Section 258.54.a. or Section 258.55.a.

(1) In determining whether a statistically significant increase has occurred, the permittee shall compare the groundwater quality of each parameter or constituent at each monitoring well designated pursuant to Section 258.51.a.(2) to the background value of that constituent, according to the statistical procedures and performance standards specified in paragraphs g. and h. above.

(2) Within a reasonable period of time after completing sampling and analysis, the permittee shall determine whether there has been a statistically significant increase over background for each metal or other hazardous constituent requiring statistical analysis at each monitoring well.

258.54. Detection Monitoring Program.

a. Detection monitoring is required at all Class Three landfill groundwater monitoring wells defined in Sections 258.51.a.(1) and a.(2). At a minimum, a detection monitoring program shall include the monitoring for the constituents listed in Appendix IV of this part.

(1) The Department may delete any of the Appendix IV monitoring parameters for a Class Three landfill if it can be shown that the deleted constituent(s) are not reasonably expected to be contained in or derived from the waste contained in the landfill.

(2) The Department may require additional groundwater monitoring parameters for routine monitoring based on the chemical and physical nature of the waste stream received by the landfill and any analytical data for the waste streams provided by the permittee.

b. The monitoring frequency for all constituents listed in Appendix IV to this part shall be at least semiannual during the active life of the facility and the post-closure care period. At least one sample from each well (background and downgradient) shall be collected and analyzed during each sampling event.

c. The Department may specify an appropriate alternative frequency for repeated sampling and analysis for Appendix IV constituents during the active life and the post-closure care period. The alternative frequency during the active life shall be no less than semiannual. The alternative frequency shall be based on consideration of the following factors:

(1) Lithology of the aquifer and unsaturated zone;

(2) Hydraulic conductivity of the aquifer and unsaturated zone;

(3) Groundwater flow rates;

(4) Minimum distance between upgradient edge of the Class Three landfill and downgradient monitoring well screen (minimum distance of travel); and,

(5) Resource value of the aquifer.

d. If the permittee determines, pursuant to Section 258.53.g., that there is a statistically significant increase over background for one or more of the metals listed in Appendix IV, or above the MCL or PQL, as applicable, for any volatile organic compound (VOC) listed in Appendix IV at any monitoring well at the boundary specified in Section 258.51.a.(2), the permittee shall:

(1) Within 14 days of this finding, notify the Department;

(2) Within 14 days of this finding, place a notice in the operating record indicating which constituents have shown statistically significant changes from background levels;

(3) Within 30 days of this finding, resample the monitoring well(s) in question for Appendix IV to determine the validity of the data; and,

(4) If the data are validated by resampling, establish an assessment monitoring program meeting the requirements of Section 258.55. within 90 days except as provided for in paragraph d.5 of this section.

(5) The permittee may demonstrate that a source other than a Class Three landfill caused the contamination or that the statistically significant increase (SSI) resulted from error in sampling, analysis, statistical evaluation, or natural variation in groundwater quality. A report documenting this demonstration shall be certified by a qualified professional, submitted to the Department for approval, and placed in the operating record. If a successful demonstration is made and documented, the permittee may continue detection monitoring as specified in this section. If, after 90 days, a successful demonstration is not made, the permittee shall initiate an assessment monitoring program as required in Section 258.55.

e. The permittee shall submit to the Department on or before the anniversary date of issuance of the permit, an annual report certified by a qualified professional containing all of the analytical and statistical analysis performed at the site for the previous year as a result of the requirements of this Part. The annual report shall contain the following:

(1) The results of all analytical testing performed at the site during the previous year, and any applicable data concerning sampling and analysis of monitoring wells at the site;

(2) A determination of the technical sufficiency of the monitoring well network in detecting a release from the facility as required by Section 258.51.;

(3) The determination of groundwater elevations, groundwater flow directions and groundwater flow rates as specified in Section 258.53.d. Groundwater flow directions shall be based upon interpretation of a potentiometric map prepared utilizing the groundwater elevations measured at the site;

(4) A summary of the results of the statistical analysis performed in accordance with Sections 258.53.g. and 258.53.h.; and,

(5) Recommendations for any necessary actions regarding the groundwater monitoring system.

f. The results of all chemical analysis of groundwater samples taken during routine monitoring shall be submitted to the Department within 60 days of sample collection. On sampling events where an annual report is to be submitted to the Department, the annual report shall satisfy this requirement.

258.55. Assessment Monitoring Program.

a. Assessment monitoring is required whenever a statistically significant increase over background has been detected and validated, in accordance with Section 258.54.d., for one or more of the metals listed in Appendix IV, or above the MCL or PQL, as applicable, for any volatile organic compound (VOC) listed in Appendix IV, unless a successful demonstration has been made in accordance with Section 258.54.d.(5).

b. Within 90 days of triggering an assessment monitoring program, and annually thereafter, the permittee shall sample and analyze the groundwater for all constituents identified in Appendix V. A minimum of one sample from each downgradient well shall be collected and analyzed during each sampling event. For any constituent detected in the downgradient wells as the result of the complete Appendix V analysis, a minimum of four (4) independent samples from each well (background and downgradient) shall be collected and analyzed to establish background for the new constituents.

c. The Department may approve an appropriate subset of wells to be sampled and analyzed for Appendix V constituents during assessment monitoring, provided the permittee provides sufficient technical rationale for the subset of wells. The Department may delete any of the Appendix V monitoring parameters for a Class Three landfill if it can be shown that the removed constituents are not reasonably expected to be in or derived from the waste contained in the landfill.

d. The Department may allow an appropriate alternate frequency for repeated sampling and analysis for the full set of Appendix V constituents required by Section 258.55.b., during the active life and post-closure care of the landfill considering the following factors:

(1) Lithology of the aquifer and unsaturated zone;

(2) Hydraulic conductivity of the aquifer and unsaturated zone;

(3) Groundwater flow rates;

(4) Minimum distance between upgradient edge of the Class Three landfill and downgradient monitoring well screen (minimum distance of travel);

(5) Resource value of the aquifer; and,

(6) Nature (fate and transport) of any constituents detected in response to this section.

e. After obtaining the results from the initial or subsequent sampling events required in paragraph b. above, the permittee shall:

(1) Within 14 days, submit to the Department analytical results identifying the Appendix V constituents that have been detected and place a copy in the operating record;

(2) Within 90 days, and on at least a semiannual basis thereafter, resample all wells specified by Section 258.51.a., conduct analyses for all constituents in Appendix IV and for those constituents in Appendix V that are detected in response to paragraph (b) above, and record their concentrations in the facility operating record. At least one sample from each well (background and downgradient) shall be collected and analyzed during these sampling events;

(3) Establish background concentrations for any constituents detected pursuant to paragraphs b., c., d. or e.(2) above; and,

(4) Establish groundwater protection standards for all constituents detected pursuant to paragraph b. or e. above. The groundwater protection standards shall be established in accordance with paragraph j. or k. below.

f. The Department may specify an alternative monitoring frequency during the active life and the post closure care period for the constituents referred to in this paragraph. The alternative frequency for Appendix V constituents during the active life (including closure) shall be no less than annual. The alternative frequency shall be based on consideration of the factors specified in paragraph (d) above.

g. If the concentrations of all Appendix V constituents are shown to be at or below background values, using the statistical procedures in Section 258.53.g., for two consecutive sampling events, the permittee may request approval from the Department to return to detection monitoring.

h. If the concentrations of any Appendix V constituents are above background values, but all concentrations are less than the groundwater protection standard established in paragraph j. or k. below, using the statistical procedures in Section 258.53.g., the permittee shall continue assessment monitoring in accordance with this section.

i. If one or more Appendix V constituents are detected at or above the groundwater protection standard established in paragraph j. or k. below in any sampling event, the permittee shall, within 14 days of this finding, submit to the Department analytical results identifying the Appendix V constituents that have exceeded the groundwater protection standard and notify the Department and all appropriate local government officials that the notice has been placed in the operating record. The permittee shall do one of the following:

(1) Either:

(a) Submit to the Department within 60 days of this finding, a groundwater quality assessment plan for characterizing the nature and extent of the release.

(b) Upon approval of the groundwater quality assessment plan, shall characterize the nature and extent of the release by installing additional monitoring wells as necessary;

(c) Install at least one additional monitoring well at the facility boundary in the direction of contaminant migration and sample this well in accordance with Section 258.55.d.(2);

(d) Notify all persons who own the land or reside on the land that directly overlies any part of the plume of contamination if contaminants have migrated off-site as indicated by sampling of wells in accordance with Section 258.55.i.(1); and,

(e) Initiate an assessment of corrective measures as required by Section 255.56. within 90 days; or,

(2) Demonstrate that a source other than a Class Three landfill caused the contamination, or that the statistically significant increase (SSI) resulted from error in sampling, analysis, statistical evaluation, or natural variation in groundwater quality. A report documenting this demonstration shall be certified by a qualified professional, submitted to the Department for approval, and placed in the operating record. If a successful demonstration is made, the permittee shall continue monitoring in accordance with the assessment monitoring program pursuant to Section 258.55., and may return to detection monitoring if the Appendix V constituents are at or below background as specified in Section 258.55.g. Until a successful demonstration is made, the permittee shall comply with Section 258.55.i. including initiating an assessment of corrective measures.

j. The permittee shall establish a groundwater protection standard for each Appendix V constituent detected in the groundwater. The groundwater protection standard shall be:

(1) For constituents for which a maximum contaminant level (MCL) has been promulgated under South Carolina R.61–58, State Primary Drinking Water Regulations, the MCL for that constituent;

(2) For constituents for which MCLs have not been promulgated, the background concentration for the constituent established from wells in accordance with 258.51.a.(1); or,

(3) For constituents for which the background level is higher than the MCL identified in paragraph j.(1) above or health based levels identified in Section 258.55.k.(1), the background concentration.

k. The Department may establish an alternative groundwater protection standard for constituents for which MCLs have not been established. These groundwater protection standards shall be appropriate health based levels that satisfy the following criteria:

(1) The level is derived in a manner consistent with Federal Environmental Protection Agency (EPA) guidelines for assessing the health risks of environmental pollutants (51 FR 33992, 34006, 34014, 34028, September 24, 1986);

(2) The level is based on scientifically valid studies conducted in accordance with the Toxic Substances Control Act Good Laboratory Practice Standards (40 CFR part 792) or equivalent;

(3) For carcinogens, the level represents a concentration associated with an excess lifetime cancer risk level (due to continuous lifetime exposure) of 1×10^{-6}; and,

(4) For systemic toxicants, the level represents a concentration to which the human population (including sensitive subgroups) could be exposed to on a daily basis that is likely to be without appreciable risk of deleterious effects during a lifetime. For purposes of this subpart, systemic toxicants include toxic chemicals that cause effects other than cancer or mutation.

l. In establishing groundwater protection standards in paragraph j. or k. above, the Department may consider the following:

(1) Multiple contaminants in the groundwater;

(2) Exposure threats to sensitive environmental receptors; and,

(3) Other site-specific exposure or potential exposure to groundwater.

258.56. Assessment of Corrective Measures

a. Within 90 days of finding that any of the constituents listed in Appendix V have been detected at a level exceeding the groundwater protection standards defined in Section 258.55.j. or k., the permittee shall initiate an assessment of corrective measures. Such an assessment shall be completed within a reasonable period of time, not to exceed 180 days.

b. The permittee shall continue to monitor in accordance with the assessment monitoring program as specified in Section 258.55.

c. The assessment shall include an analysis of the effectiveness of potential corrective measures in meeting all of the requirements and objectives of the remedy as described in Section 258.57., addressing at least the following:

(1) The performance, reliability, ease of implementation, and potential impacts of appropriate potential remedies, including safety impacts, cross-media impacts, and control of exposure to any residual contamination;

(2) The time required to begin and complete the remedy;

(3) The costs of remedy implementation; and,

(4) The institutional requirements such as Department or local permit requirements or other environmental or public health requirements that may substantially affect implementation of the remedy(s).

d. The permittee shall discuss the results of the corrective measures assessment, prior to the selection of remedy, in a public meeting with interested and affected parties.

258.57. Selection of Remedy.

a. Based on the results of the corrective measures assessment conducted according to Section 258.56, the permittee shall select a remedy that, at a minimum, meets the standards listed in paragraph b. below. The permittee shall notify the Department within 14 days of selecting a remedy and submit a report to the Department for review and approval that describes the selected remedy and how it meets the standards in paragraph b. below.

b. Remedies shall:

(1) Be protective of human health and the environment;

(2) Attain the groundwater protection standard as specified pursuant to Section 258.55.j. or k.;

(3) Control the source(s) of releases so as to reduce or eliminate, to the maximum extent practicable, further releases of Appendix V constituents into the environment that may pose a threat to human health or the environment; and,

(4) Comply with standards for management of wastes as specified in Section 258.58.d.

c. In selecting a remedy that meets the standards in paragraph b. above, the permittee shall consider the following evaluation factors:

(1) The long- and short-term effectiveness and protectiveness of the potential remedy(s), along with the degree of certainty that the remedy will prove successful based on consideration of the following:

(a) Magnitude of reduction of existing risks;

(b) Magnitude of residual risks in terms of likelihood of further releases due to waste remaining following implementation of a remedy;

(c) The type and degree of long-term management required, including monitoring, operation, and maintenance;

(d) Short-term risks that might be posed to the community, workers, or the environment during implementation of such a remedy, including potential threats to human health and the environment associated with excavation, transportation, and redisposal or containment;

(e) Time until full protection is achieved;

(f) Potential for exposure of humans and environmental receptors to remaining wastes, considering the potential threat to human health and the environment associated with excavation, transportation, redisposal, or containment;

(g) Long-term reliability of the engineering and institutional controls; and,

(h) Potential need for replacement of the remedy;

(2) The effectiveness of the remedy in controlling the source to reduce further releases based on consideration of the following factors:

(a) The extent to which containment practices will reduce further releases; and,

(b) The extent to which treatment technologies may be used;

(3) The ease or difficulty of implementing a potential remedy(s) based on consideration of the following types of factors:

(a) Degree of difficulty associated with constructing the technology;

(b) Expected operational reliability of the technologies;

(c) Need to coordinate with and obtain necessary approvals and permits from other agencies;

(d) Availability of necessary equipment and specialists; and,

(e) Available capacity and location of needed treatment, storage, and disposal services; and,

(4) The degree to which community concerns are addressed by a potential remedy(s).

d. The permittee shall specify as part of the selected remedy a schedule(s) for initiating and completing remedial activities. Such a schedule shall require the initiation of remedial activities within a reasonable period of time taking into consideration the factors set forth in paragraphs d.(1-8). The permittee shall consider the following factors in determining the schedule of remedial activities:

(1) Extent and nature of contamination;

(2) Practical capabilities of remedial technologies in achieving compliance with groundwater protection standards established in Section 258.55.j. or k. and other objectives of the remedy;

(3) Availability of treatment or disposal capacity for wastes managed during implementation of the remedy;

(4) Desirability of utilizing technologies that are not readily available, but which may offer significant advantages over already available technologies in terms of effectiveness, reliability, safety, or ability to achieve remedial objectives;

(5) Potential risks to human health and the environment from exposure to contamination prior to completion of the remedy;

(6) Resource value of the aquifer including:

(a) Current and future uses;

(b) Proximity and withdrawal rate of users;

(c) Groundwater quantity and quality;

(d) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to waste constituent;

(e) The hydrogeologic characteristic of the facility and surrounding land;

(f) Groundwater removal and treatment costs; and,

(g) The cost and availability of alternative water supplies;

(7) Practicable capability of the permittee; and,

(8) Other relevant factors.

e. The Department may determine that remediation of a release of an Appendix V constituent from a Class Three landfill is not necessary if the permittee demonstrates to the Department that:

(1) The groundwater is additionally contaminated by substances that have originated from a source other than a Class Three landfill and those substances are present in concentrations such that cleanup of the release from the Class Three landfill would provide no significant reduction in risk to actual or potential receptors; or,

(2) The constituent(s) is present in groundwater that:

(a) Does not currently meet the definition of an underground source of drinking water per South Carolina Water Classifications and Standards R.61–68; and,

(b) Is not hydraulically connected with waters to which the hazardous constituents are migrating, or are likely to migrate in a concentration(s) that would exceed the groundwater protection standards established in Section 258.55.j. or k. or,

(3) Remediation of the release(s) is technically impracticable; or,

(4) Remediation results in unacceptable cross-media impacts.

f. A determination by the Department pursuant to paragraph e. above of this section shall not affect the authority of the Department to require the permittee to undertake source control measures or other measures that may be necessary to eliminate or minimize further releases to the groundwater, to prevent exposure to the groundwater, or to remediate the groundwater to concentrations that are technically practicable and significantly reduce threats to human health or the environment.

258.58. Implementation of the Corrective Action Program.

a. Based on the schedule established in Section 258.57.d. for initiation and completion of remedial activities, the permittee shall:

(1) Establish and implement a corrective action groundwater monitoring program that:

(a) At a minimum, meets the requirements of an assessment monitoring program in Section 258.55.;

(b) Indicates the effectiveness of the corrective action remedy; and,

(c) Demonstrates compliance with groundwater protection standards pursuant to Section 258.58.e;

(2) Implement the corrective action remedy selected in Section 258.57.; and,

(3) Take any interim measures necessary to ensure the protection of human health and the environment. Interim measures should, to the greatest extent practicable, be consistent with the objectives of and contribute to the performance of any remedy that may be required pursuant to Section 258.57. The following factors shall be considered by a permittee in determining whether interim measures are necessary:

(a) Time required to develop and implement a final remedy;

(b) Actual or potential exposure of nearby populations or environmental receptors to hazardous constituents;

(c) Actual or potential contamination of drinking water supplies or sensitive ecosystems;

(d) Further degradation of the groundwater that may occur if remedial action is not initiated expeditiously;

(e) Weather conditions that may cause hazardous constituents to migrate or be released;

(f) Risks of fire or explosion, or potential for exposure to hazardous constituents as a result of an accident or failure of a container or handling system; and,

(g) Other situations that may pose threats to human health and the environment.

b. A permittee may determine, based on information developed after implementation of the remedy or other information, that compliance with requirements of Section 258.57.b. are not being achieved through the remedy selected. In such cases, the permittee shall implement other methods or techniques that could practicably achieve compliance with the requirements, unless the permittee makes the determination under 258.c.

c. If the permittee determines that compliance with requirements in Section 258.57.b. cannot be practically achieved with currently available methods, the permittee shall:

(1) Obtain certification of a qualified professional and approval by the Department that compliance with requirements in Section 258.57.b. cannot be practically achieved with any currently available methods;

(2) Implement alternate measures to control exposure of humans or the environment to residual contamination, as necessary to protect human health and the environment;

(3) Implement alternate measures for control of the sources of contamination, or for removal or decontamination of equipment, units, devices, or structures that are:

(a) Technically practicable; and,

(b) Consistent with the overall objective of the remedy; and,

(4) Notify the Department within 14 days that a report justifying the alternative measures prior to implementing the alternative measures has been placed in the operating record.

d. All solid wastes that are managed pursuant to a remedy required in Section 258.57., or an interim measure required in Section 258.58.a.(3), shall be managed in a manner:

(1) That is protective of human health and the environment; and,

(2) That complies with applicable Resource Conservation and Recovery Act (RCRA) requirements.

e. Remedies selected pursuant to Section 258.57. shall be considered complete when:

(1) The permittee complies with the groundwater protection standards established in Section 258.55.j. or k. at all points within the plume of contamination that lie beyond the groundwater monitoring well system established in Section 258.51.a.

(2) Compliance with the groundwater protection standards established in Section 258.55.j. or k. has been achieved by demonstrating that concentrations of Appendix V constituents have not exceeded the groundwater protection standard(s) for a period of three consecutive years using the statistical procedures and performance standards in Section 258.53.g. and h. The Department may specify an alternative length of time during which the permittee shall demonstrate that concentrations of Appendix V constituents have not exceeded the groundwater protection standard(s) taking into consideration:

(a) Extent and concentration of the release(s);

(b) Behavior characteristics of the hazardous constituents in the groundwater;

(c) Accuracy of monitoring or modeling techniques, including any seasonal, meteorological, or other environmental variabilities that may affect the accuracy; and,

(d) Characteristics of the groundwater.

(3) All actions required to complete the remedy have been satisfied.

f. Within 14 days of completion of the remedy, the permittee shall submit to the Department a certification signed by a qualified professional stating that the remedy has been completed in compliance with the requirements of Section 258.58.e.

g. Upon the Department's approval of the certification required in 258.58.f., the permittee shall be released from the requirements for financial assurance for corrective action.

258.59. Reserved.

Subpart F. Closure and Post-closure Care.

258.60. Closure Criteria.

a. Owners/operators of all Class Three landfills shall install a final cover system that is designed to minimize infiltration and erosion. The final cover system shall be designed and constructed to:

(1) Have a permeability less than or equal to the permeability of any bottom liner system or natural subsoils present, or a permeability no greater than 1×10^{-5} cm/sec, whichever is less;

(2) Minimize infiltration through the closed Class Three landfill by the use of an infiltration layer that contains a minimum eighteen (18) inches of earthen material;

(3) Minimize erosion of the final cover by the use of an erosion layer that contains a minimum one (1) foot of earthen material that is capable of sustaining native plant growth; and,

(4) Have a storm water conveyance system for the landfill cap designed to ensure that the hydraulic head at any point does not exceed one (1) foot for a 24-hour period as the result of a 24-hour, 25-year storm event on all areas that have received final cover.

b. The Department may approve an alternative final cover design that includes:

(1) An infiltration layer that achieves an equivalent reduction in infiltration as the infiltration layer specified in paragraphs a.(1) and a.(2) above; and,

(2) An erosion layer that provides equivalent protection from wind and water erosion as the erosion layer specified in a.(3) above.

c. The permittee shall prepare a written closure plan that describes the steps necessary to close all Class Three landfills at any point during their active life in accordance with the cover design requirements in Section 258.60.a. or b., as applicable. The closure plan, at a minimum, shall include the following information:

(1) A description of the final cover, designed in accordance with Section 258.60.a. and the methods and procedures to be used to install the cover;

(2) An estimate of the largest area of the Class Three landfill ever requiring a final cover as required in Section 258.60.a. at any time during the active life;

(3) An estimate of the maximum inventory of wastes ever on-site over the active life of the landfill facility; and,

(4) A schedule for completing all activities necessary to satisfy the closure criteria in Section 258.60.

d. Prior to permit issuance, the permittee shall submit to the Department a closure plan. The closure plan shall be updated if any changes occur at the facility which require a deviation from the approved closure plan.

e. Prior to beginning closure of each Class Three landfill as specified in Section 258.60.f., a permittee shall submit a notice of intent to close to the Department to include a schedule outlining closure activities.

f. The permittee shall begin closure activities of each Class Three landfill no later than 30 days after the date on which the Class Three landfill receives the known final receipt of wastes, or if the Class Three landfill has remaining capacity and there is a reasonable likelihood that the Class Three landfill will receive additional wastes, no later than one year after the most recent receipt of wastes. Extensions beyond the one-year deadline for beginning closure may be granted by the Department if the permittee demonstrates that the Class Three landfill has the capacity to receive additional wastes and the permittee has taken and will continue to take all steps necessary to prevent threats to human health and the environment from the unclosed Class Three landfill.

g. The permittee of all Class Three landfills shall complete closure activities of each Class Three landfill in accordance with the closure plan within 180 days following the beginning of closure as specified in Section 258.60.f. Extensions of the closure period may be granted by the Department if the permittee demonstrates that closure will take longer than 180 days and they have taken and will continue to take all steps to prevent threats to human health and the environment from the unclosed Class Three landfill.

h. Following closure of each Class Three landfill, the permittee shall submit to the Department for approval certification, that is signed by a South Carolina registered professional engineer other than the design engineer, verifying that closure has been completed in accordance with the closure plan. A copy of this certification shall be placed in the operating record. The certification testing shall be conducted at a minimum rate of one (1) permeability test per acre and four (4) density/thickness tests per acre.

i. Within 30 days of the Department's issuance of final closure approval of a Class Three landfill, and using a form approved by the Department, the permittee shall record with the appropriate Register of Deeds, a notation in the record of ownership of the property - or some other instrument which is normally examined during title search - that will in perpetuity notify any potential purchaser of the property that the land or a portion thereof was used for the disposal of solid waste. This notice shall define the final boundaries of the waste disposal area including the latitude and longitude, identify the type, location, and quantity of solid waste disposed on the property, and advise potential owners of the property that there are land use restrictions.

j. The permittee may request permission from the Department to remove the notation from the deed if all wastes are properly removed from the facility and there is no environmental impact.

k. All facilities constructed with liner systems in accordance with this regulation shall install a final cover system which, at a minimum, consists of:

(1) A gas management layer or layers, or other gas management design, as necessary;

(2) Eighteen (18) inches of soil with a maximum permeability of 1×10^{-5} centimeters per second, and capable of providing a suitable foundation for the flexible membrane liner specified in paragraph (3) below;

(3) A 20-mil flexible membrane liner with a maximum permeability equal to or less than the bottom liner system, if HDPE is used as the FML, then a sixty (60) mil thickness is required;

(4) A drainage layer; and,

(5) A minimum of two feet of soil capable of supporting native vegetation.

l. All Class Three landfills closed utilizing a flexible membrane cover system shall be constructed to preclude precipitation migration into the landfill. All flexible membrane cover systems shall be constructed in accordance with the requirements of the approved engineering plans, reports, specifications and manufacturer's recommendations.

m. The erosion layer shall be designed to maintain vegetative growth over the landfill by seeding with native grasses or other suitable cover. A 75% or greater vegetative ground cover with no substantial bare spots shall be established and maintained throughout the post-closure period.

n. The final cover system shall promote positive drainage by grading to create at least a 3%, but not greater than 5%, surface slope and a side slope that does not exceed three horizontal feet to one vertical foot, i.e., a 3:1 slope.

o. The Department may, on a case-by-case basis, approve other landfill closure designs, provided there is adequate information to demonstrate that the proposed design meets or exceeds the environmental and public health protection standards outlined in Subparts B, D and E of this regulation.

258.61. Post-closure Care Requirements.

a. Following closure of each Class Three landfill, the permittee shall conduct post-closure care. Post-closure care shall be conducted for a minimum 30 years, except as provided in paragraph b. below, and consist of at least the following:

(1) Maintaining the integrity and effectiveness of any final cover, including making repairs to the cover as necessary to correct the effects of settlement, subsidence, erosion, or other events, and preventing run-on and run-off from eroding or otherwise damaging the final cover;

(2) Maintaining and operating the leachate collection system in accordance with the requirements in 258.40., if applicable. The Department may allow the permittee to stop managing leachate if the permittee demonstrates to the Department's satisfaction that leachate no longer poses a threat to human health and the environment;

(3) Monitoring the groundwater in accordance with the requirements of Subpart E and maintaining the groundwater monitoring system, if applicable; and,

(4) Maintaining and operating the gas monitoring system in accordance with the requirements of Section 258.23.

b. The length of the post-closure care period may be:

(1) Increased by the Department if the Department determines that the lengthened period is necessary to protect human health and the environment; or,

(2) Decreased by the Department if the permittee can provide technical rationale that the decreased post-closure care period is sufficient to protect human health and the environment.

c. The permittee of all Class Three landfills shall prepare a written post-closure plan that includes, at a minimum, the following information:

(1) A description of the monitoring and maintenance activities required in paragraph a. for each Class Three landfill, and the frequency at which these activities will be performed;

(2) Name, address, and telephone number of the person or office to contact about the facility during the post-closure period; and,

(3) A description of the planned uses of the property during the post-closure period. Post-closure use of the property shall not disturb the integrity of the final cover, liner(s), or any other components of the containment system, or the function of the monitoring systems unless necessary to comply with the requirements in this Part. The Department may approve any other disturbance of the containment system if the permittee demonstrates that disturbance of the final cover, liner or other component of the containment system, including any removal of waste, will not increase the potential threat to human health or the environment.

d. Prior to permit issuance, the permittee shall submit to the Department a post-closure plan for review and approval. The post-closure plan shall be updated if any changes occur at the facility which require a deviation from the approved post-closure plan.

e. Following completion of the post-closure care period for each Class Three landfill, the permittee shall submit to the Department, certification that is signed by a South Carolina registered professional engineer other than the design engineer, verifying that post-closure care has been completed in accordance with the post-closure plan.

258.62.–258.69. (Reserved.)

Subpart G. Financial Assurance Criteria. (See Part I., Section E. of this regulation.)

Subpart H. Permit Application Requirements. Prior to the construction, operation, expansion or modification of a Class Three landfill, a permit shall be obtained from the Department.

1. Prior to submitting a permit application to the Department, the applicant shall satisfactorily complete the following:

a. Determination of Need. The applicant shall submit to the Department a request pursuant to Regulation 61–107.17. for determining need of the proposed landfill or landfill expansion, if applicable.

b. Consistency Determination. The applicant shall submit to the Department a request for a determination of consistency with items listed below.

(1) State and County/Region Solid Waste Management Plans. The permit applicant shall demonstrate consistency with the State Solid Waste Management Plan in effect at the time of submittal of the request for the Determination of Consistency. The permit applicant shall demonstrate consistency with the county/region plan in effect at the time of the submittal of the request for the Determination of Consistency. Class Three landfills managing solid waste

generated solely in the course of normal operation on property under the same ownership or control as the Class Three landfill are not required to demonstrate consistency with the State and host County/Region Solid Waste Management Plans;

(2) Local zoning and land-use ordinances. Documentation demonstrating consistency with local zoning and land-use plans, e.g., zoning map, land-use map, and applicable part of the zoning ordinance shall be submitted to the Department; and,

(3) All other applicable local ordinances. Supporting documentation to include a copy of the ordinance shall be submitted to the Department.

(4) Buffer Requirement. The applicant shall demonstrate that it meets the buffer requirement set forth in Subpart B, Section 258.18. a of this Part at the time of submittal of the demonstration. The Department must notify by certified mail, return receipt requested, the applicant and any other affected person who requests to be notified of its determination of compliance with this buffer requirement.

c. If the Department's final determination of need is terminated, pursuant to R.61–107.17, all other determinations under Section H.1.a. and b. above will also be void.

d. Landfill Siting Study. If the Department determines there is a need for the proposed landfill/expansion pursuant to R.61–107.17., the applicant shall conduct a landfill siting study and submit the results of the study to the Department for a site suitability determination. This study shall be used to eliminate those sites which, due to location restrictions, are unsuitable sites and to determine if the site conditions warrant further permitting activities. The landfill siting study shall include, at a minimum, the following steps:

(1) A preliminary hydrogeologic characterization report on the site, which contains readily available information on the regional, local, and site hydrogeology and groundwater use. The preliminary hydrogeologic characterization report shall be used to eliminate hydrogeologically unsuitable sites, and to determine if site conditions warrant further investigation;

(2) Pending approval of the preliminary hydrogeologic characterization report, a work plan detailing the site specific hydrogeologic investigations to be performed at the site shall be submitted to the Department for review and approval; and,

(3) Upon approval of the work plan specified in paragraph b. above, a site hydrogeologic characterization report shall be prepared and submitted to the Department detailing the findings of the site specific investigations. The landfill siting investigation shall ensure that the proposed landfill location complies with the location criteria outlined in Subpart B of this Part. During review by the Department of the suitability of the site based on the site hydrogeologic characterization report, the permit applicant may proceed with site design, and submittal of a groundwater monitoring plan as specified in Subpart H, Section 5.b.(14) below. Approval of the site shall be required before the Department will comment on engineering plans associated with the construction of the facility.

2. Administrative Review. Upon satisfactory completion of Subpart H.1. above, the applicant shall submit to the Department a complete permit application. The applicant shall submit to the Department a minimum of three copies of the following documents:

a. A completed permit application, on a form provided by the Department.

b. Tonnage Limit. The applicant shall submit to the Department a request for a determination of the maximum annual tonnage limit.

(1) Prior to the issuance of a permit for a new or expanded commercial Class Three landfill, the Department shall approve an allowable maximum annual tonnage limit based on the facility's design capacity, operational capacity, the expected operational life, and the planning area as determined by R.61–107.17, SWM: Demonstration-of-Need provided, however, that the maximum annual tonnage limit must not exceed the maximum yearly disposal rate pursuant to Regulation 61–107.17.

(2) Prior to issuance of a permit for a new or expanded noncommercial Class Three landfill, the Department shall approve a maximum annual tonnage limit based on the facility's design capacity, operational capacity, and the expected operational life.

c. A cost estimate for hiring a third party to close the sum of all active areas of the landfill requiring a final cover at any time during the operating life when the extent and manner of its operation would make closure the most expensive, as indicated in the closure plan. This estimate requires Department approval prior to the permittee establishing a financial assurance mechanism pursuant to Part I., Section E. of this regulation;

d. A Disclosure Statement pursuant to Part I, Section F.1. of this regulation. The Department may accept one disclosure statement for multiple facility permit applicants. This requirement shall not apply if the applicant is a local government or a region comprised of local governments;

e. Complete engineering plans and reports that are signed and stamped by a South Carolina Licensed Professional Engineer in accordance with Item 5. below;

f. The names and addresses of the owners of real property as they appear on the county tax maps as contiguous landowners of the proposed permit area.

3. When the submittal is administratively complete, the Department will notify, in writing, the applicant, the host local government if different from the applicant, and any other person who has made a written request for notification to the Department of the determination. Within 15 days of the Department's notification that the submittal is administratively complete:

a. The applicant for a Class Three landfill that will accept municipal solid waste shall submit to the Department demonstration and documentation that the facility issues negotiation process has been initiated in accordance with S.C. Code Section 44–96–470, to include an affidavit of publication of the public notice in the newspaper as required by Code Section 44-96-470(A).

b. The applicant for a Class Three landfill that will not accept municipal solid waste shall publish notice of the permit application pursuant to Part I, Section D.2. of the regulation, and submit an affidavit of publication of the public notice in the newspaper to the Department.

4. Upon completion of the facility issues negotiation process, the facilitator shall provide to the Department a summary of the results of the negotiations within 14 days of the certification of the facilitator's final report of resolution of the host local government as required by S.C. Code Section 44–96–470.

5. Technical Review. After determining that the permit application is administratively complete, the Department will conduct a Technical Review of the proposed project. The Department's technical review of the permit application will involve the documents and issues addressed in this Section. All individual drawings and plans shall be signed and stamped by a professional engineer duly licensed to practice in the State of South Carolina.

a. Engineering Drawings and Plans. All applications for new Class Three landfills and landfill expansions shall contain engineering drawings that set forth the proposed landfill location, property boundaries, adjacent land uses and construction details. Additional requirements for landfills with leachate recirculation are outlined in SubPart A, Section 258.4. of this Part. All construction drawings shall be bound and rolled and shall contain the following:

(1) A vicinity plan or map that shows the area within one mile of the property boundaries of the landfill in terms of: the existing and proposed zoning and land uses within that area at the time of permit application; and, residences, public and private water supply wells, known aquifers, surface waters (with quality classifications), access roads, bridges, railroads, airports, historic sites, and other existing and proposed man-made or natural features relating to the facility. The plan shall be on a scale of not greater than 500 feet per inch unless otherwise approved by the Department.

(2) Site plans that show: the landfill's property boundaries, as certified by an individual licensed to practice land surveying in the State of South Carolina; off-site and on-site utilities (such as, electric, gas, water, storm, and sanitary sewer systems), rights-of-way and easements; the names and addresses of abutting property owners; the location of soil borings, excavations, test pits, gas venting structures, wells, piezometers, environmental and facility monitoring points and devices, benchmarks and permanent survey markers; on-site buildings and appurtenances, fences, gates, roads, parking areas, drainage culverts, and signs; the delineation of the total landfill area including planned staged development of the landfill's construction and operation, and the lateral limits of any previously filled areas; the location and identification of the sources of cover materials; the location and identification of special waste handling areas; and site topography with five feet minimum contour intervals; and, any other relevant information as necessary for proper

operation. The site plan shall show wetlands, property lines, existing wells, water bodies, and soil stockpiles that will be used as cover material. The plan shall show all buildings, to include residences and schools, on adjacent properties. The plan shall be on a scale of not greater than 200 feet per inch unless otherwise approved by the Department.

(3) Detailed plans of the landfill that clearly show in plan and cross-sectional views the following: the original, undeveloped site topography before excavation or placement of solid waste; the existing site topography, if different, including the location and approximate thickness and nature of any existing solid waste; plan view of the location of the seasonal high water table in relation to the bottom elevation of the proposed landfill; a cross sectional view of existing and final elevations, bottom elevation and deflected bottom elevation, and seasonal high water table; geologic units; known and interpolated bedrock elevations; the proposed limits of excavation and waste placement; other devices as needed to divert or collect surface water run-on or run-off; a plan and cross section view of fill progression for the life of the landfill; the final elevations and grades of the landfill; groundwater monitoring system; and, the building locations and appurtenances.

(4) Detailed plans of the sedimentation ponds. These plans shall clearly show in plan and cross sectional views the following: the existing site topography, the seasonal high water table, pond bottom elevation, permanent pool elevation, first flush elevation, maximum elevation for sedimentation clean-out, emergency spillway 100-yr storm elevation, riser pipe, antiseep collars, outlet protection, emergency spillway, dewatering riser, trash/antivortex rack, and sedimentation pond gauge legend.

(5) Detailed plans shall show: the location and placement of each liner system and each leachate collection system, locating and showing all critical grades and elevations of the collection pipe inverts and drainage envelopes, manholes, cleanouts, valves and sumps; and, leachate storage, treatment and disposal systems including the collection network and any treatment, pre-treatment, or storage facilities.

b. Engineering Report. An Engineering Report comprehensively describing the existing site conditions and an analysis of the landfill, including closure and post-closure criteria. Additional requirements for landfills with leachate recirculation are outlined in Section 5.c. below. All engineering reports shall be bound. This report shall:

(1) Specify the filling rate (in tons per day) of the landfill describing the number, types, and specifications of all necessary machinery and equipment needed to effectively operate the landfill at the prescribed filling rate;

(2) Contain a detailed description of all construction phases, including, but not limited to, the liner system, leachate collection system, and final cover system;

(3) Contain an analysis of the site to include:

(a) The name, address, and location of all adjacent landowners; the closest population centers;

(b) A description of the primary transportation systems and waste transportation routes to the landfill (i.e., highways, airports, railways, etc.); and,

(c) An analysis of the existing topography, surface water and subsurface geological conditions;

(4) Discuss the closure and post-closure maintenance and operation of the landfill which shall include, but not be limited to:

(a) A closure design consistent with the requirements contained in Section 258.60;

(b) A post-closure water quality monitoring program consistent with requirements contained in Section 258.61;

(c) Methane monitoring and control systems as needed;

(d) An operation and closure plan for the leachate collection, treatment, and storage facilities consistent with the requirements of this Part; and,

(e) A discussion of the future use of the site including the specific proposed or alternative use. Future uses shall conform to the stabilization plan, required by this regulation and shall not adversely affect the final cover system;

(5) Include appendices demonstrating compliance with pertinent local laws and regulations pertaining to air, land, noise, and water pollution, and other supporting data, including literature citations;

(6) Describe the materials and construction methods for the placement of: each monitoring well; all gas venting systems; each liner and leachate collection and removal system; leachate storage, treatment, and disposal systems; and, cover systems. This description also shall include a discussion of provisions to be taken to prevent frost action upon each liner system in areas where refuse has not been placed;

(7) Estimate the expected quantity of leachate to be generated, including:

(a) An annual water budget estimating leachate generation quantities, prepared for periods of time of initial operation, the interim between the last receipt of waste and application of final cover, and following facility closure. At a minimum, the following factors shall be considered in the preparation of the precipitation infiltration into the landfill: average monthly temperature; average monthly precipitation; evaporation; evapotranspiration, which should consider the vegetation type and root zone depth; surface/cover soil conditions and their relation to precipitation runoff which shall account for the surface conditions and soil moisture holding capacity; and, all other sources of moisture contribution to the landfill;

(b) Liner and leachate collection system efficiencies calculated using an appropriate analytical or numerical assessment. The factors to be considered in the calculation of collection system efficiency shall include, as a minimum, the saturated hydraulic conductivity of the liner, the liner thickness, the saturated hydraulic conductivity of the leachate collection system, the leachate collection system porosity, the base slope of the liner and leachate collection and removal system interface, the maximum flow distance across the liner and leachate collection and removal system interface to the nearest leachate collection pipe, and the estimated leachate generation quantity as computed in accordance with the requirements of the preceding subparagraph; and,

(c) Information gained from the collection efficiency calculations required in the preceding two paragraphs used to predict the static head of leachate on the liners, volume of leachate to be collected, and the volume of leachate that may permeate through the entire liner system on a monthly basis. This assessment shall also address the amount of leachate expected to be found in the leachate collection and removal system in gallons per acre per day;

(8) Include a design of the leachate storage facility based upon the leachate generation calculation. The design capacity for the leachate storage facility shall be based on the proposed leachate disposal method that allows sufficient lead time for either:

(a) Development of a separate set of engineering reports, plans and specifications for the construction and operation of a leachate treatment facility on-site and to obtain approval of this document before any discharge from the leachate storage facility; or,

(b) Development of a plan to handle leachate destined for off-site treatment at a wastewater treatment facility, and to ensure that the amount of leachate stored on-site is not in excess of the storage capacity available. This plan shall include a legal document (contract, local permit, etc.) certifying acceptance of leachate from the operator of the wastewater treatment facility with all conditions stipulated by the operator of the wastewater treatment facility and all such stipulations addressed in the operations plan;

(9) Include a Construction Plan describing how the landfill will fulfill the requirements of protecting human health and the environment. The plan shall be presented in a manner sufficiently clear and comprehensive for use by the landfill's operator during the life of the landfill. It shall depict the fill progression with respect to site life and shall:

(a) Describe the site's preparation and fill progression for the life of the site in terms of method, depth, location and sequence;

(b) Contain a method of elevation control for the operator including the location and description of the permanent surveying benchmark at the site;

(c) Contain a fill progression discussion describing the placement and compacted thickness of daily, intermediate and final cover;

(d) For soils excavated during construction, identify the stockpile location and volume of soils; and,

(e) Contain a description of stormwater diversion from leachate collection system in areas of constructed cells that have not had waste placement;

(10) Include an Operation and Maintenance Report prepared to demonstrate how the landfill will meet all the operational requirements. This report shall include, at a minimum, the following:

(a) A description of the project's personnel requirements, stating personnel responsibilities and duties including discussions for training and lines of authority at the landfill;

(b) A description of all machinery and equipment to be used at the landfill, their authorized uses, and safety features;

(c) A description of the operational controls, including but not limited to, signs, hours and days of operation, landfill usage rules and regulations, and traffic flow controls;

(d) A description of the anticipated solid waste to be received per day, specifying the quantities received in tons per day, the fill progression of the landfill, and the method of solid waste placement and compaction, and the anticipated in-place density;

(e) A description of the landfill's solid waste receiving process, including inspection of incoming loads, identification of any waste streams to be excluded, and those wastes to receive special handling, or to require treatment before receipt, and a copy of the Special Waste Analysis and Implementation Plan (SWAIP);

(f) A description of the cover material management plan, specifying the types of cover material (daily, intermediate, and final), identifying the quantities required and sources for each cover material by type, including the method of cover material placement, compaction, and the anticipated density;

(g) A description of the project's gas monitoring program that discusses explosive gas generation at the landfill and the controls used to ensure that gas generated at the landfill will not create a hazard to health, safety, or property;

(h) A description of how winter and inclement weather operations will be conducted; and,

(i) If applicable, a description of the operation of a convenience station at the landfill for smaller private vehicles to unload refuse at an area other than the landfill's working face;

(11) Contain a Stabilization Plan. Measures shall be taken within 30 days of establishing soil stockpiles to stabilize the stockpiles not in active use. The Stabilization Plan shall address adequate seeding or other erosion control measures of the site and:

(a) Identify and locate existing vegetation to be retained and proposed vegetation to be used for cover, soil stockpiles, and other purposes;

(b) If appropriate, provide a seeding and planting schedule, including the identification of the rationale for the seed mixture choice and fertilization and procedures for seed application, mulching, and maintenance; and,

(c) Describe the planting plan and schedule which identifies plants to be used consistent with future use proposals;

(12) Include a Quality Assurance/Quality Control (QA/QC) Report prepared in accordance with accepted QA/QC practices. This report shall address the construction requirements set forth in this Part for each phase of construction and shall include, but not be limited to:

(a) A delineation of the QA/QC management organization, including the chain of command of the QA/QC inspectors and contractors;

(b) A description of the required level of experience and training for the contractor, his crew, and QA/QC inspectors for every major phase of construction, in sufficient detail to demonstrate that the installation methods and procedures required in this document are properly implemented; and,

(c) A description of the QA/QC testing protocols for every major phase of construction, including, but not limited to, the base liner system, leachate collection system, and final cover

system. The QA/QC testing protocol shall include at a minimum: the frequency of inspection; field testing; sampling for laboratory testing, the sampling and field testing procedures and equipment to be utilized; the calibration of field testing equipment, the frequency of performance audits; the sampling size; the soils or geotechnical laboratory to be used; the laboratory procedures to be utilized; the calibration of laboratory equipment and QA/QC of laboratory procedures, the limits for test failure; and, a description of the corrective procedures to be used upon test failure;

(13) Include a Contingency Plan that addresses an organized, planned and coordinated, technically and financially feasible course of action to be taken in responding to contingencies during the construction and operation of the landfill. The plan shall provide a description of the criteria to be utilized in evaluating deficiencies, and selecting and implementing corrective actions. The plan shall, at a minimum, address:

(a) Procedures for responding to deficiencies during the construction phase resulting from circumstances including, but not limited to, inclement weather, defective materials or construction inconsistent with specifications as demonstrated by quality control testing;

(b) Actions to be taken during operation of the landfill with respect to: personnel and user safety; on-site personal injury; fires; explosive landfill gases detected on site; dust; litter; odor; noise; equipment breakdown; unusual traffic conditions; vectors; disposition of unapproved wastes; receipt of unauthorized wastes; releases of hazardous or toxic materials; groundwater and surface water contamination which may include public water supply contamination as a result of an accidental spill; and, the occurrence of the leachate storage facility being at or above capacity; and,

(c) Procedures to be used in response to: tank and surface impoundment spills or leakage, including removal of the waste and repair of such structures; and, the inability of the approved leachate treatment facility to accept leachate from the landfill for an indefinite period of time;

(14) Include a Groundwater Monitoring Plan. Upon obtaining approval of the investigations performed to satisfy the landfill siting study, a groundwater monitoring plan shall be submitted to the Department for review and approval. The groundwater monitoring plan shall detail the activities to be performed to ensure compliance with the requirements of Section 258.51., Section 258.53., and Section 258.54.;

(15) Include a Closure Plan in the permit application that details the activities to be performed to satisfy the requirements of Section 258.60.; and,

(16) Include a Post-closure Plan that details the activities to be performed to satisfy the requirements of Section 258.61.

c. South Carolina Coastal Zone Management Plan. The proposed landfill project shall be consistent with the South Carolina Coastal Zone Management Plan, if the landfill is located in the coastal zone as defined in accordance with the Coastal Zone Management Act.

d. Leachate Recirculation. All landfills proposing leachate recirculation shall comply with the requirements outlined in Subpart I below.

Subpart I. Leachate Recirculation.

1. Leachate recirculation at Class Three Landfills shall be limited to facilities which meet the following criteria:

a. Leachate recirculation shall be allowed only in facilities that were designed and constructed with a minimum of a composite liner system or equivalent, and that comply with all requirements for a Class 3 Landfill.

b. Leachate recirculation shall be allowed only in facilities which have a leachate collection system capable of maintaining less than one foot of leachate head on the liner system at all times.

c. Leachate and gas condensate collected from the facility shall be the only liquids allowed for recirculation back into the landfill.

d. Leachate recirculation will not be allowed in an area of the footprint which exhibits evidence of significant leakage of the liner system. A buffer approved by the Department shall be maintained between the suspected leaking area and the area of leachate recirculation.

e. Leachate recirculation shall be allowed only at facilities which are designed and constructed to have final slopes which are no steeper than three to one.

f. The Class Three Landfill shall have sufficient storage capacity onsite to handle all leachate generated by the facility in the event leachate recirculation activities are suspended.

g. Contracts to handle the total leachate generated by the facility, or approved and permitted onsite treatment facilities capable of handling all leachate generated by the facility shall be maintained at all Class Three Landfills performing leachate recirculation.

h. The permittee shall have adequate landfill gas control measures in place at the start of leachate recirculation to control the migration of methane and to control the presence of any odors associated with leachate recirculation.

i. A minimum thickness of 30 feet of waste shall be placed in a new cell before leachate recirculation can begin.

2. Class Three landfills performing leachate recirculation shall maintain the following buffer distances from facility side slopes:

a. If leachate is applied to the landfill by way of spraying the leachate at the working face, at a minimum, a 50 foot buffer shall be maintained at all times.

b. If leachate is applied to the landfill by way of pumping into a trench system, at a minimum, a 100 foot buffer shall be maintained at all times.

c. If leachate is applied to the landfill by way of injecting the leachate into vertical wells installed into the waste, at a minimum, a 100 foot buffer shall be maintained at all times.

d. Other methods of leachate recirculation into the facility shall have buffer zones from side slopes approved by the Department.

e. The Department may require additional buffer distances should evidence exist that the current buffer zones are not sufficient to protect stability of the landfill, to prevent the outbreak of leachate seeps, or to otherwise protect human health and the environment.

3. Approval to perform leachate recirculation shall be requested by the facility and approved by the Department on an annual basis. Upon a request for annual renewal of approval to leachate recirculate, the facility shall submit to the Department the following information in the form of an annual report:

a. Analytical results from leachate testing for the parameters specified in Appendix VI;

b. A summary of daily leachate recirculation rates along with injection locations;

c. Monthly leachate recirculation system inspection records, training procedures, and notification procedures;

d. Monthly landfill leachate and gas generation rate (if applicable) results; and,

e. Any requests for modification to the leachate recirculation system.

4. If problems associated with leachate recirculation are identified, the permittee shall:

a. Take all steps necessary to ensure protection of human health and the environment; and,

b. Within seven days of detection of a problem with leachate recirculation, place in the operating record and submit to the Department a copy of all actions taken to remedy the problem, and any proposed changes to the leachate recirculation system to prevent future problems.

5. Engineering Report. In addition to the permitting requirements outlined for Class Three Landfills in this Part, the permit application shall contain, at a minimum, the following:

a. Engineering drawings with detailed plans of the landfill that clearly show in plan and cross-sectional views the following: each leachate injection well; pipe lines; pipe inverts; drainage envelopes; manholes; cleanouts; valves; sumps; other devices as needed for leachate injection and monitoring, if applicable; and, a proposed waste saturation profile;

b. An engineering report containing a description of the existing site conditions and an analysis of the proposed landfill. The report shall:

(1) Contain design calculations using waste shear strength at 100% saturation that demonstrate that all containment structures, including liners, leachate collection systems, and surface water control systems, are designed to resist the maximum horizontal acceleration in lithified earth

material for the site. Class Three landfills shall have a minimum 1.7 safety factor against failure, where the soil conditions are complex and when available strength data do not provide a consistent, complete, or logical picture of the strength characteristics. Where the soil conditions are uniform and high quality strength data provides a consistent, complete, and logical picture of the strength characteristics as determined by the Department, a minimum 1.2 safety factor against failure shall be used.

(2) Specify the leachate application rate of the landfill in gallons per day, specify the current leachate generation rates, and list the number, types, and specifications of all necessary machinery and equipment needed to effectively operate the application system at the landfill.

(3) Contain liner and leachate collection system efficiencies calculated using an appropriate analytical or numerical assessment. The factors to be considered in the calculation of collection system efficiency shall include, at a minimum, the saturated hydraulic conductivity of the liner, the liner thickness, the saturated hydraulic conductivity of the leachate collection system, the leachate collection system porosity, the base slope of the liner and leachate collection and removal system interface, the maximum flow distance across the liner and leachate collection and removal system interface to the nearest leachate collection pipe, the estimated leachate generation, including both natural quantity and the approved injection rate. The estimated leachate generation shall be used to predict the static head of leachate on the liners, volume of leachate to be collected, and the volume of leachate that may permeate through the entire liner system on a monthly basis. This assessment shall also address the amount of leachate expected to be found in the leachate collection and removal system in gallons per acre per day.

(4) Contain a leachate recirculation operation and maintenance report for the landfill that includes, at a minimum, the following:

(a) A description of the project's personnel requirements, stating personnel responsibilities and duties including discussions for training and lines of authority at the landfill; and,

(b) A description of all machinery and equipment to be used at the landfill for leachate recirculation, their authorized uses, and safety features.

(5) Contain a contingency plan discussing the course of action to be taken in responding to fires, leachate seeps, leachate releases, and other pertinent situations.

(6) Contain a description of the method for collecting and controlling landfill gases based on calculations of the estimated landfill gas generation during life of the landfill.

(7) Contain a demonstration of adequate storage capacity for all leachate generated at the site.

(8) Contain analytical results from leachate testing for the parameters specified in Appendix VI. prior to the start of leachate recirculation at the site.

Subpart J. Permit Conditions and Permit Review.

1. Application forms for permits shall be provided by the Department and shall be submitted with sufficient detail to support a judgment that operation of the disposal system will not violate the laws and regulations of the State of South Carolina. The application shall be signed by the permittee of the Class Three landfill. The approved application and associated plans and drawings shall be an enforceable part of the permit. Permits shall be effective for the design and operational life of the facility.

2. Prior to issuance of a permit for major modifications, as determined by the Department, and for new construction, the Department will make the draft permit available for public review and comment pursuant to Part I, Section D of this regulation.

3. The Department shall review the permit for each Class Three landfall at least once every five years, unless otherwise specified by the Department. Upon notification from the Department, the landfill shall submit to the Department a topographic survey map of the site that shows the contours at the beginning and the end of the period since the last permit review.

a. If, upon review, the Department finds that material or substantial violations of the permit demonstrate the permittee's disregard for, or inability to comply with, applicable laws, regulations, or requirements, and would make continuation of this permit not in the best interests of human health and safety or the environment, the Department may, after a hearing, amend or revoke the permit, as appropriate and necessary. When a permit is reviewed, the Department shall include

additional limitations, standards, or conditions when the technical limitations, standards, or regulations on which the original permit was based have been changed by statute or amended by regulation.

b. The Department may amend or attach conditions to a permit when:

(1) There is a significant change in the manner and scope of operation which may require new or additional permit conditions or safeguards to protect human health and safety and the environment;

(2) The investigation has shown the need for additional equipment, construction, procedures, and testing to ensure the protection of human health and safety and the environment; and,

(3) The amendment is necessary to meet changes in applicable regulatory requirements.

4. Any permits issued pursuant to this regulation shall not be valid after a period of twelve (12) months from the effective date of the permit, if construction of the facility has not begun by the end of this period unless granted a variance by the Department.

Subpart K. Transfer of Ownership. The Department may, upon written request, transfer a permit to a new permittee where no other change in the permit is necessary pursuant to Part I, F.2.c. of this regulation.

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Appendix I. ACCEPTABLE WASTE FOR CLASS TWO LANDFILLS

The following types of waste have been determined by the Department to be environmentally safe and may be accepted at Class Two Landfills unless specifically prohibited by the Department. Acceptable wastes may be generated by construction, demolition, land-clearing, industrial, and/or manufacturing activities, and/or obtained from segregated commercial waste. However, any of the materials listed in this appendix that have been contaminated by any hazardous constituent listed in the S.C. Hazardous Waste Management Regulations 61–79.261, or petroleum products, are prohibited from disposal at a Class Two Landfill.

Acceptable Land-Clearing Debris Such As:

- brush & limbs
- earthen material, e.g., clays, sands, gravels, & silts
- logs
- rock
- root mats
- top soil
- tree stumps
- vegetation

Acceptable Debris Such As:

- asbestos-containing material [2]
- bricks & masonry blocks
- cardboard
- dry paint cans
- dry caulking tubes
- fiberglass matting
- floor covering
- glass
- glass wire (optical fiber)
- hardened asphaltic concrete [3]
- hardened cement
- other items physically attached to structure, e.g., signs, mailboxes, awning, vinyl siding
- other structural fabrics
- packaging material
- painted waste (includes lead-based paint)
- pallets & crates
- pipes
- plaster & plasterboard
- polyfiberglass (highly polished, cured material used for shower stalls, roofing, etc.)
- shingles & roofing materials

[2] Friable and nonfriable asbestos-containing material shall be disposed in a designated area and covered immediately upon receipt with at least six inches (6″) of acceptable material. Prior to disposal of asbestos-containing material, the generator of the asbestos waste shall obtain a ''permission for disposal'' letter from the Department's Bureau of Air Quality (BAQ) and submit this letter to the landfill. All landfills accepting asbestos-containing material for disposal are subject to the BAQ regulation 61–86.1 Standards of Performance for Asbestos Abatement Operations, and the National Emissions Standards for Hazardous Air Pollutants[40CFR61, Subpart M;]

[3] Tar sealant material is not acceptable.

- hardened concrete (may include re-bar)
- insulation material
- lumber (includes treated lumber)
- mirrors
- structural steel
- tile (floor, wall & ceiling)
- tires [4]
- tubing
- wall coverings

Acceptable Brown Goods:

- box springs
- mattresses
- wooden swing sets
- nonmotorized bulky outdoor children's toys
- furniture including lawn furniture:
  - laminated
  - metal [5]
  - plastic
  - PVC
  - vinyl
  - wooden

Animal Carcasses Acceptable Under Following Conditions:

. Animal carcasses shall be buried in a separate designated area. The facility shall submit to the Department a written request to dispose of animal carcasses including a plan that shows the portion of the landfill to be used for this type of disposal. The permit will be modified to reflect the designated disposal area, and;

. Animal carcasses shall be buried and covered with at least twelve inches (12″) of dirt immediately upon receipt.

. Hydrated lime shall be added to the carcass and surrounding area before cover is applied to control bacterial growth and odor.

. Mass kill burial shall not be acceptable at Class Two Landfills unless approved by the Department prior to disposal.

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Appendix II. UNACCEPTABLE WASTE FOR CLASS TWO LANDFILLS

The following types of waste have been determined to pose a potential threat to the environment and shall not be accepted at Class Two Landfills. Wastes are considered to be contaminated if a waste has come into contact with and maintains a residue or characteristic of the contaminated materials as described herein.

Any Waste That Has Been Contaminated by Petroleum Products Such As:

- absorbent (vermiculite)
- concrete
- containers
- filters (oil, etc.)
- mechanical/machine parts
- paper towels & rags
- pipes
- soil
- storage tanks
- tar sealant material

Any Waste That Has Been Contaminated by Polychlorinated Biphenyls (PCBs) Such As:

- any waste that has come in contact with any liquid-containing PCBs
- capacitors
- electrical components
- lighting ballasts
- transformers

Any Waste That Has Been Contaminated by Organic Chemicals or Solvents (industrial plants, chemical plants, laboratories, construction sites, etc.) Such As:

- absorbent
- mechanical/machine parts (valves, etc.)

[4] Tires shall be reduced in size by a minimum of one-eighth the size of the original tire prior to landfill disposal.

[5] The Department recommends that all metal furniture be recycled if feasible.

- adhesives
- caulking compounds
- cement
- containers (packaging)
- filters
- flooring (wood, carpet, etc.)
- glazing compound
- paint thinner
- pipes
- pumps
- soil
- storage tanks
- tar
- vats

Any Waste That Has Been Contaminated by Preservatives, (pentachlorophenol & creosote) Such As:

- containers
- mechanical parts used in manufacturing processes
- railroad ties
- soil
- utility poles

Any Waste That Has Been Contaminated by Pesticides/Herbicides Such As:

- concrete
- containers (packaging)
- equipment used for application
- mechanical/machine parts
- pallets & crates
- soil
- vats
- wood (storage area)

Miscellaneous Waste Such As:

- lamps [6]
- liquid waste (paint, paint thinner, etc.)
- unpolished fiberglass (Bondo)
- wastes/substances determined by the Department to be unacceptable

Cathode Ray Tubes (CRTs) and Electronic Equipment Such As:

- cameras
- compact discs (CDs)
- computers
- computer monitors
- communication & navigation equipment
- Digital Versatile Disc (DVDs)
- displays
- hand-held video game machines
- mainframes
- microwave ovens
- personal digital assistants (PDAs)
- radios
- stereos
- televisions
- test equipment (oscilloscopes, etc.)
- video cassette recorders (VCRs)
- video game machines

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

APPENDIX III. CONSTITUENTS FOR DETECTION MONITORING FOR CLASS TWO LANDFILLS

Common name	CAS RN
pH	
Specific Conductance	
Temperature	
Inorganic Constituents:	
(1) Arsenic	(Total)
(2) Barium	(Total)
(3) Cadmium	(Total)
(4) Chromium	(Total)
(5) Lead	(Total)
(6) Mercury	(Total)
(7) Selenium	(Total)

[6] Fluorescent lamps and high intensity discharge (HID) lamps such as metal halide and mercury vapor lamps.

(8)	Silver	(Total)
(9)	Chloride	(Total)
(10)	Nitrate	(Total)
(11)	Sulfate	(Total)
Organic Constituents:		
(12)	Benzene	71–43–2
(13)	Carbon tetrachloride	56–23–5
(14)	Chlorobenzene	108–90–7
(15)	Chloroform; Trichloromethane	67–66–3
(16)	1,1-Dichloroethane; Ethylidene chloride	75–34–3
(17)	1,2-Dichloroethane; Ethylene dichloride	107–06–2
(18)	1,1-Dichloroethylene; 1,1-Dichloroethene; Vinylidene chloride	75–35–4
(19)	cis-1,2-Dichloroethylene; cis-1,2-Dichloroethene	156–59–2
(20)	trans-1,2-Dichloroethylene; trans-1,2-Dichloroethene	156–60–5
(21)	Ethylbenzene	100–41–4
(22)	Methylene chloride	75–09–2
(23)	Tetrachloroethylene; Tetrachloroethene; Perchloroethylene	127–18–4
(24)	Toluene	108–88–3
(25)	1,1,1-Trichloroethane; Methylchloroform	71–55–6
(26)	1,1,2-Trichloroethane	79–00–5
(27)	Trichloroethylene; Trichloroethene	79–01–6
(28)	Vinyl chloride	75–01–4
(29)	Xylenes	1330–20–7

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Appendix IV. CONSTITUENTS FOR DETECTION MONITORING FOR CLASS THREE LANDFILLS

Common name [7]		CAS RN [8]
pH		
Specific Conductance		
Inorganic Constituents:		
(1)	Antimony	(Total)
(2)	Arsenic	(Total)
(3)	Barium	(Total)
(4)	Beryllium	(Total)
(5)	Cadmium	(Total)
(6)	Chromium	(Total)
(7)	Cobalt	(Total)
(8)	Copper	(Total)
(9)	Lead	(Total)
(10)	Nickel	(Total)
(11)	Selenium	(Total)
(12)	Silver	(Total)
(13)	Thallium	(Total)
(14)	Vanadium	(Total)
(15)	Zinc	(Total)
Organic Constituents:		
(16)	Acetone	67–64–1
(17)	Acrylonitrile	107–13–1
(18)	Benzene	71–43–2
(19)	Bromochloromethane	74–97–5
(20)	Bromodichloromethane	75–27–4
(21)	Bromoform; Tribromomethane	75–25–2

[7] Common names are those widely used in government regulations, scientific publications, and commerce; synonyms exist for many chemicals.

[8] Chemical Abstracts Service registry number. Where "Total" is entered, all species in the ground water that contain this element are included.

(22)	Carbon disulfide	75–15–0
(23)	Carbon tetrachloride	56–23–5
(24)	Chlorobenzene	108–90–7
(25)	Chloroethane; Ethyl chloride	75–00–3
(26)	Chloroform; Trichloromethane	67–66–3
(27)	Dibromochloromethane; Chlorodibromomethane	124–48–1
(28)	1,2-Dibromo-3-chloropropane; DBCP	96–12–8
(29)	1,2-Dibromoethane; Ethylene dibromide; EDB	106–93–4
(30)	o-Dichlorobenzene; 1,2-Dichlorobenzene	95–50–1
(31)	p-Dichlorobenzene; 1,4-Dichlorobenzene	106–46–7
(32)	trans-1,4-Dichloro-2-butene	110–57–6
(33)	1,1-Dichloroethane; Ethylidene chloride	75–34–3
(34)	1,2-Dichloroethane; Ethylene dichloride	107–06–2
(35)	1,1-Dichloroethylene; 1,1-Dichloroethene; Vinylidene chloride	75–35–4
(36)	cis-1,2-Dichloroethylene; cis-1,2-Dichloroethene	156–59–2
(37)	trans-1,2-Dichloroethylene; trans-1,2-Dichloroethene	156–60–5
(38)	1,2-Dichloropropane; Propylene dichloride	78–87–5
(39)	cis-1,3-Dichloropropene	10061–01–5
(40)	trans-1,3-Dichloropropene	10061–02–6
(41)	Ethylbenzene	100–41–4
(42)	2-Hexanone; Methyl butyl ketone	591–78–6
(43)	Methyl bromide; Bromomethane	74–83–9
(44)	Methyl chloride; Chloromethane	74–87–3
(45)	Methylene bromide; Dibromomethane	74–95–3
(46)	Methylene chloride; Dichloromethane	75–09–2
(47)	Methyl ethyl ketone; MEK; 2-Butanone	78–93–3
(48)	Methyl iodide; Iodomethane	74–88–4
(49)	4-Methyl-2-pentanone; Methyl isobutyl ketone	108–10–1
(50)	Styrene	100–42–5
(51)	1,1,1,2-Tetrachloroethane	630–20–6
(52)	1,1,2,2-Tetrachloroethane	79–34–5
(53)	Tetrachloroethylene; Tetrachloroethene; Perchloroethylene	127–18–4
(54)	Toluene	108–88–3
(55)	1,1,1-Trichloroethane; Methylchloroform	71–55–6
(56)	1,1,2-Trichloroethane	79–00–5
(57)	Trichloroethylene; Trichloroethene	79–01–6
(58)	Trichlorofluoromethane; CFC-11	75–69–4
(59)	1,2,3-Trichloropropane	96–18–4
(60)	Vinyl acetate	108–05–4
(61)	Vinyl chloride	75–01–4
(62)	Xylenes	1330–20–7

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Appendix V. LIST OF HAZARDOUS INORGANIC AND ORGANIC CONSTITUENTS

Common name [9]	CAS RN [10]
Acenaphthene	83–32–9
Acenaphthylene	208–96–8
Acetone	67–64–1
Acetonitrile; Methyl cyanide	75–05–8
Acetophenone	98–86–2
2-Acetylaminofluorene; 2-AAF.	53–96–3
Acrolein	107–02–8
Acrylonitrile	107–13–1
Aldrin	309–00–2
Allyl chloride	107–05–1

[9] Common names are those widely used in government regulations, scientific publications, and commerce; synonyms exist for many chemicals.

[10] Chemical Abstracts Service registry number. Where "Total" is entered, all species in the ground water that contain this element are included.

4-Aminobiphenyl	92–67–1
Anthracene	120–12–7
Antimony	(Total)
Arsenic	(Total)
Barium	(Total)
Benzene	71–43–2
Benzo[a]anthracene; Benzanthracene	56–55–3
Benzo[b]fluoranthene	205–99–2
Benzo[k]fluoranthene	207–08–9
Benzo[ghi]perylene	191–24–2
Benzo[a]pyrene	50–32–8
Benzyl alcohol	100–51–6
Beryllium	(Total)
alpha-BHC	319–84–6
beta-BHC	319–85–7
delta-BHC	319–86–8
gamma-BHC; Lindane	58–89–9
Bis(2-chloroethoxy)methane	111–91–1
Bis(2-chloroethyl) ether; Dichloroethyl ether	111–44–4
Bis-(2-chloro-1-methylethyl) ether; 2,2[prime]-Dichlorodiisopropyl ether; DCIP.[11]	108–60–1
Bis(2-ethylhexyl) phthalate	117–81–7
Bromochloromethane; Chlorobromomethane	74–97–5
Bromodichloromethane; Dibromochloromethane	75–27–4
Bromoform; Tribromomethane	75–25–2
4-Bromophenyl phenyl ether	101–55–3
Butyl benzyl phthalate; Benzyl butyl phthalate	85–68–7
Cadmium	(Total)
Carbon disulfide	75–15–0
Carbon tetrachloride	56–23–5
Chlordane	footnote [12]
p-Chloroaniline	106–47–8
Chlorobenzene	108–90–7
Chlorobenzilate	510–15–6
p-Chloro-m-cresol; 4-Chloro-3-methylphenol	59–50–7
Chloroethane; Ethyl chloride	75–00–3
Chloroform; Trichloromethane	67–66–3
2-Chloronaphthalene	91–58–7
2-Chlorophenol	95–57–8
4-Chlorophenyl phenyl ether	7005–72–3
Chloroprene	126–99–8
Chromium	(Total)
Chrysene	218–01–9
Cobalt	(Total)
Copper	(Total)
m-Cresol; 3-Methylphenol	108–39–4
o-Cresol; 2-Methylphenol	95–48–7
p-Cresol; 4-Methylphenol	106–44–5
Cyanide	57–12–5
2,4-D; 2,4-Dichlorophenoxyacetic acid	94–75–7
4,4[prime]-DDD	72–54–8
4,4[prime]-DDE	72–55–9
4,4[prime]-DDT	50–29–3
Diallate	2303–16–4
Dibenz[a,h]anthracene	53–70–3
Dibenzofuran	132–64–9
Dibromochloromethane; Chlorodibromomethane.	124–48–1
1,2-Dibromo-3-chloropropane; DBCP.	96–12–8

[11] This substance is often called bis(2-chloroisopropyl) ether, the name Chemical Abstracts Service applies to its noncommercial isomer, propane, 2,2[sec]-oxybis[2-chloro- (CAS RN 39638–32–9).

[12] Chlordane: This entry includes alpha-chlordane (CAS RN 5103–71–9), beta-chlordane (CAS RN 5103–74–2), gamma-chlordane (CAS RN 5566–34–7), and constituents of chlordane (CAS RN 57–74–9 and CAS RN 12789–03–6).

1,2-Dibromoethane; Ethylene dibromide; EDB.	106–93–4
Di-n-butyl phthalate	84–74–2
o-Dichlorobenzene; 1,2- Dichlorobenzene.	95–50–1
m-Dichlorobenzene; 1,3- Dichlorobenzene	541–73–1
p-Dichlorobenzene; 1,4- Dichlorobenzene.	106–46–7
3,3[prime]-Dichlorobenzidine	91–94–1
trans-1,4-Dichloro-2-butene	110–57–6
Dichlorodifluoromethane; CFC 12	75–71–8
1,1-Dichloroethane; Ethyldidene chloride	75–34–3
1,2-Dichloroethane; Ethylene dichloride.	107–06–2
1,1-Dichloroethylene; 1,1-Dichloroethene	75–35–4
Vinylidene chloride cis-1,2-Dichloroethylene; cis-1,2-Dichloroethene	156–59–2
trans-1,2-Dichloroethylene trans-1,2-Dichloroethene	156–60–5
2,4-Dichlorophenol	120–83–2
2,6-Dichlorophenol	87–65–0
1,2-Dichloropropane; Propylene dichloride.	78–87–5
1,3-Dichloropropane; Trimethylene dichloride	142–28–9
2,2-Dichloropropane; Isopropylidene chloride	94–20–7
1,1-Dichloropropene	563–58–6
cis-1,3-Dichloropropene	10061–01–5
trans-1,3-Dichloropropene	10061–02–6
Dieldrin	60–57–1
Diethyl phthalate	84–66–2
O,O-Diethyl O-(2-pyrazinyl) phosphorothioate	297–97–2
Dimethoate	60–51–5
p-(Dimethylamino)azobenzene	60–11–7
7,12-Dimethylbenz[a]anthracene	57–97–6
3,3[prime]-Dimethylbenzidine	119–93–7
alpha, alpha-Dimethylphenethylamine	122–09–8
2,4-Dimethylphenol; m-Xylenol	105–67–9
Dimethyl phthalate	131–11–3
m-Dinitrobenzene	99–65–0
4,6-Dinitro-o-cresol 4,6-Dinitro-2- methylphenol	534–52–1
2,4-Dinitrophenol	51–28–5
2,4-Dinitrotoluene	121–14–2
2,6-Dinitrotoluene	606–20–2
Dinoseb; DNBP; 2-sec-Butyl-4,6- methylphenol dinitrophenol.	88–85–7
Di-n-octyl phthalate	117–84–0
Diphenylamine	122–39–4
Disulfoton	298–04–4
Endosulfan I	959–98–8
Endosulfan II	33213–65–9
Endosulfan sulfate	1031–07–8
Endrin	72–20–8
Endrin aldehyde	7421–93–4
Ethylbenzene	100–41–4
Ethyl methacrylate	97–63–2
Ethyl methanesulfonate	62–50–0
Famphur	52–85–7
Fluoranthene	206–44–0
Fluorene	86–73–7
Heptachlor	76–44–8
Heptachlor epoxide	1024–57–3
Hexachlorobenzene	118–74–1
Hexachlorobutadiene	87–68–3
Hexachlorocyclopentadiene	77–47–4
Hexachloroethane	67–72–1
Hexachloropropene	1888–71–7
2-Hexanone; Methyl butyl ketone	591–78–6
Indeno(1,2,3-cd)pyrene	193–39–5
Isobutyl alcohol	78–83–1
Isodrin	465–73–6
Isophorone	78–59–1

Isosafrole	120–58–1
Kepone	143–50–0
Lead	(Total)
Mercury	(Total)
Methacrylonitrile	126–98–7
Methapyrilene	91–80–5
Methoxychlor	72–43–5
Methyl bromide; Bromomethane	74–83–9
Methyl chloride; Chloromethane	74–87–3
3-Methylcholanthrene	56–49–5
Methyl ethyl ketone; MEK; 2-Butanone	78–93–3
Methyl iodide; Iodomethane	74–88–4
Methyl methacrylate	80–62–6
Methyl methanesulfonate	66–27–3
2-Methylnaphthalene	91–57–6
Methyl parathion; Parathion methyl	298–00–0
4-Methyl-2-pentanone; Methyl isobutyl ketone	108–10–1
Methylene bromide; Dibromomethane	74–95–3
Methylene chloride; Dichloromethane	75–09–2
Naphthalene	91–20–3
1,4-Naphthoquinone	130–15–4
1-Naphthylamine	134–32–7
2-Naphthylamine	91–59–8
Nickel	(Total)
o-Nitroaniline; 2-Nitroaniline	88–74–4
m-Nitroaniline; 3-Nitroaniline	99–09–2
p-Nitroaniline; 4-Nitroaniline	100–01–6
Nitrobenzene	98–95–3
o-Nitrophenol; 2-Nitrophenol	88–75–5
p-Nitrophenol; 4-Nitrophenol	100–02–7
N-Nitrosodi-n-butylamine	924–16–3
N-Nitrosodiethylamine	55–18–5
N-Nitrosodimethylamine	62–75–9
N-Nitrosodiphenylamine	86–30–6
N-Nitrosodipropylamine; N-Nitroso-N-dipropylamine;. Di-n-propylnitrosamine	621–64–7
N-Nitrosomethylethalamine	10595–95–6
N-Nitrosopiperidine	100–75–4
N-Nitrosopyrrolidine	930–55–2
5-Nitro-o-toluidine	99–55–8
Parathion	56–38–2
Pentachlorobenzene	608–93–5
Pentachloronitrobenzene	82–68–8
Pentachlorophenol	87–86–5
Phenacetin	62–44–2
Phenanthrene	85–01–8
Phenol	108–95–2
p-Phenylenediamine	106–50–3
Phorate	298–02–2
Polychlorinated biphenyls; PCBs;.	Footnote [13]
Pronamide	23950–58–5
Propionitrile; Ethyl cyanide	107–12–0
Pyrene	129–00–0
Safrole	94–59–7
Selenium	(Total)
Silver	(Total)
Silvex; 2,4,5-TP	93–72–1
Styrene	100–42–5
Sulfide	18496–25–8

[13] Polychlorinated biphenyls (CAS RN 1336–36–3); this category contains congener chemicals, including constituents of Aroclor 1016 (CAS RN 12674–11–2), Aroclor 1221 (CAS RN 11104–28–2), Aroclor 1232 (CAS RN 11141–16–5), Aroclor 1242 (CAS RN 53469–21–9), Aroclor 1248 (CAS RN 12672–29–6), Aroclor 1254 (CAS RN 11097–69–1), and Aroclor 1260 (CAS RN 11096–82–5).

2,4,5-T; 2,4,5-Trichlorophenoxyacetic acid	93–76–5
2,3,7,8-TCDD; 2,3,7,8-Tetrachlorodibenzo-p-dioxin	1746–01–6
1,2,4,5-Tetrachlorobenzene	95–94–3
1,1,1,2-Tetrachloroethane	630–20–6
1,1,2,2-Tetrachloroethane	79–34–5
Tetrachloroethylene; Tetrachloroethene; Perchloroethylene	127–18–4
2,3,4,6-Tetrachlorophenol	58–90–2
Thallium	(Total)
Tin	(Total)
Toluene	108–88–3
o-Toluidine	95–53–4
Toxaphene	Footnote [14]
1,2,4-Trichlorobenzene	120–82–1
1,1,1-Trichloroethane; Methylchloroform.	71–55–6
1,1,2-Trichloroethane	79–00–5
Trichloroethylene; Trichloroethene	79–01–6
Trichlorofluoromethane; CFC-11	75–69–4
2,4,5-Trichlorophenol	95–95–4
2,4,6-Trichlorophenol	88–06–2
1,2,3-Trichloropropane	96–18–4
O,O,O-Triethyl phosphorothioate	126–68–1
sym-Trinitrobenzene	99–35–4
Vanadium	(Total)
Vinyl acetate	108–05–4
Vinyl chloride; Chloroethene	75–01–4
Xylene (total)	Footnote [15]
Zinc	(Total)

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

Appendix VI. LEACHATE TESTING PARAMETERS FOR CLASS THREE LANDFILLS

1. BOD
2. TOC
3. COD
4. Total Suspended Solids
5. TKN Nitrogen
6. Ammonia Nitrogen
7. Nitrate
8. Total Phosphorus
9. Alkalinity as CaCO3
10. Total Hardness as CaCO3
11. pH
12. Calcium
13. Magnesium
14. Potassium
15. Sodium
16. Chloride
17. Sulfate
18. Total Iron
19. VOC's Listed in Appendix III

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

61–107.279. SOLID WASTE MANAGEMENT: USED OIL.

[14] Toxaphene: This entry includes congener chemicals contained in technical toxaphene (CAS RN 8001–35–2), i.e., chlorinated camphene.

[15] Xylene (total): This entry includes o-xylene (CAS RN 96–47–6), m-xylene (CAS RN 108–38–3), p-xylene (CAS RN 106–42–3), and unspecified xylenes (dimethylbenzenes) (CAS RN 1330–20–7).

SUBPART A: Definitions.
SUBPART B: Applicability.
SUBPART C: Standards for Used Oil Generators.
SUBPART D: Standards for Used Oil Collection Centers and Aggregation Points.
SUBPART E: Standards for Used Oil Transporter and Transfer Facilities.
SUBPART F: Standards for Used Oil Processors and Re-refiners.
SUBPART G: Standards for Burners Who Burn Off-Specification Used Oil for Energy Recovery.
SUBPART H: Standards for Used Oil Fuel Marketers.
SUBPART I: Disposal of Used Oil.
SUBPART J: Retail Sales Requirements.
SUBPART K: Monitoring.
SUBPART L: Used Oil Filter Management.
SUBPART M: Penalties.
SUBPART N: Severability.
SUBPART O: Variances.

SUBPART A
Solid Waste Management: Used Oil.

279.1. Definitions.

Terms that are defined in the South Carolina Hazardous Waste Management Regulations R.61-79.260.10, and 261.1, and South Carolina Underground Storage Tank Control Regulations R.61-92.280.12 but are not defined in this regulation have the same meanings when used in this regulation.

a. "Aboveground tank" means a tank used exclusively to store or process used oil that is not an underground storage tank as defined in the South Carolina Underground Storage Tank Control Regulations, R.61-92.280.12.

b. "Container" means any portable device in which a material is stored, transported, treated, disposed of, or otherwise handled.

c. "Department" means the South Carolina Department of Health and Environmental Control.

d. "Do-it-yourselfer used oil collection center" means any site or facility that accepts/aggregates and stores used oil collected only from household do-it-yourselfers.

e. "Energy recovery" means the beneficial use, reuse, recycling, or reclamation of solid waste through the use of the waste to recover energy therefrom.

f. "Existing tank" means a tank that is used for the storage or processing of used oil and that is in operation, or for which installation has commenced on or prior to the effective date of the authorized used oil program for the State in which the tank is located. Installation will be considered to have commenced if the owner or operator has obtained all federal, state, and local approvals or permits necessary to begin installation of the tank and if either (1) a continuous on-site installation program has begun, or (2) the owner or operator has entered into contractual obligations —which cannot be canceled or modified without substantial loss —for installation of the tank to be completed within a reasonable time.

g. "Facility" means all contiguous land, structures, other appurtenances and improvements on the land used for treating, storing, or disposing of solid waste. A facility may consist of several treatment, storage, or disposal operational units, including, but not limited to, one or more landfills, surface impoundments, or combination thereof.

h. "Hazardous substance" means any substance the Environmental Protection Agency (EPA) has designated for special consideration under the Clean Air Act (CAA), Clean Water Act (CWA), or Toxic Substances Control Act (TSCA), and any hazardous waste, as defined.

i. "Hazardous waste" has the meaning provided in Section 44-56-20 of the South Carolina Hazardous Waste Management Act.

j. "Hot-drained" means that the oil filter is drained near engine operating temperature and above room temperature.

k. "Household 'do-it-yourselfer' used oil" means used oil that is derived from households, such as used oil generated by individuals who generate used oil through the maintenance of their personal vehicles.

l. "Household 'do-it-yourselfer' used oil generator" means an individual who generates household "do-it-yourselfer" used oil.

m. "Landfill" means a disposal facility or part of a facility where solid waste is placed in or on land, and which is not a land treatment facility, a surface impoundment, or an injection well.

n. "Motor oil" and "similar lubricants" mean the fraction of crude oil or synthetic oil that is classified for the use in the crankcase, transmission, gearbox, or differential of an internal combustion engine, including automobiles, buses, trucks, lawn mowers and other household power equipment, industrial machinery, and other mechanical devices that derive their power from internal combustion engines. The terms include re-refined oil but do not include heavy greases and specialty industrial or machine oils, such as spindle oils, cutting oils, steam cylinder oils, industrial oils, electrical insulating oils, or solvents which are not sold at retail in this State.

o. "New tank" means a tank that will be used to store or process used oil and for which installation has commenced after the effective date of this regulation.

p. "Owner/operator" means the person who owns the land on which a solid waste management facility is located or the person who is responsible for the overall operation of the facility, or both.

q. "Person" means an individual, corporation, company, association, partnership, unit of local government, state agency, federal agency, or other legal entity.

r. "Petroleum refining facility" means an establishment primarily engaged in producing gasoline, kerosene, distillate fuel oils, residual fuel oils, and lubricants, through fractionation, straight distillation of crude oil, re-distillation of unfinished petroleum derivatives, cracking or other processes (i.e., facilities classified as SIC 2911).

s. "Processing" means chemical or physical operations designed to produce from used oil, or to make used oil more amenable for production of, fuel oils, lubricants, or other used oil-derived product. Processing includes, but is not limited to: blending used oil with virgin petroleum products, blending used oils to meet the fuel specification, filtration, simple distillation, chemical or physical separation and re-refining.

t. "Re-refining distillation bottoms" means the heavy fraction produced by vacuum distillation of filtered and dehydrated used oil. The composition of still bottoms varies with column operation and feedstock.

u. "Recycling" means any process by which materials which would otherwise become solid waste, are separated or processed and reused or returned to use in the form of raw materials or products (including composting).

v. "Resource recovery" means the process of obtaining material or energy resources from solid waste which no longer has any useful life in its present form and preparing the waste for recycling.

w. "Tank" means any stationary device, designed to contain an accumulation of used oil which is constructed primarily of non-earthen materials (e.g., wood, concrete, steel, plastic) which provides structural support.

x. "Terne plated" means oil filters which are plated with an alloy of tin and lead.

y. "Used oil" means any oil which has been refined from crude or synthetic oil and, as a result of use, storage, or handling, has become unsuitable for its original purpose due to the presence of impurities or loss of original properties, but which may be suitable for further use and may be economically recyclable.

z. "Used oil aggregation point" means any site or facility that accepts, aggregates, and/or stores used oil collected only from other used oil generation sites owned or operated by the owner or operator of the aggregation point, from which used oil is transported to the aggregation point in shipments of no more than 55 gallons. Used oil aggregation points may also accept used oil from household do-it-yourselfers.

aa. "Used oil burner" means a facility where used oil not meeting the specification requirements in 279.11 is burned for energy recovery in devices identified in 279.61.a.

bb. "Used oil collection center" means a facility which, in the course of business, accepts used oil for subsequent disposal or recycling. Used oil collection centers may also accept used oil from household do-it-yourselfers.

cc. "Used oil generator" means any person, by site, whose act or process produces used oil or whose act first causes used oil to become subject to regulation.

dd. "Used oil fuel marketer" means any person who conducts either of the following activities:

(i) Directs a shipment of off-specification used oil from their facility to a used oil burner; or

(ii) First claims that used oil that is to be burned for energy recovery meets the used oil fuel specifications set forth in 279.11 of this regulation.

ee. "Used oil processor/re-refiner" means a facility that processes used oil.

ff. "Used oil transfer facility" means any transportation related facility including loading docks, parking areas, storage areas and other areas where shipments of used oil are held for more than 24 hours and not longer than 35 days during the normal course of transportation or prior to an activity performed pursuant to 279.20(b)(2). Transfer facilities that store used oil for more than 35 days are subject to regulation under subpart F of this part.

gg. "Used oil transporter" means any person who transports used oil, any person who collects used oil from more than one generator and transports the collected oil, and owners and operators of used oil transfer facilities. Used oil transporters may consolidate or aggregate loads of used oil for purposes of transportation but, with the following exception, may not process used oil. Transporters may conduct incidental processing operations that occur in the normal course of used oil transportation (e.g., settling and water separation), but that are not designed to produce (or make more amenable for production of) used oil derived products or used oil fuel.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART B
APPLICABILITY.

279.10. Applicability.

a. Except as provided in 279.11, the regulations of this part apply to used oil, and to materials identified in this section as being subject to regulation as used oil, whether or not the used oil or material exhibits any characteristics of hazardous waste identified in R.61-79.261.

b. Mixtures of used oil and hazardous waste.

(1) Listed hazardous waste.

(a) Mixtures of used oil and hazardous waste that are listed in Subpart D of R.61-79.261 are subject to regulation as hazardous waste under R.61-79.260 through 266, 268, 270, and 124, rather than as used oil under this regulation.

(b) Used oil containing more than 1,000 ppm total halogens is presumed to be a hazardous waste because it has been mixed with halogenated hazardous waste listed in Subpart D of R.61-79.261. Persons may rebut this presumption by demonstrating that the used oil does not contain hazardous waste (for example, by using an analytical method from SW-846, Edition III, to show that the used oil does not contain significant concentrations of halogenated hazardous constituents listed in Appendix VIII of R.61-79.261).

(i) The rebuttable presumption does not apply to metalworking oils/fluids containing chlorinated paraffins, if they are processed, through a tolling arrangement as described in 279.24.c, to reclaim metalworking oils/fluids. The presumption does apply to metalworking oils/fluids if such oils/fluids are recycled in any other manner, or disposed.

(ii) The rebuttable presumption does not apply to used oils contaminated with chlorofluorocarbons (CFCs) reclaimed to the extent possible from refrigeration units where the CFCs are destined for reclamation. The rebuttable presumption does apply to used oils contaminated with CFCs that have been mixed with used oil from sources other than refrigeration units.

(2) Mixtures of used oil and hazardous waste that solely exhibit one or more or the hazardous waste characteristics identified in subpart C of R.61-79.261 and mixtures of used oil and hazardous waste that are listed in subpart D solely because they exhibit one or more of the characteristics of hazardous waste identified in subpart C are subject to:

(a) Except as provided in paragraph b.(2)(c) of this regulation, regulation as hazardous waste under R.61-79.260 through 266, 268, 270, and 124 rather than as used oil under this regulation, if the resultant mixture exhibits any characteristics of hazardous waste identified in Subpart C of R.61-79.261; or

(b) Except as specified in paragraph b.(2)(c), regulation as used oil under this regulation, if the resultant mixture does not exhibit any characteristics of hazardous waste identified under Subpart C of R.61-79.261.

(c) Regulation as used oil under this regulation, if the mixture is of used oil and a waste which is hazardous solely because it exhibits the characteristic of ignitability (e.g., ignitable-only mineral spirits) and is not listed in Subpart D of R.61-79.261, provided that the mixture does not exhibit the characteristic of ignitability under R.61-79.261.21.

(3) Mixtures of used oil and conditionally exempt small quantity generator hazardous waste regulated under R.61-79.261.5 are subject to regulation as used oil under this regulation.

c. Materials containing or otherwise contaminated with used oil.

(1) Except as provided in paragraph c.(2) of this section, materials containing or otherwise contaminated with used oil waste from which the used oil has been properly drained or removed to the extent possible such that no visible signs of free-flowing oil remain in or on the solid waste are:

(a) Not used oil and thus not subject to this regulation; and

(b) Solid wastes, and if the materials are listed or identified as hazardous waste, are subject to the hazardous waste regulations R.61-79.260 through 266, 268, 270, and 124.

(2) Materials containing or otherwise contaminated with used oil that are burned for energy recovery are subject to regulation as used oil under this regulation.

(3) Used oil drained or removed from materials containing or otherwise contaminated with used oil is subject to regulation as used oil under this regulation.

d. Mixtures of used oil with other fuel products.

(1) Except as provided in paragraph d.(2) of this section, mixtures of used oil and fuels or other fuel products are subject to regulation as used oil under this regulation.

(2) Mixtures of used oil and diesel fuel mixed on-site by the generator of the used oil for use in the generator's own vehicles are not subject to this regulation once the used oil and diesel fuel have been mixed. Prior to mixing, the used oil is subject to the requirements of Subpart C of this regulation.

e. Materials derived from used oil.

(1) Materials that are reclaimed from used oil that are used beneficially and are not burned for energy recovery or used in a manner constituting disposal (e.g., re-refined lubricants) are:

(a) Not used oil and thus are not subject to this regulation, and

(b) Not solid wastes and are thus not subject to the hazardous waste regulations of R.61-79.260 through 266, 268, 270, and 124 as provided in R.61-79.261.3(c)(2)(i).

(2) Materials produced from used oil that are burned for energy recovery (e.g., used oil fuels) are subject to regulation as used oil under this regulation.

(3) Except as provided in paragraph e.(4) of this section, materials derived from used oil that are disposed of or used in a manner constituting disposal are:

(a) Not used oil and thus are not subject to this regulation, and

(b) Are solid wastes and thus are subject to the hazardous waste regulations of R.61-79.260 through 266, 268, 270, and 124 if the materials are listed or identified as hazardous waste.

(4) Used oil re-refining distillation bottoms that are used as feedstock to manufacture asphalt products are not subject to this regulation.

f. Wastewater, the discharge of which is subject to regulation under either Section 402 or Section 307(b) of the Clean Water Act (including wastewaters at facilities which have eliminated the discharge of wastewater), contaminated with de minimis quantities of used oil are not subject to the requirements of this regulation. For purposes of this paragraph, "de minimis" quantities of used oils are defined as small spills, leaks, or drippings from pumps, machinery, pipes, and other similar equipment during normal operations or small amounts of oil lost to the wastewater treatment system during washing or draining operations. This exception will not apply if the used oil is discarded as a result of abnormal manufacturing operations resulting in substantial leaks, spills, or other releases, or to used oil recovered from wastewaters.

g. Used oil introduced into crude oil pipelines or a petroleum refining facility.

(1) Used oil mixed with crude oil or natural gas liquids (e.g., in a production separator or crude oil stock tank) for insertion into a crude oil pipeline is exempt from the requirements of this part. The used oil is subject to the requirements of this part prior to the mixing of used oil with crude oil or natural gas liquids.

(2) Mixtures of used oil and crude oil or natural gas liquids containing less than 1% used oil that are being stored or transported to a crude oil pipeline or petroleum refining facility for insertion into the refining process at a point prior to crude distillation or catalytic cracking are exempt from the requirements of this regulation.

(3) Used oil that is inserted into the petroleum refining facility process before crude distillation or catalytic cracking without prior mixing with crude oil constitutes less than 1% of the crude oil feed to any petroleum refining facility process unit at any given time. Prior to insertion into the petroleum refining facility process, the used oil is subject to the requirements of this part.

(4) Except as provided in paragraph (g)(5) of this section, used oil that is introduced into a petroleum refining facility process after crude distillation or a catalytic cracking is exempt from the requirements of this part only if the used oil meets the specification of R.61-79.11. Prior to insertion into the petroleum refining facility process, the used oil is subject to the requirements of the regulation.

(5) Used oil that is incidentally captured by a hydrocarbon recovery system or wastewater treatment system as part of routine process operations at a petroleum refining facility and inserted into the petroleum refining facility process is exempt from the requirements of this part. This exemption does not extend to used oil which is intentionally introduced into a hydrocarbon recovery system (e.g, by pouring collected used oil into the wastewater treatment system).

(6) Tank bottoms from stock tanks containing exempt mixtures of used oil and crude oil or natural gas liquids are exempt from the requirements of this part.

h. Used oil produced on vessels from normal shipboard operations is not subject to this regulation until it is transported ashore.

i. Used oil containing PCBs. Used oil containing PCBs (as defined in 40 CFR 761.3) at any concentration less than 50 ppm is subject to the requirements of this regulation unless, because of dilution, it is regulated under 40 CFR Part 761 as a used oil containing PCBs at 50 ppm or greater. PCB-containing used oil subject to the requirements of this regulation may also be subject to the prohibitions and requirements found at 40 CFR Part 761, including 761.20(d) and (e). Used oil containing PCBs at concentrations of 50 ppm or greater is not subject to the requirements of this regulation, but is subject to regulation under 40 CFR Part 761. No person may avoid these provisions by diluting used oil containing PCBs, unless otherwise specifically provided for in this regulation or 40 CFR Part 761.

j. All used oil fuel marketer permits issued by the Department prior to the effective date of this regulation shall terminate on the effective date of this regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.11. Used Oil Specifications.

Used oil burned, and any fuel produced from used oil by processing, blending, or other treatment, is subject to regulation under this regulation unless it is shown not to exceed any of the allowable levels of the constituents and properties in the specification shown in Table 1 below. Once used oil that is to

be burned has been shown not to exceed any specification and the person making that showing complies with 279.72, 279.73, and 279.74.b., the used oil is no longer subject to this regulation.

Table: USED OIL NOT EXCEEDING ANY ALLOWABLE LEVEL SHOWN BELOW IS NOT SUBJECT TO THIS PART WHEN BURNED FOR ENERGY RECOVERY [1]

Constituent/property	Allowable level
Arsenic	5 ppm maximum.
Cadmium	2 ppm maximum.
Chromium	10 ppm maximum.
Lead	100 ppm maximum.
Flash point	100 degrees F minimum.
Total halogens	4,000 ppm maximum.[2]
Note: Applicable standards for the burning of used oil containing PCBs are imposed by 40 CFR 761.20(e)	

[1] The allowable levels do not apply to mixtures of used oil and hazardous waste that continue to be regulated as hazardous waste (see 279.10(b))

[2] Used oil containing more than 1,000 ppm total halogens is presumed to be a hazardous waste under the rebuttable presumption provided under 279.10.b.(1). Such used oil is subject to Subpart H of R.61–79.266 rather than this regulation when burned for energy recovery unless the presumption of mixing can be successfully rebutted.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.12. Prohibitions.

a. Used oil shall not be managed in surface impoundments or waste piles unless the units are subject to regulation under R.61-79.264 or 265.

b. No person shall utilize used oil for road oiling, dust control, weed abatement, or other similar uses which have potential to cause harm to the environment.

c. Off-specification used oil fuel may be burned only in the following devices:

(1) Industrial furnaces identified in R.61-79.260.10;

(2) Boilers, as defined in R.61-79.260.10, that are identified as follows:

(a) Industrial boilers located on the site of a facility engaged in a manufacturing process where substances are transformed into new products, including the component parts of products, by mechanical or chemical processes;

(b) Utility boilers used to produce electric power, steam, heated or cooled air, or other gases or fluids for sale; or

(c) Used oil-fired space heaters provided that the burner meets the provisions of 279.23 of Subpart C.

(3) Hazardous waste incinerators subject to regulation under Subpart O of R.61-79.264 or 265.

d. No person shall knowingly mix or commingle used oil with municipal solid waste that is to be disposed in a municipal solid waste landfill, discard or otherwise dispose of used oil, except by delivery to a used oil collection facility, used oil energy recovery facility, oil recycling facility, or to an authorized agent for delivery to a used oil collection facility, used oil energy recovery facility, or oil recycling facility.

e. No person shall knowingly dispose of used oil in a solid waste disposal facility unless such disposal is approved by the Department.

f. No person shall knowingly place in a solid waste disposal facility wipers (shop towels, rags and industrial wipers) or sorptive materials (clays and diatomaceous earths) which are capable of releasing

free flowing used oil. For the purposes of this regulation, free flowing used oil means any material determined to contain "free liquids" as defined by Method 9095 (Paint Filter Liquids Test), as described in "Test Methods for Evaluating Solid Wastes, Physical/Chemical Methods" (EPA Pub. No. SW-846).

g. No person shall knowingly collect, transport, store, recycle, use or dispose of used oil in any manner which endangers public health or welfare or the environment.

h. No person shall knowingly discharge used oil into sewers, drainage systems, septic tanks, surface water or groundwater, or any other waters of this State, or onto the ground.

i. No person shall knowingly mix or commingle used oil with hazardous substances that make it unsuitable for recycling or beneficial use.

j. Notwithstanding any other provision of law, any person who knowingly disposes of any used oil which has not been properly segregated or separated from other solid wastes by the generator is guilty of a violation of this subsection.

k. No person shall knowingly violate any applicable South Carolina Air Pollution Control Regulations and Standards (R.61-62).

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.13. Exemptions.

The following activities are exempted from the permitting requirements of this regulation, but must comply with the used oil management standards set forth in this regulation:

a. an electric utility, an industrial facility or a governmental organization which generates during its operation used oil that is then reused, recycled, or refined on-site by the electric utility, an industrial facility or a governmental organization for use in its operations, or

b. the use of used oil for the benefication or flotation of phosphate rock.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART C
STANDARDS FOR USED OIL GENERATORS.

279.20. Applicability.

a. Except as provided in paragraphs a.(1) through a.(4) of this section, this subpart applies to all used oil generators. A used oil generator is any person, by site, whose act or process produces used oil or whose act first causes used oil to become subject to regulation.

(1) Household "do-it-yourselfer" used oil generators are not subject to regulation under this regulation.

(2) Vessels at sea or at port are not subject to this subpart. For purposes of this subpart, used oil produced on vessels from normal shipboard operations is considered to be generated at the time it is transported ashore. The owner or operator of the vessel and the person(s) removing or accepting used oil from the vessel are co-generators of the used oil and are both responsible for managing the waste in compliance with this subpart once the used oil is transported ashore. The co-generators may decide among them which party will fulfill the requirements of this subpart.

(3) Mixtures of used oil and diesel fuel mixed by the generator of the used oil for use in the generator's own vehicles are not subject to this regulation once the used oil and diesel fuel have been mixed. Prior to mixing, the used oil fuel is subject to the requirements of this subpart.

(4) Farmers who generate an average of 25 gallons per month or less of used oil from vehicles or machinery used on the farm in a calendar year are not subject to the requirements of this regulation.

b. Used oil generators who conduct the following activities are subject to the requirements of other applicable provisions of this regulation as indicated below.

(1) Generators who transport used oil, except under the self-transport provisions of 279.24.a. and b. of this regulation, must also comply with Subpart E: Standards for Used Oil Transporters and Transfer Facilities of this regulation.

(2) Generators who process or re-refine used oil must also comply with Subpart F: Standards for Used Oil Processors and Re-refiners of this regulation.

(3) Generators who burn off-specification used oil for energy recovery, except under the on-site space heater provisions of 279.23 of this regulation, must also comply with Subpart G: Standards for Used Oil Burners who Burn Off-Specification Used Oil for Energy Recovery of this regulation.

(4) Generators who direct shipments of off-specification used oil from their facility to a used oil burner or first claim that used oil that is to be burned for energy recovery meets the used oil fuel specifications set forth in 279.11 of this regulation must also comply with Subpart H: Standards for Used Oil Fuel Marketers of this regulation.

(5) Generators who perform the following activities are not processors provided that the used oil is generated on-site and is not being sent off-site to a burner of on-or off-specification used oil fuel.

(a) Filtering, cleaning or otherwise reconditioning used oil before returning it for reuse by the generator;

(b) Separating used oil from wastewater generated on-site to make the wastewater acceptable for discharge or reuse pursuant to section 402 or section 307(b) of the Clean Water Act or other applicable Federal or state regulations governing the management or discharge of wastewaters;

(c) Using oil mist collectors to remove small droplets of used oil from in-plant air to make plant air suitable for continued recirculation;

(d) Draining or otherwise removing used oil from materials containing or otherwise contaminated with used oil in order to remove excessive oil to the extent possible pursuant to the regulation, or;

(e) Filtering, separating or otherwise reconditioning used oil before burning it in a space heater pursuant to the regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.21. Hazardous Waste Mixing.

a. Mixtures of used oil and hazardous waste must be managed in accordance with 279.10.b.

b. The rebuttable presumption for used oil of 279.10.b.(1)(b) applies to used oil managed by generators.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.22. Used Oil Storage.

a. Used oil generators shall not store used oil in units other than tanks, containers, or units subject to regulation under R.61-79.264 or 265.

b. Containers and aboveground tanks used to store used oil at generator facilities must be:

(1) In good condition (no severe rusting, apparent structural defects or deterioration);

(2) Not leaking (no visible leaks); and

(3) Closed to prevent spillage or contamination from precipitation.

c. Labels.

(1) Containers and aboveground tanks used to store used oil at generator facilities must be labeled or marked clearly with the words "Used Oil."

(2) Fill pipes used to transfer used oil into underground storage tanks at generator facilities must be labeled or marked clearly with the words "Used Oil."

d. Upon detection of a release of used oil to the environment not subject to the requirements of the Underground Storage Tank Control Regulations R.61-92 Part 280 Subpart F which has occurred in South Carolina, a generator must perform the following cleanup steps:

(1) Stop the release;

(2) Contain the released used oil;

(3) Clean up and manage properly the released used oil and other materials; and

(4) If necessary to prevent future releases, repair or replace any leaking used oil storage containers or tanks prior to returning them to service.

e. Used oil generators are subject to all applicable Spill Prevention, Control and Countermeasures (40 CFR Part 112) in addition to the requirements of this subpart. Used oil generators are also subject to R.61-92.280 standards for used oil stored in underground tanks whether or not the used oil exhibits any characteristics of hazardous waste, in addition to the requirements of this subpart.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.23. On-site Burning in Space Heaters.

a. Generators may burn used oil in used oil-fired space heaters provided that:

(1) The heater burns only used oil that the owner or operator generates or used oil received from household do-it-yourself used oil generators;

(2) The heater is designed to have a maximum capacity of not more than 0.5 million Btu per hour; and

(3) The combustion gases from the heater are vented to outside ambient air.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.24. Off-site Shipments.

Except as provided in paragraphs a. through c. of this section, generators must ensure that their used oil is transported only by transporters who have obtained a Department identification number and a permit from the Department.

a. Generators may transport, without an EPA identification number and a Department registration, used oil that is generated at the generator's site and used oil collected from household do-it-yourselfers to a used oil collection center provided that:

(1) The generator transports the used oil in a vehicle owned by the generator or owned by an employee of the generator;

(2) The generator transports no more than 55 gallons of used oil at any time; and

(3) The generator transports the used oil to a used oil collection center that is registered by the Department to manage used oil.

b. Generators may transport, without an EPA identification number and a Department registration, used oil that is generated at the generator's site to an aggregation point provided that:

(1) The generator transports the used oil in a vehicle owned by the generator or owned by an employee of the generator;

(2) The generator transports no more than 55 gallons of used oil at any time; and

(3) The generator transports the used oil to an aggregation point that is owned and/or operated by the same generator.

c. Used oil generators may arrange for used oil to be transported by a transporter without an EPA identification number and a Department registration if the used oil is reclaimed under a contractual agreement pursuant to which reclaimed oil is returned by the processor/re-refiner to the generator for use as a lubricant, cutting oil, or coolant. The contract (known as a "tolling arrangement") must indicate:

(1) The type of used oil and the frequency of shipments;

(2) That the vehicle used to transport the used oil to the processing/re-refining facility and to deliver recycled used oil back to the generator is owned and operated by the used oil processor/re-refiner; and

(3) That reclaimed oil will be returned to the generator.

d. Used oil generators shall maintain a copy of the used oil manifest provided by the used oil transporter. A copy of each used oil manifest shall be maintained by the generator for a minimum of three (3) years.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART D
STANDARDS FOR USED OIL COLLECTION CENTERS AND AGGREGATION POINTS.

279.30. Do-It-Yourselfer Used Oil Collection Centers.

a. This section applies to owners or operators of all do-it-yourselfer (DIY) used oil collection centers. A DIY used oil collection center is any site or facility that accepts/aggregates and stores used oil collected only from household do-it-yourselfers.

b. Owners or operators of all DIY used oil collection centers must comply with the generator standards in Subpart C of this regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.31. Used Oil Collection Centers.

a. This section applies to owners or operators of used oil collection centers. A used oil collection center is any site or facility that accepts/aggregates and stores used oil collected from used oil generators regulated under Subpart C of this regulation who bring used oil to the collection center in shipments of no more than 55 gallons under the provisions of 279.24.a. Used oil collection centers may also accept used oil from household do-it-yourselfers.

b. Owners or operators of all used oil collection centers must:

(1) Comply with the generator standards in Subpart C of this regulation;

(2) Be registered by the Department to manage used oil;

(3) Obtain a registration from the Department prior to first accepting used oil at the site. All used oil collection centers in operation at the effective date of this regulation shall submit an application for a registration from the Department within ninety (90) days; and,

(4) Submit to the Department on or before March 15, an annual report for the previous year which contains at a minimum the following information:

(a) if the collection facility is accepting used oil from the public;

(b) the quantities of used oil collected in the previous year;

(c) the total quantity of used oil handled in the previous year; and,

(d) where the used oil is being recycled or processed.

c. All used oil collection facilities shall notify the Department in writing if they intend to cease the collection of used oil. Closure shall consist of, at a minimum, the removal of all oil collected at the site, dismantling and removal or proper cleaning and capping of all collection equipment and ancillary equipment, and removal and proper disposal or treatment of any oil stained soils. Further assessment and remediation, if necessary, shall be directed by the Department.

d. Containers and tanks used to store used oil at collection centers must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest tank or container.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dikes, berms, or retaining walls.

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.32. Used Oil Aggregation Points Owned By the Generator.

a. This section applies to owners or operators of all used oil aggregation points. A used oil aggregation point is any site or facility that accepts, aggregates, and/or stores used oil collected only from other used oil generation sites owned or operated by the owner or operator of the aggregation

point, from which used oil is transported to the aggregation point in shipments of no more than 55 gallons under the provisions of 279.24.b. Used oil aggregation points may also accept used oil from household do-it-yourselfers.

b. Owners or operators of all used oil aggregation points must comply with the generator standards in Subpart C of this regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.33. Petroleum Fund.

a. No person may recover from the owner or operator of a registered used oil collection facility that accepts used oil from the public (do-it-yourselfers) in five (5) gallon or less quantities any costs of response actions resulting from a release of either used oil or a hazardous substance from a used oil collection facility if such used oil is:

(1) not mixed with any hazardous substance by the owner or operator of the used oil collection facility;

(2) not knowingly accepted with any hazardous substances contained in it;

(3) from the public (do-it-yourselfers) and stored in a separate collection container;

(4) transported from the used oil collection facility by a registered used oil transporter; and,

(5) collected in a used oil collection facility that is in compliance with this subpart.

b. If a hazardous substance is found to be mixed with used oil accepted from the public at a registered used oil collection facility, any costs for the proper disposal of this contaminated waste will be incurred by the Petroleum Fund, if no more than five (5) gallons of used oil was accepted from any one person at any one time. This subsection applies to that portion of the used oil collection facility utilized for the collection of used oil and does not apply if the owner or operator is grossly negligent in the operation of the public used oil collection facility. Nothing in this section shall affect or modify in any way the obligations or liability of any person under any other provisions of state or federal law, including common law, for injury or damage resulting from the release of used oil or hazardous substances. For the purpose of this subsection, the owner or operator of a used oil collection facility may presume that a quantity of no more than five (5) gallons of used oil accepted from any member of the public is not mixed with a hazardous substance, if the owner or operator acts in good faith and in the belief the oil is generated from the individual's personal activity.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART E
STANDARDS FOR USED OIL TRANSPORTER AND TRANSFER FACILITIES.

279.40. Applicability.

a. Except as provided in paragraphs a.(1) through a.(4) of this section, this subpart applies to all used oil transporters. Used oil transporters are persons who transport used oil, persons who collect used oil from more than one generator and transport the collected oil, and owners and operators of used oil transfer facilities.

(1) This subpart does not apply to on-site transportation.

(2) This subpart does not apply to generators who transport shipments of used oil totalling 55 gallons or less from the generator to a used oil collection center as specified in 279.24.a. of this regulation.

(3) This subpart does not apply to generators who transport shipments of used oil totalling 55 gallons or less from the generator to a used oil aggregation point owned or operated by the same generator as specified in 279.24.b. of this regulation.

(4) This subpart does not apply to transportation of used oil from household do-it-yourselfers to a regulated used oil generator, collection center, aggregation point, processor/re-refiner, or burner subject to the requirements of this regulation. Except as provided in paragraphs a.(1) through a.(3) of this section, this subpart does, however, apply to transportation of collected household do-it-yourselfer used oil from regulated used oil generators, collection centers, aggregation points, or other facilities where household do-it-yourselfer used oil is collected.

b. Transporters who import used oil from abroad or export used oil outside of the United States are subject to the requirements of this subpart from the time the used oil enters and until the time it exits the United States.

c. Unless trucks previously used to transport hazardous waste are emptied as described in R.61-79.261.7 prior to transporting used oil, the used oil is considered to have been mixed with the hazardous waste and must be managed as hazardous waste unless, under the provisions of 279.10.b. of this regulation, the hazardous waste/used oil mixture is determined not to be hazardous waste.

d. Used oil transporters who conduct the following activities are also subject to other applicable provisions of this regulation as indicated below:

(1) Transporters who generate used oil must also comply with Subpart C: Standards for Used Oil Generators of this regulation;

(2) Transporters who process or re-refine used oil, except as provided in 279.41, must also comply with Subpart F: Standards for Used Oil Processors and Re-refiners of this regulation;

(3) Transporters who burn off-specification used oil for energy recovery must also comply with Subpart G: Standards for Used Oil Burners who Burn Off-Specification Used Oil for Energy Recovery of this regulation; and

(4) Transporters who direct shipments of off-specification used oil from their facility to a used oil burner or first claim that used oil that is to be burned for energy recovery meets the used oil fuel specifications set forth in 279.11 of this regulation must also comply with Subpart H of this regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.41. Restrictions on Transporters Who Are Not Also Processors or Re-refiners.

a. Used oil transporters may consolidate or aggregate loads of used oil for purposes of transportation. However, except as provided in paragraph b. of this section, used oil transporters may not process used oil unless they also comply with the requirements for processors/re-refiners in Subpart F of this regulation.

b. Transporters may conduct incidental processing operations that occur in the normal course of used oil transportation (e.g., settling and water separation), but that are not designed to produce (or make more amenable for production of) used oil derived products unless they also comply with the processor/re-refiner requirements in Subpart F of this regulation.

c. Transporters of used oil that is removed from oil bearing electrical transformers and turbines and filtered by the transporter or at a transfer facility prior to being returned to its original use are not subject to the processor/re-refiner requirements in this regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.42. Notification and Insurance Requirements.

a. Used oil transporters that have previously notified EPA of hazardous waste and other used oil management activities and obtained an EPA identification number must also register with the Department to identify their used oil transportation activities.

b. A used oil transporter who has not received an EPA identification number may obtain one by notifying the Department of their used oil activity by submitting a completed SCDHEC Form 2701.

c. In addition to obtaining an EPA identification number, each transporter of used oil shall register with the Department. Registration shall be made by completion of an application form provided by the Department.

d. A transporter of used oil shall have and maintain financial responsibility for sudden and accidental occurrences in the amount of at least one million dollars ($1,000,000) per occurrence exclusive of legal defense costs. Coverage must provide for claims arising out of injury to persons, property or the environment including the spillage of used oil while such wastes are being transported and including the costs of cleaning up the spill. Such liability coverage must be maintained at all times while the registration is in force.

e. The financial responsibility required in subsection d. may be established by any one or a combination of the following:

(1) Evidence of liability insurance, either on a claim made or an occurrence basis, with or without a deductible, with the deductible, if any, to be on a per occurrence or per accident basis and not to exceed ten (10) percent of the equity of the registered transporter;

(2) self insurance, the level of which shall not exceed ten (10) percent equity of the registered transporter; or

(3) other evidence of financial responsibility approved by the Department.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.43. Used Oil Transportation.

a. A used oil transporter must deliver all used oil received to:

(1) Another used oil transporter, provided that the transporter has obtained an EPA identification number and is registered with the Department;

(2) A used oil processing/re-refining facility which has obtained an EPA identification number;

(3) An off-specification used oil burner facility which has obtained an EPA identification number; or

(4) An on-specification used oil burner facility.

b. Used oil transporters must comply with all applicable requirements under the US Department of Transportation regulations in 49 CFR parts 171-180. Persons transporting used oil that meets the definition of a hazardous material in 49 CFR 171.8 must comply with all applicable regulations in 49 CFR parts 171-180.

c. Used oil discharges.

(1) In the event of a discharge of used oil during transportation, the transporter must take appropriate immediate action to protect human health and the environment (e.g., notify local authorities, dike the discharge area).

(2) If a discharge of used oil occurs during transportation and an official (State or local government or a Federal Agency) acting within the scope of official responsibilities determines that immediate removal of the used oil is necessary to protect human health or the environment, that official may authorize the removal of the used oil by a transporter who is not registered with the Department.

(3) An air, rail, highway, or water transporter who has discharged used oil must:

(a) Give notice, if required by 49 CFR 171.15 to the National Response Center (800-424-8802 or 202-426-2675); and

(b) Report in writing as required by 49 CFR 171.16 to the Director, Office of Hazardous Materials Regulations, Materials Transportation Bureau, Department of Transportation, Washington, D.C. 20590.

(c) Immediately telephone the Department's 24-hour emergency telephone number (803) 253-6488, giving all requested information.

(4) A water transporter who has discharged used oil must give notice as required by 33 CFR 153.203.

(5) A transporter must clean up any used oil discharge that occurs during transportation or take such action as may be required or approved by federal, state, or local officials so that the used oil discharge no longer presents a hazard to human health or the environment. Further assessment and remediation, if necessary, shall be directed by the Department.

d. All registered used oil transporters shall show evidence of familiarity with laws and regulations governing used oil transportation by submitting a training program for approval by the Department which includes provisions for at least the following:

(1) compliance with state and federal regulations governing used oil;

(2) proper used oil management practices, including appropriate response action to any release or spill;

(3) introduction of a new employee to the applicable laws and rules before unsupervised driving of a used oil transportation vehicle;

(4) verification that company personnel handling or transporting used oil have successfully completed the training program. New employees directly involved with handling or transporting used oil shall complete the training program as soon as possible, but no later than ninety (90) days after beginning employment.

e. Any used oil transporter which transports used oil through South Carolina and does not stop to accept or deliver used oil is not subject to the requirements of this regulation, with the exception of sections 279.43.b. and 279.43.c.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.44. Rebuttable Presumption for Used Oil.

a. To ensure that used oil is not a hazardous waste under the rebuttable presumption of 279.10.b.(1)(b) of this regulation, the used oil transporter must determine whether the total halogen content of used oil being transported or stored at a transfer facility is above or below 1,000 ppm.

b. The transporter must make this determination by:

(1) Testing the used oil; or

(2) Applying knowledge of the halogen content of the used oil in light of the materials or processes used.

c. If the used oil contains greater than or equal to 1,000 ppm total halogens, it is presumed to be a hazardous waste because it has been mixed with halogenated hazardous waste listed in Subpart D of R.61-79.261. The owner or operator may rebut the presumption by demonstrating that the used oil does not contain hazardous waste (for example, by using an analytical method from SW-846, Edition III, to show that the used oil does not contain significant concentrations of halogenated hazardous constituents listed in Appendix VIII of R.61-79.261).

(1) The rebuttable presumption does not apply to metalworking oils/fluids containing chlorinated paraffins, if they are processed, through a tolling arrangement as described in 279.24.c., to reclaim metalworking oils/fluids. The presumption does apply to metalworking oils/fluids if such oils/fluids are recycled in any other manner, or disposed.

(2) The rebuttable presumption does not apply to used oils contaminated with chlorofluorocarbons (CFCs) removed from refrigeration units if the CFCs reclaimed to the extent possible are destined for reclamation. The rebuttable presumption does apply to used oils contaminated with CFCs that have been mixed with used oil from sources other than refrigeration units.

d. Records of analyses conducted or information used to comply with paragraphs a., b., and c. of this section must be maintained by the transporter for at least three (3) years.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.45. Used Oil Storage at Transfer Facilities.

a. This section applies to used oil transfer facilities. Used oil transfer facilities are transportation related facilities including loading docks, parking areas, storage areas, and other areas where shipments of used oil are held for more than twenty-four (24) hours during the normal course of transportation and not longer than thirty-five (35) days. Transfer facilities that store used oil for more than thirty-five (35) days are subject to regulation under Subpart F of this regulation.

b. Owners or operators of used oil transfer facilities may not store used oil in units other than tanks, containers, or units subject to regulation under R.61-79.264 or 265.

c. Containers and aboveground tanks used to store used oil at transfer facilities must be:

(1) In good condition (no severe rusting, apparent structural defects or deterioration);

(2) Not leaking (no visible leaks); and

(3) Closed to prevent spillage or contamination from precipitation.

d. Containers and tanks used to store used oil at transfer facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest tank or container.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dikes, berms, or retaining walls.

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

e. Existing aboveground tanks used to store used oil at transfer facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest tank.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dike, berm, or retaining wall except areas where existing portions of the tank meet the ground; or

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

f. New aboveground tanks used to store used oil at transfer facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest tank.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dike, berm, or retaining wall; or

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

g. Labeling.

(1) Containers and aboveground tanks used to store used oil at transfer facilities must be labeled or marked clearly with the words "Used Oil."

(2) Fill pipes used to transfer used oil into underground storage tanks at transfer facilities must be labeled or marked clearly with the words "Used Oil."

h. Upon detection of a release of used oil to the environment not subject to the requirements of R.61-92.280 Subpart F, the owner/operator of a transfer facility must perform the following cleanup steps:

(1) Stop the release;

(2) Contain the released used oil;

(3) Clean up and manage properly the released used oil and other materials; and

(4) If necessary, repair or replace any leaking used oil storage containers or tanks prior to returning them to service.

(5) Further assessment and remediation, if necessary, shall be directed by the Department.

i. Used oil transporters are subject to all applicable Spill Prevention, Control and Countermeasures (40 CFR Part 112) in addition to the requirements of this subpart. Used oil generators are also subject to R.61-92.280 standards for used oil stored in underground tanks whether or not the used oil exhibits any characteristics of hazardous waste, in addition to the requirements of this subpart.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.46. Manifesting and Reporting.

a. Used oil transporters must prepare a used oil manifest as designated by the Department for each used oil shipment accepted for transport. A copy of the used oil manifest shall accompany each vehicle at all times. Manifests for each shipment must include, at a minimum:

(1) The name and address of the generator, transporter, or processor/re-refiner who provided the used oil for transport;

(2) The EPA identification number (if applicable) of the generator, transporter, or processor/re-refiner who provided the used oil for transport;

(3) The quantity of used oil accepted;

(4) The date of acceptance; and

(5) The signature, dated upon receipt of the used oil, of a representative of the generator, transporter, or processor/re-refiner who provided the used oil for transport. Intermediate rail transporters are not required to sign the record of acceptance.

b. Used oil transporters must maintain manifests and keep a record of each shipment of used oil that is delivered to another used oil transporter, or to a used oil burner, processor/re-refiner, or disposal facility. Records of each delivery must include:

(1) The name and address of the receiving facility or transporter;

(2) The EPA identification number of the receiving facility or transporter;

(3) The quantity of used oil delivered;

(4) The date of delivery;

(5) The signature, dated upon receipt of the used oil, of a representative of the receiving facility or transporter. Intermediate rail transporters are not required to sign the record of delivery.

c. Used oil transporters must maintain the records described in paragraphs b.(1) through b.(4) of this section for each shipment of used oil exported to any foreign country.

d. The records described in paragraphs a., b., and c. of this section must be maintained for at least three (3) years.

e. Used oil transporters shall deliver the shipment of used oil to the facility identified on the used oil manifest, and provide the facility and the generator with a copy of the used oil manifest.

f. All used oil transporters shall maintain records and submit annual reports on or before March 15, which identify, at a minimum:

(1) the sources of the used oil transported;

(2) the quantity of used oil received;

(3) the date of receipt;

(4) the destination or the end use of the used oil within South Carolina; and,

(5) proof of liability insurance or other means of financial responsibility for any liability which may be incurred in the transport of used oil.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.47. Management of Residues.

Transporters who generate residues from the storage or transport of used oil must manage the residues as specified in 279.10.e.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART F
STANDARDS FOR USED OIL PROCESSORS AND RE-REFINERS.

279.50. Applicability.

a. The requirements of this subpart apply to owners and operators of facilities that process used oil. Processing means chemical or physical operations designed to produce from used oil, or to make used oil more amenable for production of, fuel oils, lubricants, or other used oil-derived products. Processing includes, but is not limited to: blending used oil with virgin petroleum products, blending used oils to meet the fuel specification, filtration, simple distillation, chemical or physical separation and re-refining. The requirements of this subpart do not apply to:

(1) Transporters that conduct incidental processing operations that occur during the normal course of transportation as provided in 279.41 of this regulation; or

(2) Burners that conduct incidental processing operations that occur during the normal course of used oil management prior to burning as provided in 279.61.b.

b. Used oil processors/re-refiners who conduct the following activities are also subject to the requirements of other applicable provisions of this regulation as indicated in paragraphs b.(1) through b.(4) of this section.

(1) Processors/re-refiners who generate used oil must also comply with Subpart C: Standards for Used Oil Generators of this regulation;

(2) Processors/re-refiners who transport used oil must also comply with Subpart E: Standards for Used Oil Transporters and Transfer Facilities;

(3) Except as provided in paragraphs b.(3)(a) and b.(3)(b) of this section, processors/re-refiners who burn off-specification used oil for energy recovery must also comply with Subpart G : Standards for Used Oil Burners who Burn Off-Specification Used Oil for Energy Recovery. Processor/re-refiners burning used oil for energy recovery under the following conditions are not subject to Subpart G of this regulation:

(a) The used oil is burned in an on-site space heater that meets the requirements of 279.23; or

(b) The used oil is burned for purposes of processing used oil, which is considered burning incidentally to used oil processing.

(4) Processors/re-refiners who direct shipments of off-specification used oil from their facility to a used oil burner or first claim that used oil that is to be burned for energy recovery meets the used oil fuel specifications set forth in 279.11 of this regulation must also comply with Subpart H of this regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.51. Notification and Permitting.

a. Used oil processors/re-refiners that have previously notified EPA of hazardous waste and other used oil activities and obtained an EPA identification number must notify the Department to identify the used oil processor/re-refiner activities. In addition, the processor/re-refiner must obtain a permit from the Department.

b. A used oil processor or re-refiner who has not received an EPA identification number may obtain one by notifying the Department of the used oil activity by submitting a completed SCDHEC Form 2701.

c. Each person who intends to operate, modify, or close a used oil recycling facility shall obtain an operation or closure permit from the Department prior to operating, modifying, or closing the facility.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.52. General Facility Standards.

a. Owners and operators of used oil processors and re-refiners facilities must comply with the following requirements:

(1) Facilities must be maintained and operated to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of used oil to air, soil, or surface water which could threaten human health or the environment.

(2) All facilities must be equipped with the following, unless none of the hazards posed by used oil handled at the facility could require a particular kind of equipment specified below:

(a) An internal communications or alarm system capable of providing immediate emergency instruction (voice or signal) to facility personnel;

(b) A device, such as a telephone (immediately available at the scene of operations) or a hand-held two-way radio, capable of summoning emergency assistance from local police departments, fire departments, or State or local emergency response teams;

(c) Portable fire extinguishers, fire control equipment (including special extinguishing equipment, such as that using foam, inert gas, or dry chemicals), spill control equipment and decontamination equipment; and

(d) Water at adequate volume and pressure to supply water hose streams, or foam producing equipment, or automatic sprinklers, or water spray systems.

(3) All facility communications or alarm systems, fire protection equipment, spill control equipment, and decontamination equipment, where required, must be tested and maintained as necessary to assure its proper operation in time of emergency.

(4) Whenever used oil is being poured, mixed, spread, or otherwise handled, all personnel involved in the operation must have immediate access to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, unless such a device is not required in paragraph a.(2) of this section.

(a) If there is ever just one employee on the premises while the facility is operating, the employee must have immediate access to a device, such as a telephone (immediately available at the scene of operation) or a hand-held two-way radio, capable of summoning external emergency assistance, unless such a device is not required in paragraph a.(2) of this section.

(b) [None]

(5) The owner or operator must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes.

(6) Arrangements with local authorities.

(a) The owner or operator must make the following arrangements, as appropriate for the type of used oil handled at the facility and the potential need for the services of these organizations:

(i) Arrangements to familiarize police, fire departments, and emergency response teams with the layout of the facility, properties of used oil handled at the facility and associated hazards, places where facility personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes;

(ii) Where more than one police and fire department might respond to an emergency, agreements designating primary emergency authority to a specific police and a specific fire department, and agreements with any others to provide support to the primary emergency authority;

(iii) Agreements with State emergency response teams, emergency response contractors, and equipment suppliers; and

(iv) Arrangements to familiarize local hospitals with the properties of used oil handled at the facility and the types of injuries or illnesses which could result from fires, explosions, or releases at the facility.

(b) Where State or local authorities decline to enter into such arrangements, the owner or operator must document the refusal in the operating record.

b. Owners and operators of used oil processors and re-refiners facilities must comply with the following requirements:

(1) Purpose and implementation of the contingency plan.

(a) Each owner or operator must have a contingency plan for the facility. The contingency plan must be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of used oil to air, soil, or surface water.

(b) The provisions of the plan must be carried out immediately whenever there is a fire, explosion, or release of used oil which could threaten human health or the environment.

(2) Content of the contingency plan.

(a) The contingency plan must describe the actions facility personnel must take to comply with subsections b. and f. of this section in response to fires, explosions, or any unplanned sudden or non-sudden release of used oil to air, soil, or surface water at the facility.

(b) If the owner or operator has already prepared a Spill Prevention, Control, and Countermeasures (SPCC) Plan in accordance with 40 CFR part 112, or part 1510 of chapter V, or some other emergency or contingency plan, the owner or operator need only amend that plan to

incorporate used oil management provisions that are sufficient to comply with the requirements of this regulation.

(c) The plan must describe arrangements agreed to by local police departments, fire departments, hospitals, contractors, and State and local emergency response teams to coordinate emergency services, pursuant to paragraph a.(6) of this section.

(d) The plan must list names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinator (see subsection e. of this section), and this list must be kept up to date. Where more than one person is listed, one must be named as primary emergency coordinator and others must be listed in the order in which they will assume responsibility as alternates.

(e) The plan must include a list of all emergency equipment at the facility (such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities.

(f) The plan must include an evacuation plan for facility personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of used oil or fires).

c. A copy of the contingency plan and all revisions to the plan must be:

(1) Maintained at the facility; and

(2) Submitted to all local police departments, fire departments, hospitals, and State and local emergency response teams that may be called upon to provide emergency services.

d. The contingency plan must be reviewed, and immediately amended, if necessary, whenever:

(1) Applicable regulations are revised;

(2) The plan fails in an emergency;

(3) The facility changes-in its design, construction, operation, maintenance, or other circumstances-in a way that materially increases the potential for fires, explosions, or releases of used oil, or changes the response necessary in an emergency;

(4) The list of emergency coordinators changes; or

(5) The list of emergency equipment changes.

e. At all times, there must be at least one employee either on the facility premises or on call (i.e., available to respond to an emergency by reaching the facility within a short period of time) with the responsibility for coordinating all emergency response measures. This emergency coordinator must be thoroughly familiar with all aspects of the facility's contingency plan, all operations and activities at the facility, the location and characteristic of used oil handled, the location of all records within the facility, and facility layout. In addition, this person must have the authority to commit the resources needed to carry out the contingency plan.

f. Emergency procedures.

(1) Whenever there is an imminent or actual emergency situation, the emergency coordinator (or the designee when the emergency coordinator is on call) must immediately:

(a) Activate internal facility alarms or communication systems, where applicable, to notify all facility personnel; and

(b) Notify the Department or appropriate local agencies with designated response roles if their help is needed.

(2) Whenever there is a release, fire, or explosion, the emergency coordinator must immediately identify the character, exact source, amount, and a real extent of any released materials. He may do this by observation or review of facility records of manifests and, if necessary, by chemical analysis.

(3) Concurrently, the emergency coordinator must assess possible hazards to human health or the environment that may result from the release, fire, or explosion. This assessment must consider both direct and indirect effects of the release, fire, or explosion (e.g., the effects of any toxic, irritating, or

asphyxiating gases that are generated, or the effects of any hazardous surface water run-offs from water of chemical agents used to control fire and heat-induced explosions).

g. If the emergency coordinator determines that the facility has had a release, fire, or explosion which could threaten human health, or the environment, outside the facility, he must report his findings as follows:

(1) If his assessment indicated that evacuation of local areas may be advisable, he must immediately notify appropriate local authorities. He must be available to help appropriate officials decide whether local areas should be evacuated; and

(2) He must immediately notify either the Department official designated as the on-scene coordinator for the geographical area (in the applicable regional contingency plan under part 1510 of this title), or the National Response Center (using their 24-hour toll free number 800/424-8802). The report must include:

(a) Name and telephone number of reporter;

(b) Name and address of facility;

(c) Time and type of incident (e.g., release, fire);

(d) Name and quantity of material(s) involved, to the extent known;

(e) The extent of injuries, if any; and

(f) The possible hazards to human health, or the environment, outside the facility.

h. During an emergency, the emergency coordinator must take all reasonable measures necessary to ensure that fires, explosions, and releases do not occur, recur, or spread to other used oil or hazardous waste at the facility. These measures must include, where applicable, stopping processes and operation, collecting and containing released used oil, and removing or isolating containers.

i. If the facility stops operation in response to a fire, explosion, or release, the emergency coordinator must monitor for leaks, pressure buildup, gas generation, or ruptures in valves, pipes, or other equipment, wherever this is appropriate.

j. Immediately after an emergency, the emergency coordinator must provide for recycling, storing, or disposing of recovered used oil, contaminated soil or surface water, or any other material that results from a release, fire, or explosion at the facility.

k. The emergency coordinator must ensure that, in the affected area(s) of the facility:

(1) No waste or used oil that may be incompatible with the released material is recycled, treated, stored, or disposed of until cleanup procedures are completed; and

(2) All emergency equipment listed in the contingency plan is cleaned and fit for its intended use before operations are resumed.

l. The owner or operator must notify the Department, and appropriate local authorities that the facility is in compliance with paragraph k. of this section before operations are resumed in the affected area(s) of the facility.

m. The owner or operator must note in the operating record the time, date and details of any incident that requires implementing the contingency plan. Within 15 days after the incident, he must submit a written report on the incident to the Department. The report must include:

(1) Name, address, and telephone number of the owner or operator;

(2) Name, address, and telephone number of the facility;

(3) Date, time, and type of incident (e.g., fire, explosion)

(4) Name and quantity of material(s) involved;

(5) The extent of injuries, if any;

(6) An assessment of actual or potential hazards to human health or the environment, where this is applicable; and,

(7) Estimated quantity and disposition of recovered material that resulted from the incident.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.53. Rebuttable Presumption for Used Oil.

a. To ensure that used oil managed at a processing/re-refining facility is not hazardous waste under the rebuttable presumption of 279.10.b.(1)(b), the owner or operator of a used oil processing/re-refining facility must determine whether the total halogen content of used oil managed at the facility is above or below 1,000 ppm.

b. The owner or operator must make this determination by:

(1) Testing the used oil; or

(2) Applying knowledge of the halogen content of the used oil in light of the materials or processes used.

c. If the used oil contains greater than or equal to 1,000 ppm total halogens, it is presumed to be a hazardous waste because it has been mixed with halogenated hazardous waste listed in Subpart D of R.61-79.261. The owner or operator may rebut the presumption by demonstrating that the used oil does not contain hazardous waste (for example, by using an analytical method from SW-846, Edition III, to show that the used oil does not contain significant concentrations of halogenated hazardous constituents listed in Appendix VIII of R.61-79.261).

(1) The rebuttable presumption does not apply to metalworking oils/fluids containing chlorinated paraffins, if they are processed, through a tolling agreement, to reclaim metalworking oils/fluids. The presumption does apply to metalworking oils/fluids if such oils/fluids are recycled in any other manner, or disposed.

(2) The rebuttable presumption does not apply to used oils contaminated with chlorofluorocarbons (CFCs) reclaimed to the extent possible from refrigeration units where the CFCs are destined for reclamation. The rebuttable presumption does apply to used oils contaminated with CFCs that have been mixed with used oil from sources other than refrigeration units.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.54. Used Oil Management.

a. Used oil processors/re-refiners may not store used oil in units other than tanks, containers, or units subject to regulation under R.61-79.264 or 265.

b. Containers and aboveground tanks used to store or process used oil at processing and re-refining facilities must be:

(1) In good condition (no severe rusting, apparent structural defects or deterioration);

(2) Not leaking (no visible leaks); and

(3) Closed to prevent spillage and contamination from precipitation.

c. Containers and tanks used to store or process used oil at processing and re-refining facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest container.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dike, berm, or retaining wall.

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

d. Existing aboveground tanks used to store or process used oil at processing and re-refining facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest tank.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dike, berm, or retaining wall except areas where existing portions of the tank meet the ground; or

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

e. New aboveground tanks used to store or process used oil at processing and re-refining facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest tank.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dike, berm, or retaining wall; or

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

f. Labels.

(1) Containers and aboveground tanks used to store or process used oil at processing and re-refining facilities must be labeled or marked clearly with the words ''Used Oil.''

(2) Fill pipes used to transfer used oil into underground storage tanks at processing and re-refining facilities must be labeled or marked clearly with the words ''Used Oil.''

g. Upon detection of a release of used oil to the environment not subject to the requirements of R.61-79.280 Subpart F, an owner/operator must perform the following cleanup steps:

(1) Stop the release;

(2) Contain the released used oil;

(3) Clean up and manage properly the released used oil and other materials; and

(4) If necessary, repair or replace any leaking used oil storage containers or tanks prior to returning them to service.

(5) Further assessment and remediation, if necessary, shall be directed by the Department.

h. Closure requirements.

(1) Owners and operators who store or process used oil in aboveground tanks must comply with the following requirements:

(a) At closure of a tank system, the owner or operator must remove or decontaminate used oil residues in tanks, contaminated containment system components, contaminated soils, and structures and equipment contaminated with used oil; and manage them as hazardous waste, unless the materials are not hazardous waste under this regulation. Further assessment and remediation, if necessary, shall be directed by the Department.

(b) If the owner or operator demonstrates that not all contaminated soils can be practicably removed or decontaminated as required in paragraph h.(1)(a) of this section, then the owner or operator must close the tank system and perform post-closure care in accordance with the closure and post-closure care requirements that apply to hazardous waste landfills (R.61-79.265.310).

(2) Owners and operators who store used oil in containers must comply with the following requirements:

(a) At closure, containers holding used oils or residues of used oil must be removed from the site;

(b) The owner or operator must remove or decontaminate used oil residues, contaminated containment system components, contaminated soils, and structures and equipment contaminated with used oil; and manage them as hazardous waste, unless the materials are not hazardous waste under R.61–79.261.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.55. Analysis Plan.

Owners or operators of used oil processing and re-refining facilities must develop and follow a written analysis plan describing the procedures that will be used to comply with the analysis requirements of 279.53 and, if applicable, 279.72. The owner or operator must keep the plan at the facility.

a. At a minimum, the plan must specify the following:

(1) Whether sample analyses or knowledge of the halogen content of the used oil will be used to make this determination.

(2) If sample analyses are used to make this determination:

(a) The sampling method used to obtain representative samples to be analyzed. A representative sample may be obtained using either:

(i) One of the sampling methods in Appendix I of R.61-79.261; or

(ii) A method shown to be equivalent under R.61-79.260.20 and 260.21;

(b) The frequency of sampling to be performed, and whether the analysis will be performed on-site or off-site; and

(c) The methods used to analyze used oil for the parameters specified in 279.53; and

(3) The type of information that will be used to determine the halogen content of the used oil.

b. At a minimum, the plan must specify the following if 279.72 is applicable:

(1) Whether sample analyses or other information will be used to make this determination;

(2) If sample analyses are used to make this determination:

(a) The sampling method used to obtain representative samples to be analyzed. A representative sample may be obtained using either:

(i) One of the sampling methods in Appendix I of R.61-79.261; or

(ii) A method shown to be equivalent under R.61-79.260.20 and 260.21;

(b) Whether used oil will be sampled and analyzed prior to or after any processing/re-refining;

(c) The frequency of sampling to be performed, and whether the analysis will be performed on-site or off-site; and

(d) The methods used to analyze used oil for the parameters specified in 279.72; and

(3) The type of information that will be used to make the on-specification used oil fuel determination.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.56. Tracking.

a. Used oil processors/re-refiners must keep a copy of the used oil manifest for each used oil shipment accepted for processing/re-refining. Records for each shipment must include the following information:

(1) The name and address of the transporter who delivered the used oil to the processor/re-refiner;

(2) The name and address of the generator or processor/re-refiner from whom the used oil was sent for processing/re-refining;

(3) The EPA identification number and the Department registration number of the transporter who delivered the used oil to the processor/re-refiner;

(4) The EPA identification number and the Department permit number (if applicable) of the generator or processor/re-refiner from whom the used oil was sent for processing/re-refining;

(5) The quantity of used oil accepted; and

(6) The date of acceptance.

b. Used oil processor/re-refiners must keep a copy of the manifest of each shipment of used oil that is shipped to a used oil burner, processor/re-refiner, or disposal facility. Records for each shipment must include the following information:

(1) The name and address of the transporter who delivers the used oil to the burner, processor/re-refiner or disposal facility;

(2) The name and address of the burner, processor/re-refiner or disposal facility who will receive the used oil;

(3) The EPA identification number and the Department registration number of the transporter who delivers the used oil to the burner, processor/re-refiner or disposal facility;

(4) The EPA identification number and the Department permit number of the burner, processor/re-refiner, or disposal facility who will receive the used oil;

(5) The quantity of used oil shipped; and

(6) The date of shipment.

c. The used oil manifests and records described in paragraphs a. and b. of this section must be maintained for at least three (3) years.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.57. Operating Record and Reporting.

a. Operating Record.

(1) The owner or operator must keep a written operating record at the facility.

(2) The following information must be recorded, as it becomes available, and maintained in the operating record until closure of the facility:

(a) Records and results of used oil analyses performed as described in the analysis plan required under 279.55; and

(b) Summary reports and details of all incidents that require implementation of the contingency plan as specified in 279.52.b.

b. A used oil processor/re-refiner must report to the Department, in the form of a letter, on an annual basis (by March 15 of each year), the following information concerning used oil activities during the previous calendar year:

(1) The EPA identification number, Department permit number, name, and address of the processor/re-refiner;

(2) The calendar year covered by the report; and

(3) The quantities of used oil accepted for processing/re-refining and the manner in which the used oil is processed/re-refined, including the specific processes employed.

c. Each permitted person who processes, re-refines or otherwise recycles used oil shall maintain records which identify, at a minimum:

(1) the source of the materials recycled;

(2) the quantity of materials received;

(3) the date of receipt;

(4) the destination or the end use of the materials; and,

(5) the results of analytical testing to ensure that delivered used oil is not contaminated with hazardous substances.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.58. Off-site Shipments of Used Oil.

Used oil processors/re-refiners who initiate shipments of used oil off-site must ship the used oil by means of a used oil transporter who has obtained an EPA identification number and is registered with the Department.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.59. Management of Residues.

Owners and operators who generate residues from the storage, processing, or re-refining of used oil must manage the residues as specified in 279.10.e.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART G
STANDARDS FOR USED OIL BURNERS WHO BURN OFF-SPECIFICATION USED OIL FOR ENERGY RECOVERY.

279.60. Applicability.

a. The requirements of this subpart apply to used oil burners except as specified in paragraphs a.(1) and a.(2) of this section. A used oil burner is a facility where used oil not meeting the specification requirements in 279.11 is burned for energy recovery in devices identified in 279.61.a. No person shall knowingly violate any applicable South Carolina Air Pollution Control Regulations and Standards (R.61-62). Facilities burning used oil for energy recovery under the following conditions are not subject to this subpart:

(1) The used oil is burned by the generator in an on-site space heater under the provisions of 279.23 of this regulation; or

(2) The used oil is burned by a processor/re-refiner for purposes of processing used oil, which is considered burning incidentally to used oil processing.

b. Used oil burners who conduct the following activities are also subject to the requirements of other applicable provisions of this regulation as indicated below.

(1) Burners who generate used oil must also comply with Subpart C: Standards for Used Oil Generators;

(2) Burners who transport used oil must also comply with Subpart E: Standards for Used Oil Transporters and Transfer Facilities of this regulation;

(3) Except as provided in 279.61.b., burners who process or re-refine used oil must also comply with Subpart F: Standards for Used Oil Processors and Re-refiners of this regulation; and,

(4) Burners who direct shipments of off-specification used oil from their facility to a used oil burner or first claim that used oil that is to be burned for energy recovery meets the used oil fuel specifications set forth in 279.11 of this regulation must also comply with Subpart H: Standards for Used Oil Fuel Marketers of this regulation.

c. This subpart does not apply to persons burning used oil that meets the used oil fuel specification of 279.11, provided that the burner complies with the requirements of Subpart H of this regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.61. Restrictions on Burning.

a. Off-specification used oil fuel may be burned for energy recovery in only the following devices:

(1) Industrial furnaces identified in R.61-79.260.10;

(2) Boilers, as defined in R.61-79.260.10, that are identified as follows:

(a) Industrial boilers located on the site of a facility engaged in a manufacturing process where substances are transformed into new products, including the component parts of products, by mechanical or chemical processes;

(b) Utility boilers used to produce electric power, steam, heated or cooled air, or other gases or fluids for sale; or

(c) Used oil-fired space heaters, provided that the burner meets the provisions of 279.23 of Subpart C; or

b. Exemption.

(1) With the following exception, used oil burners may not process used oil unless they also comply with requirements of Subpart F of this regulation.

(2) Used oil burners may aggregate off-specification used oil with virgin oil or on-specification used oil for purposes of burning, but may not aggregate for purposes of producing on-specification used oil.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.62. Notification.

a. Used oil burners that have not previously notified EPA of their used oil burning activities must notify EPA to identify their used oil burning activities. Even if a burner has previously notified EPA of hazardous waste management activities under section 3010 of RCRA and obtained an identification number, the used oil burner must renotify EPA to identify used oil burning activities. In addition, the burner must obtain a permit from the Department.

b. A used oil burner who has not received an EPA identification number may obtain one by notifying the Department of their used oil activity by submitting a completed SCDHEC Form 2701.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.63. Rebuttable Presumption for Used Oil.

a. To ensure that used oil managed at a used oil burner facility is not hazardous waste under the rebuttable presumption of 279.10.b.(1)(b), a used oil burner must determine whether the total halogen content of used oil managed at the facility is above or below 1,000 ppm.

b. The used oil burner must determine if the used oil contains above or below 1,000 ppm total halogens by:

(1) Testing the used oil;

(2) Applying knowledge of the halogen content of the used oil in light of the materials or processes used; or

(3) If the used oil has been received from a processor/re-refiner subject to regulation under Subpart F of this regulation, using information provided by the processor/re-refiner.

c. If the used oil contains greater than or equal to 1,000 ppm total halogens, it is presumed to be a hazardous waste because it has been mixed with halogenated hazardous waste listed in Subpart D of R.61-79.261. The owner or operator may rebut the presumption by demonstrating that the used oil does not contain hazardous waste (for example, by using an analytical method from SW-846, Edition III, to show that the used oil does not contain significant concentrations of halogenated hazardous constituents listed in Appendix VIII of R.61-79.261).

(1) The rebuttable presumption does not apply to metalworking oils/fluids containing chlorinated paraffins, if they are processed, through a tolling arrangement as described in 279.24.c., to reclaim metalworking oils/fluids. The presumption does apply to metalworking oils/fluids if such oils/fluids are recycled in any other manner, or disposed.

(2) The rebuttable presumption does not apply to used oils contaminated with chlorofluorocarbons (CFCs) reclaimed to the extent possible from refrigeration units where the CFCs are destined for reclamation. The rebuttable presumption does apply to used oils contaminated with CFCs that have been mixed with used oil from sources other than refrigeration units.

d. Records of analyses conducted or information used to comply with paragraphs a., b., and c. of this section must be maintained by the burner for at least three (3) years.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.64. Used Oil Storage.

a. Used oil burners may not store used oil in units other than tanks, containers, or units subject to regulation under R.61-79.264 or 265.

b. Containers and aboveground tanks used to store used oil at burner facilities must be:

(1) In good condition (no severe rusting, apparent structural defects or deterioration); and

(2) Not leaking (no visible leaks).

c. Containers and tanks used to store used oil at burner facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest container.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dike, berm, or retaining wall.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

d. Existing aboveground tanks used to store used oil at burner facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest tank.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dike, berm, or retaining wall except areas where existing portions of the tank meet the ground; or

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

e. New aboveground tanks used to store used oil at burner facilities must be equipped with a secondary containment system capable of retaining the volumetric contents of the largest tank.

(1) The secondary containment system must consist of, at a minimum:

(a) Dikes, berms or retaining walls; and

(b) A floor. The floor must cover the entire area within the dike, berm, or retaining wall; or

(c) An equivalent secondary containment system approved by the Department.

(2) The entire containment system, including walls and floor, must be sufficiently impervious to used oil to prevent any used oil released into the containment system from migrating out of the system to the soil, groundwater, or surface water.

f. Labels.

(1) Containers and aboveground tanks used to store used oil at burner facilities must be labeled or marked clearly with the words "Used Oil."

(2) Fill pipes used to transfer used oil into underground storage tanks at burner facilities must be labeled or marked clearly with the words "Used Oil."

g. Upon detection of a release of used oil to the environment not subject to the requirements of R.61-92.280 Subpart F, a burner must perform the following cleanup steps:

(1) Stop the release;

(2) Contain the released used oil;

(3) Clean up and manage properly the released used oil and other materials; and

(4) If necessary, repair or replace any leaking used oil storage containers or tanks prior to returning them to service.

(5) Further assessment and remediation, if necessary, shall be directed by the Department.

h. Used oil burners are subject to all applicable Spill Prevention, Control and Countermeasures (40 CFR Part 112) in addition to the requirements of this subpart. Used oil generators are also subject to R.61-92.280 standards for used oil stored in underground tanks whether or not the used oil exhibits any characteristics of hazardous waste, in addition to the requirements of this subpart.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.65. Tracking.

a. Used oil burners must keep a copy of the used oil manifest for each used oil shipment accepted for burning. Records for each shipment must include the following information:

(1) The name and address of the transporter who delivered the used oil to the burner;

(2) The name and address of the generator or processor/re-refiner from whom the used oil was sent to the burner;

(3) The EPA identification number and the Department registration number of the transporter who delivered the used oil to the burner;

(4) The EPA identification number and the Department permit number (if applicable) of the generator or processor/re-refiner from whom the used oil was sent to the burner;

(5) The quantity of used oil accepted; and

(6) The date of acceptance.

b. The used oil manifests and records described in item 61–107.279.65.a of this section must be maintained for at least three (3) years.

c. A used oil burner must report to the Department, in the form of a letter, on an annual basis (by March 15 of each year), the following information concerning used oil activities during the previous calendar year:

(1) The EPA identification number, Department permit number, name, and address of the burner;

(2) The calendar year covered by the report; and

(3) The quantities of used oil accepted for burning.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by ate Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.66. Notices.

a. Before a burner accepts the first shipment of off-specification used oil fuel from a generator, transporter, or processor/re-refiner, the burner must provide to the generator, transporter, or processor/re-refiner a one-time written and signed notice certifying that:

(1) The burner has notified the Department stating the location and general description of his used oil management activities; and

(2) The burner will burn the used oil only in an industrial furnace or boiler identified in 279.61.a.

b. The certification described in paragraph a. of this section must be maintained for three (3) years from the date the burner last receives shipment of off-specification used oil from that generator, transporter, or processor/re-refiner.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.67. Management of Residues.

Burners who generate residues from the storage or burning of used oil must manage the residues as specified in 279.10.e.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART H
STANDARDS FOR USED OIL FUEL MARKETERS.

279.70. Applicability.

a. Any person who conducts either of the following activities is subject to the requirements of this subpart:

(1) Directs a shipment of off-specification used oil from their facility to a used oil burner; or

(2) First claims that used oil that is to be burned for energy recovery meets the used oil fuel specifications set forth in 279.11 of this regulation.

b. The following persons are not marketers subject to this subpart:

(1) Used oil generators, and transporters who transport used oil received only from generators, unless the generator or transporter directs a shipment of off-specification used oil from their facility to a used oil burner. However, processors/re-refiners who burn some used oil fuel for purposes of

processing are considered to be burning incidentally to processing. Thus, generators and transporters who direct shipments of off-specification used oil to processor/re-refiners who incidentally burn used oil are not marketers subject to this subpart;

(2) Persons who direct shipments of on-specification used oil and who are not the first person to claim the oil meets the used oil fuel specifications of 279.11.

c. Any person subject to the requirements of this subpart must also comply with one of the following:

(1) Subpart C: Standards for Used Oil Generators;

(2) Subpart E: Standards for Used Oil Transporters and Transfer Facilities;

(3) Subpart F: Standards for Used Oil Processors and Re-refiners; or

(4) Subpart G: Standards for Used Oil Burners who Burn Off-Specification Used Oil for Energy Recovery.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.71. Prohibitions.

A used oil fuel marketer may initiate a shipment of off-specification used oil only to a used oil burner who:

a. Has an EPA identification number and a Department permit number; and

b. Burns the used oil in an industrial furnace or boiler identified in 279.61.a. of this regulation.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.72. On-specification Used Oil Fuel.

a. A generator, transporter, processor/re-refiner, or burner may determine that used oil that is to be burned for energy recovery meets the fuel specifications of 279.11 of this regulation by performing analyses or obtaining copies of analyses or other information documenting that the used oil fuel meets the specifications.

b. A generator, transporter, processor/re-refiner, or burner who first claims that used oil that is to be burned for energy recovery meets the specifications for used oil fuel under 279.11 of this regulation, must keep copies of analyses of the used oil (or other information used to make the determination) for three (3) years.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

279.73. Notification.

a. Used oil fuel marketers must have an EPA identification number.

b. A marketer who has not received an EPA identification number may obtain one by notifying the Department of their used oil activity by submitting a completed SCDHEC Form 2701.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.74. Tracking.

a. Any used oil marketer who directs a shipment of off-specification used oil to a burner must keep a record of each shipment of used oil to a used oil burner. Records for each shipment must include the following information:

(1) The name and address of the transporter who delivers the used oil to the burner;

(2) The name and address of the burner who will receive the used oil;

(3) The EPA identification number and the Department registration number of the transporter who delivers the used oil to the burner;

(4) The EPA identification number and the Department permit number of the burner;

(5) The quantity of used oil shipped; and

(6) The date of shipment.

b. A generator, transporter, processor/re-refiner, or burner who first claims that used oil that is to be burned for energy recovery meets the fuel specifications under 279.11 of this regulation must keep a record of each shipment of used oil. Records for each shipment must include the following information:

(1) The name and address of the facility receiving the shipment;

(2) The quantity of used oil fuel delivered;

(3) The date of shipment or delivery; and

(4) A cross-reference to the record of used oil analysis or other information used to make the determination that the oil meets the specification as required under 279.72.a.

c. The records described in paragraphs a. and b. of this section must be maintained for at least three (3) years.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.75. Notices.

a. Before a used oil generator, transporter, or processor/re-refiner directs the first shipment of off-specification used oil fuel to a burner, he must obtain a one-time written and signed notice from the burner certifying that:

(1) The burner has notified the Department stating the location and general description of used oil management activities; and

(2) The burner will burn the off-specification used oil only in an industrial furnace or boiler identified in 279.61.a.

b. The certification described in paragraph a. of this section must be maintained for three (3) years from the date the last shipment of off-specification used oil is shipped to the burner.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART I
DISPOSAL OF USED OIL.

279.80. Applicability.

The requirements of this subpart apply to all used oils that cannot be recycled and are therefore being disposed at a solid waste management facility.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

279.81. Disposal.

a. Used oils that are identified as a hazardous waste and cannot be recycled in accordance with this regulation must be managed in accordance with the hazardous waste management requirements of R.61-79.260 through 266, 268, 270 and 124.

b. Used oils that are identified as a non-hazardous waste must be disposed of by delivery to a used oil collection facility, used oil energy recovery facility, used oil fuel burner or to an authorized agent for delivery to a used oil collection facility, used oil energy recovery facility, used oil fuel burner or oil recycling facility.

c. Used oils that are not hazardous wastes and cannot be recycled under this part, must be disposed in accordance with the requirements of R.61–107.19 or another regulation promulgated pursuant to S.C. Code Ann. Section 44–96–10, et seq. (1976, as amended).

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

SUBPART J
RETAIL SALES REQUIREMENTS.

279.90. Retail Sales Requirements.

a. Any motor, lubricating, or other oil offered for sale, at retail or at wholesale for direct retail sale, for use off the premises, shall be clearly marked or labeled as containing a recyclable material which must be disposed of only at a used oil collection facility. A statement on a container of lubricating or other oil offered for sale is in compliance with this section if it contains the following statement: 'Don't pollute. Conserve resources. Return used oil to collection centers.'

b. Motor oil retailers shall post and maintain, at or near the point of sale, a durable and legible sign, not less than eleven (11) inches by fifteen (15) inches in size, informing the public of the importance of the proper collection and disposal of used oil and how and where used oil may be properly disposed.

c. The Department may inspect any place, building, or premises subject to this subpart and issue warnings and citations to any person who fails to comply with the requirements of this subsection.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART K
MONITORING.

279.91. Monitoring.

Should the Department confirm environmental and/or health problems associated with the collection, aggregation, storage, transportation, processing, re-refining or recycling of used oil, monitoring (including groundwater, surface water, and air quality monitoring and analysis, and product quality testing and analysis) may be required by the Department as appropriate and based on a case by case evaluation to ensure protection of the environment.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART L
USED OIL FILTER MANAGEMENT.

279.92. Used Oil Filter Management.

a. Non-terne plated used oil filters that are not mixed with a hazardous waste as listed in R.61-79, may be disposed of in a municipal solid waste landfill provided all used oil filters are hot-drained for a minimum of twelve (12) hours using one of the following methods:

(1) Puncturing the filter anti-drain back valve or the filter dome end and hot-draining.

(2) Dismantling and hot-draining; or

(3) Any other equivalent hot-draining method which will remove used oil.

b. Used oil filters which are compacted to their smallest practical volume do not require hot-draining prior to disposal, provided the used oil is collected during crushing.

c. The used oil drained from the oil filters shall be processed, re-refined or otherwise recycled.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART M
VIOLATIONS AND PENALTIES.

279.93. Violations and Penalties.

A violation of this regulation, or any permit or order issued pursuant to or in accordance with this regulation, subjects a violator to the issuance of a Department order, a civil penalty, or to a criminal enforcement action in accordance with S.C. Code Ann., Section 44–96–100, as amended.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995. Amended by State Register Volume 40, Issue No. 6, Doc. No. 4613, eff June 24, 2016.

SUBPART N
SEVERABILITY.

279.94. Severability.

Should any section, paragraph, sentence, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Added by State Register Volume 19, Issue No. 7, eff July 28, 1995.

SUBPART O
VARIANCES.

279.95. Variances.

Any request for variances to these rules and regulations must be directed in writing to, and will be considered by the Department, on an individual basis.

61–108. Standards for Licensing Freestanding or Mobile Technology.

(Statutory Authority: S.C. Code Ann. § 44–7–265 (1976, as amended))

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SECTION 100

DEFINITIONS, REFERENCES, AND LICENSE REQUIREMENTS

101. Definitions.

For the purpose of these standards, the following definitions shall apply:

A. Administering Medication. The direct application of a single dose of a medication to the body of a patient by injection, ingestion, or any other means.

B. Advanced Practice Registered Nurse. An individual who has official recognition to practice as an advanced practice registered nurse by the S.C. State Board of Nursing.

C. Anesthesiologist. A physician who has completed a residency in anesthesiology.

D. Anesthesiologist's Assistant. An individual currently authorized as such by the S.C. Board of Medical Examiners.

E. Anesthetic Agent. Any drug or combination of drugs administered parenterally or inhaled with the purpose of creating conscious (moderate) or deep sedation.

F. Cardiac Catheterization. The passage of a small catheter, usually through a blood vessel into chambers of the heart, under roentgenologic control, permitting the securing of blood samples, determination of intracardiac pressure, and detection of cardiac anomalies.

G. Certified Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a certified registered nurse anesthetist by the S.C. State Board of Nursing.

H. Computerized Tomography (CT). The recording of internal body images in which an emergent X-ray beam is measured by a scintillation counter. The electronic impulses are recorded on a magnetic disk and then are processed by a mini-computer for reconstruction display of the body in cross-section on a cathode ray tube.

I. Conduction Anesthesia. The administration of anesthetic agents to interrupt nerve impulses without loss of consciousness. Major conduction blocks include regional nerve blocks (epidural, caudal, and spinal anesthesia). Minor conduction blocks include local infiltration, local nerve blocks, and nerve blocks by direct pressure and refrigeration.

J. Conscious (Moderate) Sedation. The administration of drugs to obtund or reduce the intensity of pain and awareness without the loss of defensive reflexes.

K. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act and the S.C. Controlled Substances Act.

L. Consultation. A visit by individuals authorized by the Department to provide information to the licensee to enable better compliance with these regulations.

M. Department. The S.C. Department of Health and Environmental Control (DHEC).

N. Direct Care Staff Member. An individual who provides care, treatment, and/or services or performs procedures for a patient.

O. Existing Equipment. Equipment that was in operation prior to the promulgation of this regulation. The licensing standards governing new equipment apply if and when existing equipment is not continuously operated and licensed under this regulation.

P. Freestanding or Mobile Technology. Medical equipment which is to be used for diagnosis or treatment and is owned or operated by a person, other than a health care facility (as defined in S.C. Code Ann. § 44–7–130 (1976, as amended)), for which the total cost is in excess of that prescribed by R.61–15 and for which specific standards or criteria are prescribed in the State Health Plan.

Q. Gamma Knife. Stereotactic radiosurgery by which intracranial lesions are treated with high dose, high energy photons, i.e., a non-invasive procedure utilizing narrow bands of radiant energy that are directed at a treatment target in the head.

R. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, physician's assistant, or advanced practice registered nurse or by a registered nurse, pursuant to standing orders approved by a physician, as evidenced by the physician's signature in accordance with facility policy.

S. Host/Host Hospital. An acute care facility or other entity that leases or otherwise arranges for the provision of services of a mobile technology unit.

T. Ionized Radiation. Radiation that causes a neutral atom or molecule to acquire a positive or negative charge.

U. Inspection. A visit by an authorized individual(s) for the purpose of determining compliance with this regulation.

V. Investigation. A visit by an authorized individual(s) for the purpose of determining the validity of allegations received by the Department relating to this regulation.

W. Initial License. A license granted for new equipment.

X. Legally Authorized Health Care Provider. An individual authorized by law and currently licensed in S.C. to provide specific medical care, treatment, procedures, and/or services to patients. Examples of individuals who may be authorized by law to provide specific medical care, treatment, procedures, and/or services within the lawful scope of practice may include, but are not limited to, advanced practice registered nurses, radiological technicians, and physician's assistants.

Y. Legend Drug.

1. A drug required by federal law to be labeled with any of the following statements prior to being dispensed or delivered:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only."

2. A drug required by federal or state law to be dispensed pursuant to a prescription drug order or restricted to use by practitioners only;

3. Any drug products designated by the S.C. Board of Pharmacy to be a public health threat; or

4. Any prescribed compounded prescription within the meaning of the Pharmacy Act.

Z. License. A certificate issued by the Department to freestanding or mobile technology that authorizes equipment operation subject to the provisions of this regulation.

AA. Licensed Nurse. An individual authorized by the S.C. State Board of Nursing to practice as a registered nurse or licensed practical nurse.

BB. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care, treatment, procedures, and/or services and with whom rests the ultimate responsibility for compliance with this regulation.

CC. Magnetic Resonance Imaging (MRI). A diagnostic procedure used to create cross-sectional images of the body by the use of magnetic fields and radio frequency fields. It can also show certain biochemical activity and is non-invasive.

DD. Monitoring. The observation of a patient using instruments to measure, display, and/or record (continuously or intermittently) the values of certain physiologic variables such as pulse, blood pressure, oxygen saturation, and respiration.

EE. New Equipment. Equipment that is:

1. Being licensed for the first time;

2. Providing a different service that requires a change in the type of license;

3. Being licensed after the previous licensee's license has been revoked, suspended, or after the previous licensee has voluntarily surrendered the license and the equipment has not been continuously operated.

FF. Nonlegend Medication. A medication that may be sold without a prescription and that is labeled for use by the consumer in accordance with the requirements of the laws of this State and the federal government.

GG. On-Site Manager. The individual designated by the licensee to have the authority and responsibility to manage/operate the equipment. This person, or an individual designated to act in his/her absence, is the main contact with Department personnel.

HH. Pharmacist. An individual currently registered as such by the S.C. Board of Pharmacy.

II. Physician. An individual currently licensed as such by the S.C. Board of Medical Examiners.

JJ. Physician's Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

KK. Positron Emission Tomography (PET). A procedure that allows the study of metabolic processes, such as oxygen consumption and utilization of glucose and fatty acids, by capturing images of cellular activity or metabolism by tracking the movement of radioactive tracers throughout the body.

LL. Procedure Room. A room where procedures not requiring general anesthesia can be safely performed.

MM. Quality Improvement Program. The process used to examine methods and practices of providing care, treatment, procedures, and/or services, identify the ways to improve performance, and take actions that result in higher quality of care, treatment, procedures, and/or services for patients.

NN. Radiation Therapist. A person, other than an individual licensed to practice within the lawful scope of practice of medicine in this State, who applies radiation to humans for therapeutic purposes.

OO. Radiation Therapy. The use of a stream of high-energy particles or waves such as X-rays, gamma rays, and alpha and beta particles to destroy or damage cancer cells.

PP. Radiographer. A person, other than an individual licensed to practice, medicine, dentistry, podiatry, chiropractic, or osteopathy in this State, who applies radiation to humans for diagnostic purposes, including, but not limited to, mammography, cardiovascular-interventional technology, and computed tomography.

QQ. Radiologic Technologist. A person who is a limited practice radiographer, radiographer, podiatric limited practice radiographer, limited chest radiographer, radiation therapist, or nuclear medicine technologist certified by the American Registry of Radiologic Technologists or who is certified by the S.C. Radiation Quality Standards Association (SCRQSA) or who has obtained a certificate acceptable to the SCRQSA.

RR. Registered Nurse Anesthetist. A registered nurse who is authorized to practice as a registered nurse anesthetist by the S.C. State Board of Nursing.

SS. Repeat Violation. The recurrence of any violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

TT. Responsible Party. A person who is authorized by law to make decisions on behalf of a patient, including, but not limited to, a court-appointed guardian or conservator or person with a health care power of attorney or other durable power of attorney.

UU. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding its authority to operate.

VV. Staff Member. An individual who is 18 years or older and is a compensated employee on either a full or part-time basis.

WW. Suspension of License. An action by the Department requiring a licensee to cease operation for a period of time until such time as the Department rescinds that restriction.

XX. Vendor. A person who owns and/or operates mobile technology and contracts with acute care hospitals or other hosts for the purpose of providing diagnostic or therapeutic services.

YY. Volunteer. An individual who performs tasks at the direction of the on-site manager or his or her designee without compensation.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

102. References.

The following publications/standards are referenced in this regulation:

A. Departmental:

1. R.61–4, *Controlled Substances*;
2. R.61–15, *Certification of Need for Health Facilities and Services*;
3. R.61–16, *Minimum Standards for Licensing Hospitals and Institutional General Infirmaries*;
4. R.61–20, *Communicable Diseases*;
5. R.61–63, *Radioactive Materials*;
6. R.61–64, *X-Rays, (Title B)*;
7. R.61–105, *Infectious Waste Management*;
8. *Guidelines for Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*;
9. Guidelines for Preventing Transmission of Mycobacterium Tuberculosis in Health Care Facilities;
10. South Carolina Health Plan.

B. Non-Departmental:

1. Bloodborne Pathogens Standards, Occupational Safety and Health Act (OSHA) of 1970;
2. Centers for Disease Control and Prevention (CDC);
3. *Health Insurance Portability and Accountability Act of 1996 (HIPAA);*
4. National Fire Protection Association (NFPA);
5. Environmental Protection Agency (EPA);
6. Federal Food and Drug Administration (FDA).

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

103. License Requirements (II).

A. Compliance. An initial license shall not be issued to an owner/operator who has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed equipment is in substantial compliance with the licensing standards. In the event a licensee who already has a facility/activity/freestanding or mobile technology licensed by the Department makes application for another facility/activity/freestanding or mobile technology or increase in licensed capacity of a facility, the currently licensed facility/activity/freestanding or mobile technology shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility/activity/freestanding or mobile technology.

B. A copy of the licensing standards shall be maintained by the licensee and accessible to all staff members.

C. No licensee who has been issued a license for a particular type of equipment shall establish new care, treatment, procedures, and/or services without first obtaining authorization from the Department. (I)

D. Issuance and Terms of License.

1. A license is issued by the Department and shall be posted in a conspicuous place near the licensed equipment.

2. The issuance of a license does not guarantee adequacy of individual care, treatment, procedures, and/or services, personal safety, fire safety or the well-being of any patient.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this State.

4. Equipment that is licensed pursuant to this regulation and is acquired by a licensed health care facility through purchase, contract, lease, or assuming/obtaining possession, shall be included as a part of the health care facility's license, and the original equipment license shall become null and void.

5. A license shall be effective for specified equipment at a specific location(s) for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

6. Equipment owned by the same entity but not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, e.g., interstate highways, shall not be considered as dividing otherwise adjoining or contiguous property.

7. Multiple types of equipment on the same premises may be licensed separately even though owned by the same entity.

E. Application. Applicants for a license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes the applicant's oath, assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) of the equipment if an individual or partnership; in the case of a corporation, by two of its officers; or in the case of a governmental unit, by the head of the governmental department having jurisdiction. The application shall set forth the type of equipment, including the year, model of equipment, all equipment upgrades, location of the equipment for which the license is sought and of the owner in the event his or her address is different from that of the location of the equipment, and the names of the persons in control of the

equipment. A copy of the nonapplicability, exemption, or Certificate of Need shall be included as part of the initial application. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or limited partnerships shall be registered with the S.C. Office of the Secretary of State.

F. Licensing Fees. The initial and annual license fee shall be $600.00. Such fees shall be made payable by check or money order to the Department and are not refundable. The Department may charge an additional amount, if necessary, to cover the cost of inspection or investigation.

G. Late Fee. Failure to submit a renewal application or fee after the license expiration date may result in a late fee of 25% of the licensing fee amount, in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time period specified by the Department may result in an enforcement action.

H. License Renewal. To renew a license an applicant shall file an application with the Department and pay a license fee. If the license renewal is delayed due to enforcement action, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable. If an application is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure period.

I. Registered Equipment. Licensees utilizing equipment that is required to be registered by the Department's Bureau of Radiological Health shall not be licensed until such equipment is properly registered.

J. Change of License.

1. A licensee shall request issuance of a new or amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership of equipment;

b. Change of types of equipment as shown on the license;

c. Change of equipment location from one geographic site to another.

2. Changes in address (as notified by the post office) shall be accomplished by application or by letter from the licensee.

3. Replacement of equipment shall be accomplished by letter from the licensee.

K. A freestanding or mobile technology license shall not be required for, nor shall such a license be issued to, equipment operated by the federal government.

L. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the patients are not compromised and provided the standard is not specifically required by statute.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 200

ENFORCING REGULATIONS

201. General.

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation in order to enforce this regulation.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

202. Inspections/Investigations.

A. An inspection shall be conducted prior to initial licensing of equipment and subsequent inspections conducted as deemed appropriate by the Department. Regulatory related accreditations may be considered in determining the appropriateness of Department inspections.

B. All equipment and those areas of the location that impact treatment/procedures provided by the equipment are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records that are pertinent to the operation of equipment and have the authority to require the licensee to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used for purposes of enforcement of regulations, and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. (II)

D. A licensee found noncompliant with the standards of this regulation shall submit an acceptable written plan of correction to the Department that shall be signed by the on-site manager and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar);
3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the response, shall be made available upon written request with the redaction of the names of those individuals in the report as provided by S.C. Code Ann. §§ 44–7–310 and -315 (1976, as amended).

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

203. Consultations.

Consultations may be provided by the Department as requested by the facility or as deemed appropriate by the Department.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 300

ENFORCEMENT ACTIONS

301. General.

When the Department determines that a licensee is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such equipment, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, or revoke its license.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

302. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of the patients for whom the equipment is used or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time established by the Department may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of patients for whom equipment is used. The citation of a Class II violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. The notations "(I)" or "(II)", placed within sections of this regulation indicate that those standards are considered Class I or II violations if they are not met. Failure to meet standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement actions, the Department shall consider the following factors: specific conditions and their impact or potential impact on health, safety, or well-being of the patients; efforts by the licensee to correct cited violations; behavior of the licensee that reflects negatively on the licensee's character, such as illegal or illicit activities; overall conditions; history of compliance; and any other pertinent factors that may be applicable to current statutes and regulations.

F. When a decision is made to impose monetary penalties, the Department may invoke S.C. Code Ann. § 44-7-320(C) (1976, as amended), to determine the dollar amount or may utilize the following schedule:

Frequency of violation of standard within a 36-month period:

MONETARY PENALTY ACTIONS

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$ 500–1,500	$300–800	$100–300
2nd	1,000–3,000	500–1,500	300–800
3rd	2,000–5,000	1,000–3,000	500–1,500
4th	5,000	2,000–5,000	1,000–3,000
5th	7,500	5,000	2,000–5,000
6th **and more**	10,000	7,500	5,000

G. Any enforcement action taken by the Department may be appealed pursuant to the Administrative Procedures Act, S.C. Code Ann. § 1–23–310 (1976, as amended).

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 400

POLICIES AND PROCEDURES

401. General (II).

Policies and procedures addressing each section of this regulation regarding care, treatment, procedures, and/or services, rights, and the operation of the equipment shall be developed and implemented, and revised as required in order to accurately reflect actual operation. The licensee shall establish a time period for review of all policies and procedures. These policies and procedures shall be accessible at all times, either by hard copy or electronically.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 500

STAFF

501. General (II).

A. Appropriate staffing in sufficient numbers and training shall be provided to operate equipment in a manner that shall safely and effectively meet the needs and condition of the patients, to include the demands of effective emergency on-site action that might arise. Such staffing numbers and training shall:

1. Meet the recommendations of the equipment manufacturers;
2. Adhere to current professional organizational standards;
3. Comply with all local, state, and federal laws.

B. Additional staff members shall be provided if it is determined by the Department that the staff on duty is inadequate to effectively and safely operate the equipment.

C. All staff members operating and/or maintaining equipment shall be assigned duties and responsibilities in accordance with the individual's capability. Such duties shall be in writing and be reviewed on an annual basis by the staff member and supervisor.

D. There shall be accurate current information maintained regarding all staff members who operate and/or maintain equipment to include at least an address, phone number, and health and personal/work/ training background. For those staff members who are licensed/certified, a copy of the license/certificate shall be available for review.

E. Staff members who operate and/or maintain equipment shall not have a prior conviction or have pled no contest (nolo contendere) within the last 10 years for child or adult abuse, neglect, exploitation, or mistreatment, or for sexual assault or assault with a deadly weapon. The licensee may take certain considerations into account regarding criminal records when making hiring decisions, i.e., discretion may be exercised regarding convictions/nolo contendere pleas occurring more than 10 years ago and may determine that an applicant, who would otherwise be disqualified, could be hired. (I)

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

502. On-Site Manager (II).

A. Licensees shall have an on-site manager who shall be capable of meeting the responsibilities of operating and/or maintaining the equipment to ensure that it is in compliance with these regulations and shall demonstrate adequate knowledge of these regulations

B. A staff member shall be designated by name or position, in writing, to act in the absence of the on-site manager.

C. Mobile units shall maintain a list of individuals approved by the licensee to be the on-site manager(s) on a day-to-day basis.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

503. Medical Director (II).

A. There shall be a medical director who shall be a physician who is responsible for the quality of medical equipment services provided to patients.

B. The on-site manager and medical director may be the same person.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

504. Medical Staff (I).

A. Physicians and other legally authorized health care providers performing treatment/procedures shall be appropriately licensed to perform these functions as well as adequately trained in any special requirements that are necessary to perform such treatment/procedures.

B. Privileges for each medical staff member to perform treatment/procedures and anesthesia shall be in accordance with criteria that the medical staff has established and approved.

C. There shall be a roster of medical staff having treatment/procedures and anesthesia privileges, specifying the privileges and limitations of each and a current listing of all types of treatment/procedures offered.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

505. Qualifications (I).

A. Those persons who practice within the lawful scope of their practice utilizing ionizing radiation such as cardiac catheterization (fluoroscopy) shall be appropriately qualified in accordance with R.61–63 and R.61–64.

B. Those individuals providing the following services shall have the following qualifications:

1. Magnetic Resonance Imaging (MRI).

a. Physicians responsible for reviewing all indications for examinations, specifying the use and dosage of contrast agents, etc. shall be certified in radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada with documented evidence of MRI training and meet the guidelines of the American College of Radiology Standard for Continuing Medical Education.

b. Individuals conducting MRI's shall be licensed nurses or Radiologic Technologists with documented evidence of appropriate MRI training.

2. Cardiac Catheterization.

a. Any physician performing cardiac catheterization shall have:

(1) Board certification in internal medicine and the subspecialty of cardiovascular disease or be board-eligible in the subspecialty of cardiovascular disease and be examined for certification within two years of initial eligibility;

(2) Completed current training in cardiac catheterization;

(3) Met the experience requirements of the American Board of Internal Medicine.

b. All direct care personnel in the cardiac catheterization laboratory shall be certified in basic cardiac life support (BCLS), with at least one staff member/volunteer with a current certification in Advanced Cardiac Life Support (ACLS) whenever patients are present.

3. Anesthesia Services (If Provided)

a. Anesthesia shall be administered only by:

(1) An anesthesiologist;

(2) A physician, other than an anesthesiologist, or dentist or podiatrist who is qualified to administer anesthesia pursuant to the S.C. Code of Laws;

(3) A certified registered nurse anesthetist;

(4) A registered nurse anesthetist;

(5) An anesthesiologist's assistant.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

506. Inservice Training (II).

A. Training for the tasks each staff member performs shall be conducted in order to provide the care, treatment, procedures, and/or services delineated in Sections 501.A and 800.

B. The following training shall be provided by appropriate resources, e.g., licensed or registered persons, video tapes, books, etc., to all staff members as appropriate to their job duties and responsibilities prior to patient contact and at a frequency determined by the policies and procedures but at least annually:

1. Cause, effect, transmission, prevention, and elimination of infections, to include standard precautions, management and care of persons with contagious and/or communicable disease, e.g., hepatitis, tuberculosis, HIV infection;

2. OSHA standards regarding bloodborne pathogens;

3. Confidentiality of patient information and records and the protection of patient rights;

4. Emergency procedures and disaster preparedness within 24 hours of the employee's first day on the job (see Section 1100);

5. Fire response training within 24 hours of the employee's first day on the job (see Section 1203);

6. Aseptic techniques, such as handwashing, disinfecting, the handling and storage of equipment and supplies, and, if applicable, scrubbing practices, proper gowning and masking, dressing care techniques, and sterilizing techniques.

C. A staff member with a valid cardio-pulmonary resuscitation certification shall be on duty whenever patients are present.

D. All newly hired staff members shall receive orientation regarding the organization and physical plant, specific duties and responsibilities of staff members, and patients' needs.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

507. Health Status (I).

A. All staff members who have contact with patients shall have, within 12 months prior to initial patient contact, a health assessment as defined in Section 101.R.

B. The health assessment shall include tuberculin screening as described in Section 1404.

C. If a staff member is working at multiple locations operated by the same licensee, copies of records for tuberculin screening and the pre-employment health assessment shall be acceptable at each location. (II)

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 600

REPORTING

601. Incidents/Accidents (II).

A. A record of each incident and/or accident occurring in the equipment location area involving patients or staff members shall be retained.

1. Serious incidents/accidents and/or medical conditions as defined below and any illness resulting in death or inpatient hospitalization shall be reported via telephone to the next-of-kin or responsible party immediately and in writing to the Department's Division of Health Licensing within 10 days of the occurrence.

2. Serious medical conditions shall be considered as, but not limited to: major permanent loss of function, hemolytic transfusion reaction involving administration of blood or blood products, a procedure on the wrong patient or wrong body part, fractures of major limbs or joints, severe burns, lacerations, or hematomas, and actual or suspected abuse or mistreatment of patients.

B. Reports made to the Division of Health Licensing shall contain at a minimum: facility name, patient age and sex, date of incident/accident, location, extent/type of injury, and means of treatment, e.g., hospitalization.

C. Significant medication errors and significant adverse medication reactions that require intervention shall be reported immediately to the patient or next-of-kin or responsible party, prescriber, supervising staff member, and administrator. Significant medication errors and significant adverse medication reactions include events that are unintended and undesirable, as well as unexpected effects of prescribed medications or of medication errors that:

1. Require discontinuing a medication or modifying the dose;
2. Require hospitalization;
3. Result in disability;
4. Require treatment with a prescription medication;
5. Result in cognitive deterioration or impairment;
6. Are life-threatening;
7. Result in death.

D. Changes in the patient's condition, to the extent that serious health concerns are evident, e.g., heart attack, shall be reported immediately to the attending physician, the next-of-kin or responsible party, and the on-site manager. (I)

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

602. Fire/Disasters (II).

The Department's Office of Fire and Life Safety and the Division of Health Licensing shall be notified immediately via telephone or facsimile regarding any fire occurring at the equipment location and followed by a complete written report to include fire department reports, if any, submitted within a time period determined by the policies and procedures, but not to exceed 10 days from the occurrence of the fire.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

603. Communicable Diseases (I).

All cases of diseases that are required to be reported to the appropriate county health department shall be reported in accordance with R.61–20.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

604. On-site Manager Change.

The Department's Division of Health Licensing shall be notified in writing by the licensee of freestanding technology within 10 days of any change in on-site manager. The notice shall include at a minimum the name of the newly appointed individual, documented qualifications as required by Section 502, and the effective date of the appointment.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

605. Joint Annual Report.

Licensees, if required by the Department's Planning and Certificate of Need Division to submit a "Joint Annual Report," shall complete and return this report within the time period specified by that Division.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

606. Accounting of Controlled Substances and Devices (I).

In accordance with R.61–4, any licensee whose licensed equipment is housed in a facility registered with the Department's Bureau of Drug Control shall report any theft or significant loss of controlled substances to the Bureau of Drug Control upon discovery of the loss/theft. Pursuant to S.C. Code Ann. § 40–43–91 (1976, as amended), any licensee whose licensed equipment is housed in a facility permitted by the S.C. Board of Pharmacy shall report the loss or theft of controlled substances or devices within thirty working days of the discovery of the loss/theft to the S.C. Board of Pharmacy.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

607. Equipment Change.

The Department's Division of Health Licensing shall be notified in writing by the licensee within 10 days of any change, upgrade and/or replacement of licensed equipment.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

608. Equipment Location Closure.

A. Prior to the permanent closure of a business where equipment is licensed, the Department's Division of Health Licensing shall be notified in writing of the intent to close and the effective closure date. Within 10 days of the closure, the Division of Health Licensing shall be notified of the provisions for the maintenance of the records. On the date of closure, the current original license shall be returned to the Division of Health Licensing.

B. When a business where equipment is licensed temporarily closes, the Division of Health Licensing shall be given written notice within a reasonable time in advance of closure. At a minimum this notification shall include, but is not limited to: the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current standards to the equipment prior to its usage. If the location is closed for a period longer than one year, and there is a desire to re-open, the licensee shall re-apply to the Department and shall be subject to all licensing requirements at the time of that application.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 700

PATIENT RECORDS

701. Content (II).

A. An organized record shall be initiated and maintained for each patient. The record shall contain: sufficient documented information to identify the patient; the person responsible for each patient; the description of the diagnosis and the care, treatment, procedures, and/or services provided, to include the course of action taken and results; and the response and reaction to the care, treatment, procedures, and/or services provided. All entries shall be indelibly written, signed by the author, and dated.

B. Specific entries/documentation shall include at a minimum:

1. Consultations by physicians or other legally authorized health care providers;

2. Orders and recommendations for all care, treatment, procedures, and/or services from physicians or other legally authorized health care providers, completed prior to, or at the time of patient arrival, and subsequently, as warranted;

3. Care, treatment, procedures, and/or services provided;

4. Record of administration of each dose of medication and procedures followed if an error is made;

5. Special procedures and preventive measures performed, e.g., isolation for symptoms of tuberculosis;

6. Notes of observation during recovery, to include vital signs pre- and post-treatment/procedure;

7. Discharge summary, including condition at discharge or transfer, instructions for self-care and instructions for obtaining post-treatment/procedure emergency care;

8. Special information, e.g., allergies, etc.

9. Signed informed consent for treatment as required by HIPAA and, if applicable, consent for participation in research;

10. If applicable, anesthesia records of pertinent pre-treatment/procedure reports including pre-anesthesia evaluation, type of anesthesia, technique and dosage used, and post-anesthesia follow-up note.

11. Treatment/procedure report (dictated or written into the record immediately after treatment/procedure) to include at least:

a. Description of findings;

b. Techniques utilized to perform treatment/procedure;

c. Specimens removed, if applicable;

d. Primary physician and assistants.

12. Reports of all laboratory, radiological, and diagnostic procedures along with tests performed and the results appropriately authenticated.

C. Except as required by law, patient records may contain written and interpretative findings and reports of diagnostic studies, tests, and procedures, e.g., interpretations of imaging technology and video tapes without the medium itself.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

702. Record Maintenance.

A. The licensee shall provide accommodations, space, supplies, and equipment adequate for the protection, security, and storage of patient records.

B. When a patient is transferred to an emergency facility, a transfer summary, to include, at a minimum, the diagnosis, care, treatment, procedures, and/or services provided, and medication administration record, shall accompany the patient to the receiving facility at the time of transfer or forwarded immediately after the transfer. Documentation of the information forwarded shall be maintained in the patient record. (I)

C. The patient record is confidential. Records containing protected or confidential health information shall be made available only to individuals granted access to that information, in accordance with state and federal laws. The licensee shall have a written policy designating the persons allowed to access confidential patient information. Written consent by the patient shall be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's responsible party. (II)

D. Records generated by organizations or individuals with whom the licensee contracts for care, treatment, procedures, and/or services shall be maintained at the equipment location. Appropriate information shall be provided to assure continuity of care.

E. The licensee shall determine the medium in which information is stored. The information shall be readily retrievable and accessible by staff, as needed, and for regulatory compliance inspections.

F. Upon discharge of a patient, the record shall be completed within 60 days and filed in an inactive/closed file maintained by the licensee. Prior to the closing of an equipment location for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations and other applicable law. The licensee shall notify the Department's Division of Health Licensing, in writing, describing these arrangements and the location of the records.

G. Records of patients shall be retained for at least six years following the discharge of the patient. Records of minors shall be retained until after the expiration of the period of election following achievement of majority as prescribed by statute. Other documents required by this regulation, e.g., fire drills, shall be retained at least 12 months or until the next Division of Health Licensing inspection.

H. Patient records are the property of the licensee; the original record shall not be removed without court order. (II)

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 800

CARE/TREATMENT/PROCEDURES/SERVICES

801. General (I).

A. Care, treatment, procedures, and/or services shall be provided, given, or performed effectively and safely in accordance with orders from physicians or other legally authorized health care providers, and precautions shall be taken for patients with special conditions, e.g., pacemakers, pregnancy, Alzheimer's disease, etc., and/or for those who may be susceptible to deleterious effects as a result of the treatment.

B. If a patient or potential patient has a communicable disease, a physician or other legally authorized health care provider shall insure that adequate care can be provided to prevent the spread of the disease and that the staff members are adequately trained and qualified to manage the patient, or transfer the patient to an appropriate facility, if necessary.

C. When the licensee engages a source to provide services normally provided by the staff, e.g., staffing, training, equipment maintenance, there shall be a written agreement with the source that describes how and when the services are to be provided, the exact services to be provided, and a statement that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to patient care, treatment, procedures, and/or services, confidentiality, and rights. (II)

D. The licensee shall comply with all current federal, state, and local laws and regulations related to patient care, treatment, procedures, and/or services, and protection.

E. A current listing of all types of treatment and procedures offered shall be available. A chronological record of all treatment and procedures performed shall be maintained that shall include patient identification, pre-treatment/procedure diagnosis, type of treatment/procedure performed, type of anesthesia utilized (if applicable), and any unusual occurrence.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

802. Anesthesia Services (If Provided) (I).

A. Anesthesia shall be administered only by those individuals indicated in Section 505.B.3.a.

B. After the administration of a general anesthetic, a patient shall be attended by a physician until the patient may be safely placed under post-operative/procedure supervision by the nursing staff who shall then attend the patient until he or she has regained full consciousness, or until the effects of the anesthetic have sufficiently subsided for the patient to be able to summon aid when needed.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

803. Licensees Utilizing Ionizing Radiation (II).

All equipment where ionizing radiation is utilized shall be in compliance with those professional organizational standards specified in R.61–63 and R.61–64.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

804. Laboratory Services (II).

A. Laboratory services required in connection with the treatment/procedure to be performed shall be provided or arrangements made to obtain such services.

B. Should tests be conducted that involve human specimens by utilizing any laboratory equipment such as finger-stick glucose, hemoglobin, monitoring devices, etc., for the purpose of providing information for the diagnosis, prevention, or treatment of disease or impairment, or assessment of health, a Certificate of Waiver from the Clinical Laboratories Improvement Amendments (CLIA) Program shall be obtained through the Department's CLIA Program.

C. Laboratory supplies shall not be expired.

D. A pathologist shall examine all tissue specimens except for those types of specimens that the medical staff has determined and documented do not require examination.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

805. Adverse Conditions (I).

Should a patient experience any adverse condition or complication during or after the performance of the treatment/procedure, he or she shall remain at the equipment location until the condition/complication is eliminated, as determined by the physician, and the patient is stabilized. Patients requiring care beyond the capability of the equipment or staff shall be transferred to an appropriate facility.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

806. Patient Instruction (If applicable) (I).

Written instructions shall be issued to all patients upon discharge and shall include at a minimum the following:

A. Signs and symptoms of possible complications;

B. Telephone number at the location of the equipment or the attending physician or other knowledgeable professional staff member, should any complication occur or questions arise;

C. An emergency telephone number should any complication occur. It shall be the responsibility of the attending physician to arrange for needed care;

D. Limitations regarding activities, foods, etc.;

E. Date for follow-up or return visit, if applicable.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 900

RIGHTS AND ASSURANCES

901. General (II).

A. The licensee shall comply with all current federal, state, and local laws and regulations concerning patient care, treatment, procedures, and/or services, patient rights and protections, discrimination, and privacy and disclosure requirements, e.g., S.C. Code Ann. § 44–81–10 (1976, as amended).

B. The licensee shall develop and post in a conspicuous place in a public area a grievance/complaint procedure to be exercised on behalf of the patients that includes the address and phone number of the Department's Division of Health Licensing and a provision prohibiting retaliation should the grievance right be exercised.

C. Care, treatment, procedures, and/or services provided, and the charges for such, shall be delineated in writing. Patients shall be made aware of such charges and services, as verified by the signature of the patient or responsible party.

D. Patients shall be permitted to use a telephone and allowed privacy when making calls.

E. Adequate safeguards shall be provided for protection and storage of patients' personal belongings.

F. Patient rights shall be guaranteed, prominently displayed, and, the patient shall be informed of these rights, to include, at a minimum:

1. The care, treatment, procedures, and/or services to be provided;

2. Informed consent for care, treatment, procedures, and/or services;

3. Respect for the patient's property;

4. Freedom from mental and physical abuse and exploitation;

5. Privacy while being treated and while receiving care;

6. Respect and dignity in receiving care, treatment, procedures, and/or services;

7. Refusal of treatment. The patient shall be informed of the consequences of refusal of the treatment/procedure, and the reason shall be reported to the physician and documented in the patient record;

8. Refusal of experimental treatment and drugs;

9. Confidentiality and privacy of records.

G. Except in emergencies, documentation regarding informed consent shall be properly executed prior to the treatment/procedure.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1000

MEDICATION MANAGEMENT

1001. General (I).

A. Medications, including controlled substances, medical supplies, intravenous solutions, and those items necessary for the rendering of first aid shall be properly managed in accordance with local, state, and federal laws and regulations, to include the securing, storing, and administering of medications, medical supplies, first aid supplies, biologicals and their disposal when discontinued or expired, or at discharge, death, or transfer of a patient.

B. Non-legend medications may be retained and labeled as stock for administration as ordered by a physician or other legally authorized health care provider.

C. If controlled substances are to be used, a controlled substances registration from the Department's Bureau of Drug Control and a controlled substance registration from the Federal Drug Enforcement Administration (DEA) shall be obtained. The registration(s) shall be displayed in a conspicuous location.

D. Upon the advice and written approval of the Medical Director or consultant pharmacist, an emergency kit or cart of lifesaving medicines and equipment shall be maintained for the use of physicians or other legally authorized health care providers in treating the emergency needs of patients.

1. The kit/cart shall be sealed and stored in such a manner as to prevent unauthorized access and to ensure a proper environment for preservation of the medications within, but in such a manner as to allow immediate access.

2. The emergency medication kit/cart shall display the following information:

a. "For Emergency Use Only";

b. Name, address, and telephone number of the consultant pharmacist.

3. Whenever the kit/cart is opened, it shall be restocked and resealed within a reasonable time to prevent risk of harm to a patient.

4. Contents of each section of the kit/cart shall be listed and maintained on or in the kit/cart, and shall correspond to the list. Documentation of monthly checks of expiration dates of medications and supplies is to be retained for a period of two years or until the Department's Division of Health Licensing's next inspection, whichever is longer.

E. Medications shall not be expired.

F. Applicable reference materials published within the previous year shall be available in order to provide staff members with adequate information concerning medications.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1002. Medication Orders (I).

A. Medications, to include oxygen, shall be administered to patients only upon orders of a physician or other legally authorized health care provider.

B. All orders (including verbal) shall be received only by licensed nurses or other legally authorized health care providers and shall be authenticated and dated by a physician or other legally authorized health care provider pursuant to policies and procedures, but no later than 72 hours after the order is given. Verbal orders received shall include the time of receipt of the order, description of the order, and identification of the physician or other legally authorized health care provider and the individual receiving the order.

C. Medications and medical supplies ordered for a specific patient shall not be provided to or administered to any other patient.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1003. Administering Medication (I).

Each medication dose administered shall be properly recorded in the patient's record as the medication is administered. The medication administration record shall include the name of the medication, dosage, mode of administration, date, time, and the signature of the individual administering the medication. Initials may be utilized when recording administration, provided identification of the individual's initials is located within the record.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1004. Pharmacy Services (I).

Licensees that maintain stocks of legend medications and biologicals for patient use shall obtain and maintain a valid, current, applicable pharmacy permit, displayed in a conspicuous location, from the S.C. Board of Pharmacy and have a consultant pharmacist on-call during operating hours.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1005. Medication Containers (I).

Medications for each patient shall be dispensed from their original container(s), including unit dose systems. There shall be no transferring between containers or opening blister packs to remove medications for destruction or adding new medications for administration except by direction of a physician or other legally authorized health care provider.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1006. Medication Storage (I).

A. Medications shall be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety and security. Medications shall be stored in accordance with manufacturer's directions and in accordance with all applicable state and federal laws and regulations.

B. Medications shall be properly stored and safeguarded to prevent access by unauthorized persons. Expired or discontinued medications shall not be stored with current medications. Storage areas shall be of sufficient size for clean and orderly storage and shall be locked when not under direct observation by a licensed health care provider. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf-life.

C. Medications requiring refrigeration shall be stored in a refrigerator at the temperature established by the U.S. Pharmacopeia (36 – 46 degrees F.). Food and drinks and laboratory specimens shall not be stored in the same refrigerator in which medications and biologicals are stored. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals.

D. Medications shall be stored:

1. Separately from poisonous substances, blood, or body fluids;

2. In a manner that provides for separation between oral and topical medications;

3. Separately from food.

E. Records shall be maintained of all stock controlled substances that indicate an accounting of all items received and/or administered in such a manner that the disposition of each dose of any particular item may be readily traced. Records shall be maintained for a minimum of two years or until the next inspection by the Department's Division of Health Licensing.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1007. Disposition of Medications (I).

A. Medications shall not be retained in stock after the expiration date on the label and no contaminated or deteriorated medications shall be maintained. Expired, damaged, or deteriorated medications and biologicals shall be disposed of in the following manner:

1. When noncontrolled legend medications are destroyed, the following shall be documented: date of destruction, medication name, strength, quantity, mode of destruction, and the name of the individual performing the destruction and a witness. The medications may also be disposed of by returning them to the dispensing pharmacy and obtaining a receipt from the pharmacy.

2. The destruction of controlled substances shall be accomplished pursuant to the requirements of R.61–4.

B. Destruction records shall be retained by the facility for at least two years or until the Department's Division of Health Licensing's next inspection.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1100

EMERGENCY PROCEDURES/DISASTER PREPAREDNESS

1101. Emergency Services (I).

A. Appropriate equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital.

B. The licensee shall make arrangements for obtaining blood and blood products to meet emergency situations.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1102. Disaster Preparedness (II).

The licensee shall establish plans, based on equipment and staff capabilities, to meet its responsibilities for providing emergency care.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1103. Emergency Call Numbers (I).

Although the equipment may be in a location that has access to "911," emergency call data shall be immediately available and shall include, at a minimum, the telephone numbers of fire and police departments, ambulance service, and the Poison Control Center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1200

FIRE PREVENTION

1201. Arrangements for Fire Department Response/Protection (I).

A. Each licensee shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, i.e., fire plan and evacuation plan.

B. When equipment is located outside a service area or range of a public fire department, the licensee shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1202. Tests and Inspections (I).

A. Fire protection and suppression systems shall be maintained and tested in accordance with NFPA 10, 13, 14, 15, 25, 70, 72, and 96.

B. Fire alarm systems shall be maintained in a safe, operable condition in accordance with NFPA 70 and 99 and shall be inspected at least annually.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1203. Fire Response Training (I).

A. Each staff member shall receive training within 24 hours of his or her first day on the job and at least annually thereafter, addressing at a minimum, the following:

1. Fire plan;
2. Reporting a fire;
3. Use of the fire alarm system, if applicable;
4. Location and use of fire-fighting equipment;
5. Methods of fire containment;
6. Specific responsibilities, tasks, or duties of each staff member.

B. A plan for the evacuation of patients, staff members, and visitors, to include evacuation routes and procedures in case of fire or other emergencies, shall be established and posted in conspicuous public areas.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1204. Fire Drills (I).

A. An unannounced fire drill shall be conducted at least quarterly for all shifts. Each staff member shall participate in a fire drill at least once each year. Records of drills shall be maintained, indicating the date, time, shift, description, and evaluation of the drill and the names of staff members directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, the provisions of the statute or regulation shall be complied with and shall supersede the requirements of this section.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1203 above.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1300

EQUIPMENT MAINTENANCE

1301. General (II).

Equipment utilized for providing treatment/procedures, including its component parts, shall be properly maintained to perform the functions for which it is designed.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1302. Equipment (II).

A. Equipment used in the provision of care, treatment, procedures, and/or services shall meet appropriate specifications and calibrations and shall be monitored and operated in accordance with the manufacturer's guidelines and with local, state, and federal laws. Records shall be maintained to indicate all testing and maintenance.

B. If equipment for the administration of anesthesia is utilized, it shall be readily available, clean or sterile, and operating properly.

1. Anesthesia apparatus shall be equipped with a device to measure the oxygen component of the gas being inhaled by the patient. The device shall emit audible and visual alarms should the proportion of oxygen fall below a safe level. (I)

2. A record of the inspections made prior to each use of the anesthesia equipment, as well as a record of all service and repair performed on all anesthesia machines, vaporizers, and ventilators, shall be maintained and retained for a minimum of two years or until the next Department's Division of Health Licensing inspection.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1303. Preventive Maintenance of Life Support Equipment (II).

A. A written preventive maintenance program shall be developed and implemented for all life support equipment, to include, but not be limited to:

1. Patient monitoring equipment;
2. Isolated electrical systems;
3. Patient ground systems;
4. Medical gas systems.

B. This equipment shall be calibrated, if applicable, and/or tested at periodic intervals, but not less than annually, to insure proper operation. After repairs and/or alterations are made to any equipment or system, thorough testing for proper operation shall be accomplished prior to returning it to service. (I)

C. Records shall be maintained on all life support equipment to indicate its history of testing and maintenance.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1400

INFECTION CONTROL AND ENVIRONMENT

1401. Staff Practices (I).

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable guidelines of the Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970; the Centers for Disease Control and Prevention (CDC) *Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices and the Hospital Infection Control Practices Advisory Committee*; the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*, and R.61–105; and other applicable federal, state, and local laws and regulations.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1402. Vaccinations (I).

A. Hepatitis B.

1. All direct care staff who perform tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case the decision shall be documented.

2. Each staff member who elects vaccination shall have completed the initial dose of the three-dose series within 30 days of employment.

B. Influenza. All direct care staff shall have an annual influenza vaccination unless contraindicated or offered and declined. In either case the decision shall be documented.

C. MMR and Varicella. All direct care staff shall have been vaccinated or have evidence of immunity for measles, rubella, and varicella prior to patient contact unless contraindicated or offered

and declined. In either case the decision shall be documented. Immunity to mumps is recommended.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1403. Sterilization (If applicable) (I).

A. If applicable, sterilizing equipment of the appropriate type shall be available and of adequate capacity to properly sterilize instruments and treatment/procedure room materials as well as laboratory equipment and supplies. The sterilizing equipment shall have approved control and safety features. The accuracy of instrumentation and equipment shall be tested at least quarterly; periodic calibration and/or preventive maintenance shall be provided as necessary and a history of testing and service maintained.

B. The dates of sterilization and expiration shall be marked on all supplies sterilized or licensees may utilize "event-related" methodologies for determining sterile integrity in lieu of "time-related" methods provided there is an established policy and procedure.

C. Provisions shall be made for appropriate storage and distribution of sterile supplies and equipment pursuant to policies and procedures.

D. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area, appropriate to the area and the equipment's purpose or use, shall be accomplished. A method of monitoring disinfectant performance shall be employed. Disinfectants, e.g., glutraldehyde, Cidex, Sporox, hydrogen peroxide, shall be tested and maintained according to manufacturer's instructions and shall include, at a minimum, a record of readings/testings and change dates of the disinfectant solution. Disinfectants must bear the U.S. Environmental Protection Agency (EPA) registration number and be approved by EPA or FDA for the particular use.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1404. Tuberculin Screening (I).

A. Tuberculin screening, utilizing a two-step intradermal (Mantoux) method of five tuberculin units of stabilized purified protein derivative (PPD), is a procedure recommended by the CDC Guidelines for Preventing Transmission of Mycobacterium Tuberculosis in Health Care Facilities to establish baseline status. The two-step procedure involves one initial tuberculin skin test with a negative result, followed 7–21 days later by a second test. A licensed nurse may perform the tuberculin screening.

B. Testing Procedures.

1. Direct care staff members shall have a two-step tuberculin skin test within three months prior to patient contact. If there is a documented negative tuberculin skin test (at least single-step) within the previous 12 months, the individual shall be required to have only one tuberculin skin test to establish a baseline status. If two-step testing is indicated, it is acceptable for staff and volunteers who are asymptomatic for TB to begin patient contact after completion of the first skin test with a documented negative result.

2. Individuals with negative test results from the initial two-step procedure shall be required to have an annual one-step skin test.

C. Positive Reactions/Exposure.

1. Individuals with tuberculin skin test reactions of 10mm or more of induration and known human immunodeficiency virus (HIV)-positive individuals with tuberculin skin test reactions of 5mm or more of induration shall be referred to a physician or other legally authorized health care provider for appropriate evaluation.

2. All persons who are known or suspected to have tuberculosis (TB) shall be evaluated by a physician or other legally authorized health care provider. These individuals shall not be allowed to return to work until they have been declared non-contagious.

3. Patients with symptoms of TB shall be isolated and/or treated or referred as necessary by a physician or other legally authorized health care provider, and documented in the patient record.

4. Individuals who have a prior history of TB shall be required to have a chest radiograph and certification within one month prior to employment by a physician or other legally authorized health care provider that they are not contagious.

5. If an individual who was previously documented as skin test negative has an exposure to a documented case of TB, the local county health department or the Department's TB Control Division shall be contacted immediately for consultation.

6. An individual with TB infection who remains asymptomatic shall not be required to have a chest radiograph but shall have an annual documented assessment by a physician or other legally authorized health care provider for symptoms suggestive of TB, e.g., cough, weight loss, night sweats, fever, etc.

D. Treatment.

1. Preventive treatment of individuals who are new positive reactors is recommended unless specifically contraindicated.

2. Individuals who complete treatment either for disease or infection are exempt from further treatment unless they develop symptoms of TB.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1405. Housekeeping (II).

The equipment location shall be neat, uncluttered, clean, and free of vermin and offensive odors; housekeeping shall at a minimum include:

A. Cleaning each specific area;

B. Cleaning treatment/procedure rooms in accordance with established written procedures.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1406. Infectious Waste (I).

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be segregated, stored, and disposed of in a manner compliant with *Infectious Waste Management* R.61–105, OSHA Bloodborne Pathogens Standard, and the Department's *Guidelines For Prevention and Control of Antibiotic Resistant Organisms in Health Care Settings*.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1407. Clean/Soiled Linen (II).

A. A supply of clean, sanitary linen shall be available at all times and not stored with other items. In order to prevent the contamination of clean linen by dust or other airborne particles or organisms, it shall be stored and transported in a sanitary manner, i.e., enclosed and covered. Linen storage rooms shall be used only for the storage of linen.

B. Soiled linen.

1. Provisions shall be made for collecting, transporting, and storing soiled linen and surgical clothing;

2. Soiled linen shall be kept in enclosed/covered containers.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1500

QUALITY IMPROVEMENT PROGRAM

1501. General (II).

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care, treatment, procedures, and/or services provided.

B. The quality improvement program, as a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is systematically, objectively, and regularly accomplished at a frequency as determined by policies and procedures to ensure that policies and procedures and this regulation are met, but not less than every three months:

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Analyze all serious incidents and accidents, to include all patient deaths and significant medication errors;

5. At least every three months, review an established percentage of patient records to verify the accuracy and integrity of the system and take corrective action as needed;

6. Establish a systematic method of obtaining feedback from patients and other interested persons, e.g., family members and peer organizations, as expressed by the level of satisfaction with care, treatment, procedures, and/or services received.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1600

DESIGN AND CONSTRUCTION

1601. General (II).

The building in which equipment is utilized shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1602. Local and State Codes and Standards (II).

Buildings and mobile units shall meet requirements for "Business Occupancy," and shall comply with State Fire Marshal regulations and pertinent local and state laws, codes, ordinances, and standards with reference to design and construction. No equipment shall be licensed unless the Department has assurance that responsible local officials (zoning and building) have approved the building in which it is housed.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1700

FIRE PROTECTION EQUIPMENT AND SYSTEMS

1701. Firefighting Equipment (I).

Firefighting equipment such as fire extinguishers, standpipes and automatic sprinklers shall be provided as required by the State Fire Marshal.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1702. Flammable Liquids (I).

The storage and handling of flammable liquids shall be in accordance with NFPA 30 and 99.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1703. Gases (I).

A. Gases, i.e., flammable and nonflammable, shall be handled and stored in accordance with the provisions of NFPA 99 and 101.

B. Installation, maintenance, and testing of piped gas systems shall meet the provisions of NFPA 99.

C. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously and placed on oxygen cylinders. All cylinders shall be properly secured in place.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

1704. Furnishings/Equipment (I).

A. The physical plant shall be maintained free of fire hazards and impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted at the equipment location except as permitted by the State Fire Marshal Regulations.

C. Wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant in accordance with NFPA 701, *Standard Methods of Fire Tests for Flame-Resistant Textiles and Films*.

EXCEPTION: Window blinds require no flame treatments or documentation thereof.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1800

MOBILE UNITS

1801. Care/Services.

A. All mobile units, e.g., self-contained vans or tractor trailers, that transport equipment from one host site to another, shall meet the current standards of this regulation and of the local, state, and federal Departments of Transportation for the permitting and safe operation of the vehicle. Such compliance includes approval by the Federal Food and Drug Administration (FDA) for the provision of diagnostic or therapeutic services in the mobile unit.

B. A mobile cardiac catheterization laboratory shall only provide services on the campus of a host hospital that has emergency medical and intensive coronary care services.

C. A procedure shall not be performed on a patient in a mobile cardiac catheterization laboratory if any of the following are present:

1. Recent myocardial infarction (within 10 days or less);
2. Uncontrolled arrhythmias;
3. Severe uncontrolled congestive heart failure;
4. Current hospitalization with highly unstable angina;
5. The patient is under 18 years of age.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 1900

SEVERABILITY

1901. General.

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

SECTION 2000

GENERAL

2001. General.

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Added by State Register Volume 28, Issue No. 5, eff May 28, 2004.

61–109. Standards for Permitting Body Piercing Facilities.

(Statutory Authority: 1976 Code Section 44–32–10, et seq.)

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SECTION 100–DEFINITIONS

For the purpose of this regulation, the following definitions shall apply:

A. Administrator. The individual designated by the facility permit holder to have the authority and responsibility to manage the facility and to be in charge of all functions and activities of the facility.

B. Adult. A person eighteen (18) years of age or older.

C. Aftercare. Services provided to clients, when necessary, after their release from a facility.

D. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific treatments, care, or services to technicians and/or clients.

E. Body Piercing. The creation of an opening in the body of a human being so as to create a permanent hole for the purpose of inserting jewelry or other decoration. This includes, but is not limited to, piercing of an ear, lip, tongue, nose, or eyebrow, but does not include piercing an ear lobe with a disposable, single-use stud or solid needle that is applied using a mechanical device to force the needle or stud through the ear lobe.

F. Client. A person who has a body piercing procedure performed on his or her body.

G. Consultation. A visit by Department representative(s) who will provide information to facilities with the goal of facilitating compliance with these regulations.

H. Contaminated or Contamination. The presence of blood, infectious materials, or other types of impure materials that have corrupted a surface or item through contact.

I. Department. The South Carolina Department of Health and Environmental Control.

J. Disinfection. The action of using an agent, such as isopropyl alcohol solution, that kills germs or microorganisms.

K. Ear Lobe. The lower portion of the ear which contains no cartilage.

L. Facility. Any room, space, location, area, structure, mobile unit or business, or any part of any of these places, identifiable by a mailing address, where body piercing is practiced or where the business of body piercing is performed.

M. Inspection. A visit by a Department representative(s) for the purpose of determining compliance with this regulation.

N. Investigation. A visit by a Department representative(s) to a permitted or unpermitted entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

O. Minor. Any person who has not attained eighteen (18) years of age.

P. Picture Identification. A valid driver's license from any state or an official photographic identification card issued by the South Carolina Department of Revenue, a federal or state law enforcement agency, an agency of the United States Department of Defense, or the United States Department of State, such as a military ID or passport.

Q. Probation. An action taken by the Department in which a facility is notified that it must comply with the provisions of this regulation within a specified period of time or enforcement actions may be imposed.

R. Release. The point at which the client's active involvement with a facility is terminated and the facility no longer maintains active responsibility for the client.

S. Repeat Violation. The recurrence of any violation cited under the same section of the regulation within a thirty-six (36) month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

T. Responsible Party. A person who is authorized by the client or by law to make decisions on behalf of the client, to include but not be limited to, a court-appointed guardian or conservator, or a person with a health care or other durable power of attorney.

U. Sanitize or Sanitization. A procedure that reduces the level of microbial contamination so that the item or surface is considered safe.

V. Sterilization. The approved procedure of making an object free of live bacteria, spores, or other microorganisms including pathogens, usually by heat or chemical means.

W. Suspend Permit. An action by the Department requiring a facility to cease operations for a period of time until such time as the Department rescinds that restriction.

X. Technician. A person who practices body piercing in South Carolina and is in compliance with this regulation.

SECTION 200—PERMIT REQUIREMENTS

201. Scope of Permit

A. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself, such as advertising or marketing, as a body piercing facility in South Carolina without first obtaining a permit from the Department. Facilities that perform body piercing prior to the effective date of permitting are in violation of S.C. Code Sections 44–32–10, *et seq*.

B. When it has been determined by the Department that body piercing is being performed at a location, and the owner has not been issued a permit from the Department to perform such procedures, the owner shall cease operation immediately.

C. Current or previous violations of the South Carolina Code of Laws and/or Department regulations may jeopardize the issuance of a permit for the facility or the permitting of any other facility or addition to an existing facility which is owned or operated by the permit holder. The facility shall provide only the procedures or services it is permitted to provide pursuant to the definition in Section 100 of this regulation.

202. Permit Application

A. Prior to applying to the Department for a permit, a proposed facility shall:

1. Obtain a copy of this regulation from the Department, and sign and return to the Department an acknowledgement upon receipt; and

2. Ensure that all technicians comply with all applicable federal Office of Safety and Health Administration (OSHA) requirements or guidelines, and obtain certificates attesting to the successful completion of courses in: Bloodborne pathogens; body piercing infection control as approved by the Department; American Red Cross First Aid; and adult cardiopulmonary resuscitation (CPR).

B. Applicants for a permit shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial permitting and annually thereafter. The application includes both the applicant's oath assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two (2) of its officers. The

application shall set forth the full name and address of the facility for which the permit is sought and of the owner in the event his or her address is different from that of the facility, and the name(s) of the person(s) in control of the facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with this regulation. Corporations or partnerships shall be registered with the South Carolina Office of the Secretary of State. Other required application information includes:

1. Copy of the business license, as applicable;
2. Permitting fee (see Section 205); and
3. Written agreement with a public fire department arranging for emergency response in case of fire, if applicable (see Section 1401).

203. Compliance

An initial permit shall not be issued to a proposed facility that has not been previously and continuously permitted under Department regulations until the permit holder has demonstrated to the Department that the proposed facility is in substantial compliance with this regulation. In the event a permit holder who already has a facility or activity licensed or permitted by the Department makes application for another facility, the currently licensed or permitted facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a permit to the proposed facility. A copy of this regulation shall be maintained at the facility. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations, to include applicable federal Office of Safety and Health Administration (OSHA) requirements or guidelines.

204. Issuance and Terms of Permit

A. A permit is issued by the Department and shall be posted in a conspicuous place in a public area within the facility. (II)

B. The issuance of a permit does not guarantee safety conditions, or the adequacy of sanitation or sterilization procedures provided. (II)

C. A permit is not assignable or transferable and is subject to suspension or revocation at any time by the Department for the permit holder's failure to comply with the laws and regulations of this state. (II)

D. A permit shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A permit shall remain in effect until the facility is otherwise notified by the Department. (II)

E. Mobile units shall have a permanent mailing address, permits shall indicate that address, and that the facility is mobile. Schedules of mobile unit locations shall be submitted quarterly to the Department.

F. Permitted facilities shall be allowed to continue utilizing the previously-permitted structure without building modification and shall comply with the remainder of the standards within this regulation.

205. Permitting Fees

A. Method of Payment. Permitting fees shall be made payable by check, credit card, or money order to the Department.

B. Fees include an initial fee and annual renewal fee of three hundred dollars ($300.00), and an additional amount may be charged if necessary to cover the cost of inspection.

C. If a permit renewal is denied, a portion of the fee shall be refunded based upon the remaining months of the permitted year.

206. Permit Renewal

To renew a permit, applicants shall file an application with the Department and pay a permit fee.

207. Change of Permit

A. A facility shall request issuance of an amended permit by application to the Department prior to any change of ownership of the facility.

B. Change of facility location from one geographic site to another shall be by letter or application to the Department in accordance with Section 202. Section 207.B is not applicable to mobile facilities.

C. Changes in a facility name or address as notified by the post office shall be accomplished by application or letter from the permit holder.

208. Exceptions to Permitting Standards

The Department has the authority to make exceptions to these standards when it is determined that the health, safety, and well-being of the clients will not be compromised and provided the standard is not specifically required by statute.

SECTION 300—ENFORCEMENT OF REGULATIONS

301. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or permitted facility in order to enforce this regulation.

302. Inspections and Investigations

A. Inspections shall be conducted prior to initial permitting of a facility. The Department, at its own determination, may also conduct subsequent inspections.

B. All facilities are subject to inspection or investigation at any time without prior notice by legally authorized individuals.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records at the time of the inspection. If photocopies are made for the Department inspector(s), they shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or effect upon clients as determined by the inspector(s). (II)

D. A facility found noncompliant with the standards of this regulation or governing statute shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified by the Department. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences, actual and similar; and
3. The actual or expected completion dates of those actions.

E. In accordance with S.C. Code Section 44–32–40, the Department may charge a fee for permitting inspections.

303. Probation

A. The Department may place a facility on probation when it has been determined that the facility has failed to maintain a business address or telephone number at which the facility may be reached during business hours, or violated any other standard of this regulation, as deemed appropriate.

B. The facility shall post the probationary letter from the Department in a conspicuous place in the facility until such time that the Department has determined that sufficient corrective action has been taken.

SECTION 400—ENFORCEMENT ACTIONS

401. General (II)

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice to the permit holder, may deny, refuse to renew, suspend, or revoke permits.

402. Violation Classifications

Violations of standards in regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time,

as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety, or well-being of persons in the facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, as "(I)" or "(II)." Sections not annotated in that manner denote Class III violations. A classification at the beginning of a section and/or subsection applies to all subsections following, unless otherwise indicated.

E. In arriving at a decision to take enforcement action, the Department will consider the following factors: the number and classification of violations, including repeat violations; specific conditions and their impact or potential impact on health, safety, or well-being of the clients; efforts by the facility to correct cited violations; behavior of the permit holder that would reflect negatively on the permit holder's character, such as illegal or illicit activities; overall conditions of the facility; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations.

SECTION 500—POLICIES AND PROCEDURES

A. Policies and procedures addressing each section of this regulation regarding client procedures or services, rights, infection control, and the operation of the facility shall be developed and implemented by the facility, and revised as appropriate in order to accurately reflect actual facility operation. Facilities shall establish a time-period for review of all policies and procedures. These policies and procedures shall be accessible at all times and a hard copy shall be available or be readily accessible electronically.

B. By its application, the permit holder agrees to comply with all standards of this regulation. The policies and procedures shall describe the means by which the facility shall ensure that the standards described in this regulation are met.

C. Each facility shall conspicuously display a clearly legible notice to clients informing them of any disqualification that body piercing may confer upon a prospective blood donor according to the standards of the American Association of Blood Banks. This notice shall also appear in any informed consent or release form which a technician uses, and shall be signed by the prospective client, and contain, at a minimum, aftercare suggestions for the specific piercing site.

SECTION 600—STAFF AND TRAINING

601. General (II)

A. Appropriate technicians in numbers and training shall be available at the facility to provide appropriate, safe body piercing procedures to clients and meet the demands of effective emergency on-site action that may arise. Training and qualifications for the tasks each performs shall be in compliance with all professional standards and applicable federal and state laws and regulations.

B. Technicians shall not be under the influence of any drugs, alcohol, or other substance that would impair his or her ability to perform body piercing. (I)

C. All new technicians shall be oriented to acquaint them with the organization and environment of the facility, their specific duties and responsibilities, and client needs.

D. The facility shall maintain accurate current information regarding all technicians of the facility, to include at least address, phone number, health, work, and training background, as well as current health and education information. The facility shall assign duties and responsibilities to all technicians in writing and in accordance with the individual's capability.

602. Administrator

The permit holder shall designate an individual to serve as administrator. The administrator shall have the authority and responsibility for the overall operation of the facility and is responsible for ensuring

compliance with these regulations. An individual shall be designated, in writing, to act in the absence of the administrator. A facility technician may also serve as the administrator.

603. Inservice Training (II)

A. The following training shall be provided by appropriate resources as approved by the Department to all technicians in the context of their job duties and responsibilities prior to client contact and at a frequency determined by the facility, but at least annually:

1. Adult cardiopulmonary resuscitation (CPR), renewed annually;
2. American Red Cross First Aid certification, American Safety and Health Institute Certification, or certification from a program that meets or exceeds the certification standards of the Red Cross First Aid or the American Safety and Health Institute, required for each technician every three (3) years;
3. OSHA standards in bloodborne pathogens; and
4. Body piercing infection control.

B. Prior to independently performing body piercing procedures, a new technician shall complete a minimum of four hundred (400) training hours under the direct supervision of an experienced technician who shall sign and maintain a statement attesting to the completion of such training.

604. Health Status (I)

No person infected with or a carrier of a serious communicable disease, such as tuberculosis, which may be transmitted to clients in the facility, or having boils, open or infected skin lesions shall have client contact.

SECTION 700—REPORTING

701. Accidents and/or Incidents (II)

A. The facility shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin, responsible party, or emergency contact for each affected individual at the earliest practicable hour, not to exceed twenty-four (24) hours. The permit holder shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email, facsimile, or other method as determined by the Department. The permit holder shall submit a report of the permit holder's investigation of the accident and/or incident to the Department within five (5) calendar days. Accidents and/or incidents requiring reporting include, but are not limited to,:

1. Actual or suspected abuse by technicians;
2. Criminal event against client(s);
3. Those resulting in hospitalization;
4. Severe lacerations; and
5. Severe hematomas.

B. Reports submitted to the Department shall contain only: facility name, permit number, type of accident and/or incident, date accident and/or incident occurred and location, number of clients directly injured or affected, client age and sex, number of staff directly injured or affected, witness(es) name(s), identified cause of accident and/or incident, internal investigation results if cause unknown, a brief description of the accident and/or incident including location where occurred, treatment of injuries, identity of other agencies notified, if applicable, and date of the report. The report retained by the facility, in addition to the minimum reported to the Department, shall contain: name(s) of client(s), staff and/or technicians, the injuries and treatment associated with each client, staff, and/or technician. Records of all accidents and/or incidents shall be retained by the facility for six (6) years after the date of the report.

702. Fire and Disasters (II)

The Department shall be notified immediately via telephone, email, facsimile, or other method as determined by the Department regarding any fire in the facility, or natural disaster, which jeopardizes the safety of any persons in the facility, followed by a complete written report, to include fire department reports, if any, to be submitted within a time-period determined by the facility, but not to exceed seventy-two (72) hours from the occurrence of the fire or natural disaster.

703. Administrator Change

The Department shall be notified in writing by the permit holder within ten (10) days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual and effective date of the appointment.

704. Facility Closure

A. Prior to the permanent or temporary closure of a facility, the facility permit holder shall notify the Department in writing of the intent to close and the effective closure date. Within ten (10) days of closure, the facility shall notify the Department of the provisions for the maintenance of the facility records as required by regulation. On the date of permanent closure, the current original permit shall be returned to the Department.

B. In instances where a facility temporarily closes, the permit holder shall notify the Department in writing within fifteen (15) days prior to temporary closure. In the event of temporary closure due to an emergency, the facility shall notify the Department in writing within twenty-four (24) hours of the closure. At a minimum this notification shall include, but not be limited to, the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the facility prior to its reopening. If the facility is closed for a period longer than one (1) year, and there is a desire to reopen, the facility shall reapply to the Department for a permit and shall be subject to all permitting requirements at the time of that application, including construction-related requirements for a new facility.

SECTION 800—CLIENT RECORDS

801. Content (II)

A. The facility shall initiate and maintain a client record for every individual who has undergone body piercing. The record shall contain sufficient documented information to identify the client and verify the procedure(s) performed. All entries shall be written legibly in ink or typed, signed and dated, and shall identify the author.

B. Specific entries and/or documentation shall include at a minimum:

1. Identification of the client including a means of verification of client's identity, such as a copy of client's photo identification;

2. Explanation of client rights in accordance with Section 1000, as evidenced by the technician's and client's signature, including a clearly legible notice informing him or her of any disqualification which body piercing may confer upon a prospective blood donor in accordance with Section 500.C;

3. Body piercing procedure performed, including the site of the piercing;

4. Procedures followed if an unexpected event occurs, and emergency procedures taken if there is an adverse reaction; and

5. Emergency contact information for the client in case of emergency, including name, address, phone number, and other pertinent contact information.

C. The facility shall provide clients with a release or aftercare note.

802. Record Maintenance

A. The facility shall adequately produce, protect, and store client records.

B. The facility shall determine the medium in which information is stored.

C. The facility shall maintain client records for at least six (6) years following the release of the client. The information shall be readily available to staff as needed and for Department inspections.

SECTION 900—CLIENT PROCEDURES AND SERVICES

901. General (I)

A. The facility shall perform body piercing only for those persons for which the facility can provide the appropriate accommodations and services.

B. Body piercing shall be rendered effectively and safely.

C. Body piercing shall not be performed upon a person impaired by drugs or alcohol to the extent that he or she is incapable of consenting to body piercing and incapable of understanding body piercing procedures and aftercare suggestions.

D. Body piercing shall not be performed on skin surfaces having sunburn, rash, keloids, pimples, boils, infections, open lesions, or manifest any evidence of unhealthy conditions.

E. Prior to performing a procedure on a client, the technician shall obtain information from the client regarding any existing condition(s) that could affect the healing process, such as allergies to latex or nickel, or taking medications such as anticoagulants that thin the blood and/or interfere with blood clotting. If a client indicates the presence of such a condition, the facility shall obtain documentation from a physician or other legally authorized healthcare provider that the procedure is not contraindicated, prior to the body piercing procedure.

F. Clients shall be given the opportunity to participate in aftercare programs if offered by the facility. (II)

G. The facility shall provide aftercare recommendations to the client prior to performing body piercing as part of the informed consent process in accordance with Section 1001.C to include but not be limited to:

1. Instructions for care following body piercing procedures;
2. Possible side effects;
3. Restrictions; and
4. Infection control information.

902. Age Restrictions (II)

A. The facility shall verify by means of a picture identification that a recipient is at least eighteen (18) years of age.

B. A body piercing technician shall not perform or offer to perform body piercing upon a person under eighteen (18) years of age, unless the body piercing is performed in the presence of, or as directed by a notarized statement by the minor's responsible party, or if the client is emancipated in accordance with state law.

SECTION 1000—CLIENT RIGHTS

1001. Informed Consent (II)

A. The facility shall inform the client or responsible party if the client is a minor, of the potential for any risks, and/or adverse effects or consequences regarding the body piercing procedure(s) to be performed. In all instances of body piercing, the client must voluntarily choose, in writing, to receive the procedure.

B. The facility shall inform clients of the metal content of jewelry utilized in each procedure and its safety for human implant. Such content shall comply with the American Society for Testing Materials Specifications.

C. The informed consent process shall include, at a minimum:

1. Information relating to disqualification that body piercing may confer upon a prospective blood donor in accordance with Section 500.C; and
2. Aftercare recommendations for the body piercing procedure.

1002. Grievances and Complaints (II)

The facility shall inform the client or responsible party in writing of the grievance procedure should the client consider one or more of his or her rights violated. The facility shall include the address and phone number of the Department in the grievance procedure.

1003. Procedures and Charges

Body piercing procedures performed by the facility and the charges for such procedures shall be stated in writing, and the client, or responsible party if client is a minor, shall be made aware of such charges and procedures as verified by his or her signature, prior to the procedure.

SECTION 1100—MAINTENANCE

A. A facility shall keep the structure, component parts, amenities, and equipment in good repair and operating condition to perform the functions for which they were designed. (II)

B. The physical plant shall be maintained free of fire hazards or impediments to fire prevention. (I)

SECTION 1200—INFECTION CONTROL AND ENVIRONMENT

1201. Staff Practices (I)

Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures or practices shall be in compliance with applicable regulations and guidelines of the Occupational Safety and Health Administration (OSHA), for example, the Bloodborne Pathogens Standard; the Centers for Disease Control and Prevention; Regulation 61–105, Infectious Waste Management; and other applicable state, federal, and local laws and regulations.

1202. Hepatitis B Vaccination (I)

A. All technicians shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case, the decision shall be documented.

B. Each technician who elects to have the series shall have completed the initial dose of the three (3) dose series within thirty (30) days of employment.

1203. Infection Control (I)

A. A technician shall utilize the following infection control measures:

1. Before and after each body piercing procedure, wash his or her hands thoroughly for a minimum of twenty (20) seconds with water and a liquid germicidal solution approved by the Department, used in accordance with the manufacturer's directions, and dried with single-use disposable paper towels or electric air dryer;

2. When necessary to perform a procedure on certain individuals who must undergo shaving of hair, utilize a single-use disposable razor;

3. The site of the body piercing shall be cleaned in a sterile surgical manner with a liquid germicidal solution approved by the Department and used in accordance with the manufacturer's direction and then swabbed with a disinfectant prior to piercing;

4. Utilize single-use sterile disposable gloves when setting up equipment and performing procedures on a client and immediately replace upon notice of a tear, any contamination, or other defect;

5. Prior to any direct contact with the client, place in a sterile manner all sterile instruments and body piercing items or jewelry on a sterile disposable towel or drape to be used as a single sterile field throughout the procedure;

6. Re-gloving with single-use sterile disposable surgical gloves must occur prior to initiation of the procedure, which is to be performed using strict sterile surgical techniques. Any non-sterile contact or contamination of the instruments, jewelry, or field shall immediately result in cessation of the procedure and nonuse of all equipment until re-sterilized; and

7. After use, all single-use needles, razors, and other sharps shall be immediately disposed of in approved sharps containers; these used containers shall be labeled with the Universal Biohazard Symbol and the word "biohazard" and be disposed of in accordance with Regulation 61–105, Infectious Waste Management Regulations.

B. The use of gauze, alum, styptic pencils, or medical supplies deemed necessary to control bleeding is permissible provided that a separate disposable single-use sterile item is used on each client.

C. Food, drink, and the use of tobacco products in the procedure and disinfection or sterilization rooms shall be prohibited.

D. Live animals shall not be permitted in the procedure and disinfection or sterilization rooms.

EXCEPTION: This standard does not apply to patrol dogs accompanying security or police officers, guide dogs, or other service animals accompanying individuals with a disability into the procedure room.

1204. Sterilization of Equipment (I)

A. All used surgical equipment intended for reuse shall be properly scrubbed clean of visible materials and soaked for a minimum of twenty (20) minutes in a liquid germicidal solution approved by the Department, which shall be used in accordance with the manufacturer's direction. The equipment shall then be immediately placed in a mechanical ultrasonic cleanser for at least twenty-five (25) minutes prior to being re-sterilized by autoclave. The ultrasonic cleanser shall be clearly labeled as "biohazardous" and shall be located as far as possible from the autoclave within the disinfection or sterilization room.

B. Facilities shall properly package and sterilize by autoclave those needles, instruments, other surgical equipment, and body piercing items or jewelry that are not single-use or disposable, shall include a sterile indicator, and shall include a label with the date of sterilization.

C. A facility utilizing single-use or disposable equipment and/or instruments shall not be required to re-sterilize by autoclave those single-use and/or disposable items provided they are utilized and disposed of in accordance with the manufacturer's directions and not reused in any manner on another client.

D. Single-use items shall not be used on more than one (1) client for any reason unless properly sterilized. After use, all single-use needles, razors, and other sharps shall be immediately disposed of in approved sharps containers.

E. Each facility shall keep a written log for two (2) years of autoclave use, to include, but not be limited to, date and time of use and sterilization spore test strip results conducted at least monthly. (II)

1205. Housekeeping (II)

The interior and exterior of the facility shall be uncluttered, clean, free of safety hazards, and free of vermin and offensive odors.

A. Interior housekeeping of the facility shall, at a minimum, include:

1. Cleaning each specific area of the facility;

2. Cleaning and disinfection, as needed, of equipment and supplies used and/or maintained in each area, appropriate to the area and purpose or use of the equipment or supplies; and

3. Safe storage and use of chemicals indicated as harmful on the product label, cleaning materials, and supplies in cabinets or well-lighted closets and/or rooms, inaccessible to clients.

B. Exterior housekeeping at a facility shall, at a minimum, include:

1. Cleaning of all exterior areas, such as porches and ramps, and removal of safety impediments such as snow or ice; and

2. Keeping the facility grounds reasonably free of weeds, rubbish, overgrown landscaping, and other potential breeding sources of vermin.

1206. Refuse Disposal

A. A facility shall deposit all garbage and refuse in suitable watertight containers. A facility shall dispose of rubbish and garbage in accordance with local requirements.

B. A facility shall cover and store refuse containers outside on an approved platform constructed of concrete, wood, or asphalt and secured in such a manner so as to prevent overturning by animals, the entrance of flies, or the creation of a nuisance. A facility shall thoroughly clean garbage and trash containers as necessary to prevent the creation of a nuisance.

1207. Infectious Waste (I)

Accumulated waste, including all contaminated sharps, dressings, pathological, and/or similar infectious waste, shall be disposed of in a manner compliant with OSHA Bloodborne Pathogens Standards and R.61–105.

SECTION 1300—EMERGENCY PROCEDURES

1301. Emergency Call Numbers (I)

A facility shall post emergency call data in a conspicuous place and shall include at least the telephone numbers of fire and police departments, ambulance service, and the poison control center. Other

emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

1302. Medical Emergencies (I)

Medical emergencies shall be managed in a manner as to ensure the health, safety, and well-being of clients.

SECTION 1400—FIRE PREVENTION AND PROTECTION

1401. Arrangements for Fire Department Response (I)

Facilities located outside of a service area or range of a public fire department shall arrange by written agreement to have the nearest fire department respond in case of fire. A copy of the agreement shall be kept on file in the facility and a copy shall be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department.

1402. Inspections (I)

A facility shall maintain and test fire protection systems in accordance with the applicable provisions of the codes officially adopted by the South Carolina State Fire Marshal.

1403. Fire Response Training (I)

A. A facility shall provide fire response training for each technician and staff member within forty-eight (48) hours of his or her first day of employment in the facility and at least annually thereafter. A new facility seeking an initial permit shall provide the Department with evidence of fire response training for each technician and staff member prior to the initial permitting inspection. Fire response training shall address, at a minimum, the following:

1. Fire plan, including the training of staff members and technicians;
2. Reporting a fire;
3. Use of the fire alarm system, if applicable;
4. Location and use of fire-fighting equipment;
5. Methods of fire containment;
6. Specific responsibilities, tasks, and/or duties of each individual; and
7. Fire evacuation plan, including routes and procedures.

B. A facility shall establish a plan for the evacuation of clients, staff members, and technicians, to include procedures and evacuation routes out of the facility, in case of fire or other emergencies, and the plan shall be posted in conspicuous public areas throughout the facility.

SECTION 1500—DESIGN AND CONSTRUCTION

1501. General (II)

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each client.

1502. Adopted Codes and Standards (II)

Facility design and construction shall comply with applicable provisions of this regulation and the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

SECTION 1600—FACILITY ACCOMMODATIONS

1601. General (II)

A. A facility shall include a room for the purpose of disinfecting and sterilization of equipment that shall be physically separate from the room used for body piercing procedures to avoid cross-contamination of equipment. These areas shall be separated from each other and from waiting customers by a door, divider, or wall. A facility shall not store or otherwise keep supplies or equipment not utilized for disinfection or sterilization in this area.

B. Adequate artificial lighting shall be provided in the procedure rooms and disinfection or sterilization rooms.

C. Emergency electrical service shall be provided for procedure room lighting, corridor egress, and exit sign lighting.

1602. Procedure Rooms

A. The procedure room shall be sized to accommodate necessary equipment or supplies, staff, and procedure table, but not less than sixty-four (64) square feet of floor space, exclusive of fixed cabinets or shelves. The procedure room shall be utilized exclusively for body piercing. Multiple work stations shall be separated by dividers, curtains, walls, or partitions measuring at least four (4) feet in height.

1. Wall and floor surfaces of the procedure and disinfection or sterilization rooms shall be nonporous and easily cleanable.

2. A separate, properly identified sink, with hot and cold running water, used for disinfection practices only shall be located in the disinfection or sterilization room.

B. Procedure tables shall be constructed of a nonporous, sanitizable material.

C. Each procedure room shall have a high efficiency particulate air (HEPA) filter.

1603. First Aid Kit

A standard first aid kit or equivalent first aid supplies shall be readily accessible in the facility, and shall contain at a minimum:

A. 4″ × 4″ gauze pads;

B. Benzalkonium swabs;

C. 2″ × 2″ gauze pads;

D. Gauze roller bandage; and

E. Cardiopulmonary resuscitation (CPR) mouth barrier device.

1604. Restrooms (II)

A. There shall be an appropriate number of restrooms in the facility, to accommodate clients, staff, and visitors. The restrooms shall be accessible during all operating hours of the facility.

B. A restroom(s) shall be equipped with at least one (1) toilet fixture, toilet paper installed in a dispenser, a sink equipped with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle.

C. Equipment and supplies used in the course of body piercing procedures or disinfection and sterilization procedures shall not be stored or utilized in the restroom(s).

D. There shall be at least one (1) sink for every two (2) toilet fixtures located within a restroom.

E. Privacy shall be provided at toilet fixtures and urinals.

F. Restrooms for persons with disabilities shall be provided as required by local codes whether or not any of the staff or clients are disabled.

G. All restroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surfaces to the highest level of splash.

SECTION 1700—MOBILE UNITS

All mobile units shall meet the current and existing standards of the state, federal, and local departments of transportation for the permitting and safe operation of the vehicle. In addition, all interior aspects of the vehicle shall meet the same standards as described in this regulation for nonmobile facilities. (II)

SECTION 1800—SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

SECTION 1900—GENERAL

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Added by State Register Volume 26, Issue No. 5, Part 1, eff May 24, 2002. Amended by State Register Volume 40, Issue No. 5, Doc. No. 4569, eff May 27, 2016.

61–110. Total Maximum Daily Loads for Pollutants in Water.

(Statutory Authority: 1976 Code § 48–1–10 et seq.)

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B. Definitions.
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D. Public Informational Hearing.
E. Notice of Proposed Decision.
F. Administrative Appeal Process.
G. Revisions to an Approved TMDL
H. Severability.

A. Purpose and Scope.

(1) Section 48–1–50(20), S.C. Code of Laws (1976), authorizes the Department to conduct investigations of conditions in the air or waters of the State to determine whether or not standards are being contravened and the origin of materials which are causing the polluted condition. Section 48–1–50(6) authorizes the Department to conduct studies, investigations and research with respect to pollution abatement, control or prevention.

(2) The Department establishes Total Maximum Daily Loads (TMDLs) for pollutants in waters of the state, including those listed in accordance with the Federal Water Pollution Control Act (Public Law 92 500, as amended by Pub. L. 95–217, Pub. L. 95–276, Pub. L. 96–483, Pub. L. 97–117, and Pub. L. 100–4; 33 U.S.C. 1251 et seq.) Section 303(d) (33 USC Section 1313(d)) and 40 CFR Part 130. These regulations establish the process for public participation in and administrative appeal of TMDLs developed under section 303(d) of the Act.

B. Definitions.

(1) Other than those terms defined below, any term used in this regulation shall mean the same as defined in S.C. Regulation 61–68 or Section 48–1–10 et seq. of the Code of Laws, 1976, as amended.

(2) "Total Maximum Daily Load" (TMDL) means a written quantitative analysis of water quality for a pollutant at one or more sites in a watershed. A TMDL shall include identification of the pollutant, a calculation of the maximum amount of the pollutant that a waterbody can receive and still meet state water quality standards, load allocations for nonpoint sources and natural background, individual or categorical wasteload allocations for point sources, and a margin of safety.

(3) "Margin of safety" means a consideration of any lack of knowledge concerning the relationship between load and wasteload allocations and water quality. The margin of safety may be implicit, i.e., incorporated into the TMDL through conservative assumptions in the analysis, or explicit, i.e., expressed in the TMDL as a specific loading, or both. If the margin of safety is implicit, the conservative assumptions in the analysis that account for it shall be described. If the margin of safety is explicit, the loading set aside shall be identified. The Department shall present a detailed justification and rationale for use of the selected margin of safety.

C. Public Notice

(1) A notice will be published on the Department website or equivalent publicly available electronic media, when available, upon commencement of development of each TMDL, until such time as a draft is completed or the Department elects not to proceed with TMDL development, to solicit data and information in support of TMDL development. All data and information submitted, including characterizations of local conditions that affect attainment of water quality standards, shall be considered by the department before completing the TMDL and answered in a responsiveness summary that would be included in the TMDL.

(2) A public notice of each initial draft TMDL shall provide at least thirty (30) days from the date of notice within which interested persons may submit their views and information concerning the TMDL to the Department. The comment period shall be extended for an additional 30 days if a request is made in the initial 30 day comment period by any party, including an affected local public body. Comments will be considered in development of the final draft TMDL and addressed in a responsiveness summary, which will be provided to all commenters.

(3) Public notice of the draft TMDL shall be made by each of the following methods:

(a) publication of a notice in a daily or weekly newspaper within or near the area included in the TMDL; and

(b) notification of anyone who has specifically requested public notices. The list of such persons may be updated periodically and persons will be deleted who fail to respond to Department requests to identify continued interest; and

(c) publication on the Department website or equivalent publicly available electronic media, when available.

(4) All information supporting the TMDL, such as, but not limited to, data, models, inputs, and output, shall be available upon request from the outset of the public comment period.

D. Public Informational Hearing

(1) Any person may request a public informational hearing during the public comment period discussed in Article C.(1) above. Requests shall be in writing and shall state the nature of the issues to be raised at the informational hearing.

(2) The Department shall hold a public informational hearing upon request through an affirmative vote by an elected or appointed public body, or whenever fifteen (15) or more individual written requests are received during the public comment period and which raise issues specifically related to the development of the TMDL. An informational hearing may also be held whenever the Department staff determines that it may be beneficial. Such informational hearing will be conducted by Department staff.

(3) A notice of informational hearing shall be mailed to those persons providing comment in response to the public notice at least fifteen (15) days prior to the informational hearing.

(4) The close of the comment period shall be at the end of the informational hearing or later date if so specified by the Department.

(5) All public informational hearings shall be reported verbatim. A copy of the transcript shall be made available upon request.

E. Notice of Proposed Decision

Department staff shall issue a notice of proposed decision to submit a TMDL to the U.S. Environmental Protection Agency for approval. Such notice shall advise of availability of the final draft TMDL and related file information. Such notice shall be made available to those persons providing comment in response to the public notice and to those persons participating at an informational hearing.

F. Administrative Appeal Process

(1) The Notice of Proposed Decision may be appealed as a contested case in accordance with S.C. Regulation 61–72 and the S.C. Administrative Procedures Act.

(2) A person desiring to appeal a TMDL must submit a written request for an adjudicatory hearing to the Clerk of the Board of Health and Environmental Control within thirty (30) days after the date of the notice of proposed decision. The request must set forth the manner in which the person requesting the hearing would be injured by issuance of the TMDL. If no appeal of the proposed decision is timely received, the proposed decision of the Department shall become final.

(3) Upon timely request for a hearing, the matter shall be heard as a "contested case" under the South Carolina Administrative Procedures Act, and shall be processed according to law. Determinations of whether a person has legal standing to contest a determination shall be made in the course of the contested case proceeding.

G. Revisions to an Approved TMDL

The Department may revise an approved TMDL to accommodate new information. Revisions to load or wasteload allocations in approved TMDLs shall be subject to the same public participation and administrative appeal processes set forth herein.

H. Severability

Should any section, paragraph, sentence, word, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

HISTORY: Added by State Register Volume 29, Issue No. 5, eff May 27, 2005.

61–111. Standards for Licensing Tattoo Facilities.

(Statutory Authority: 1976 Code Sections 44–34–10, et seq.)

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SECTION 100—DEFINITIONS

For the purpose of this regulation, the following definitions shall apply:

A. Administrator. The individual designated by the licensee to have the authority and responsibility to manage the facility and to be in charge of all functions and activities of the facility.

B. Adult. A person eighteen (18) years of age or older.

C. Aftercare Suggestions. Specific written information given to clients following tattooing procedures on how to promote successful healing of various tattoo sites, including infection control information and instruction.

D. Aseptic Technique. Any health care procedure in which added precautions are used to prevent contamination of a person, object, or area by microorganisms, such as by use of sterile gloves and instruments.

E. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina to provide specific treatments, care, or services to staff members and/or clients.

F. Biohazardous. Any biological material capable of causing harm to humans, animals, or plants, including both biohazardous organisms and agents.

G. Church. An establishment, other than a private dwelling, where religious services are usually conducted.

H. Client. A person who has a tattoo procedure performed on his or her body.

I. Consultation. A visit by a Department representative(s) who will provide information to the licensee with the goal of facilitating compliance with this regulation.

J. Contaminated or Contamination. The presence of blood, infectious materials, or other types of impure materials that have corrupted a surface or item through contact.

K. Department. The South Carolina Department of Health and Environmental Control.

L. Direct Supervision. The on-site training, observation, and evaluation of a trainee by an experienced tattoo artist, including the provision of consultation and instruction.

M. Disinfection. The action of using an agent, for example, isopropyl alcohol solution, that kills germs or microorganisms.

N. Experienced Tattoo Artist. An individual who has a current and valid tattoo license or permit from a state with requirements that meet the minimum requirements of this regulation, such as training, age, or who has one thousand (1000) or more hours during the last three (3) years performing tattooing procedures in a licensed or permitted tattoo facility, as confirmed in writing by the licensee, from a state with requirements that meet the minimum requirements of this regulation.

O. Facility. Any room, space, location, area, structure, mobile unit, or business, or any part of any of these places, where tattooing is practiced or where the business of tattooing is conducted and which is licensed by the Department as a tattoo facility.

P. Germicidal. Preventing infection by inhibiting the growth or action of microorganisms.

Q. Injection Equipment. Equipment used in the practice of tattooing, including the needle(s) and the needle bar. Injection equipment does not include other parts of the tattoo machine such as grips, tubes or barrels, motors, coils, frames, binding posts, rubber bands, foot pedals, and power units.

R. Inspection. A visit by a Department representative(s) for the purpose of determining compliance with this regulation.

S. Investigation. A visit by a Department representative(s) to a licensed or unlicensed facility for the purpose of determining the validity of allegations received by the Department relating to this regulation.

T. License. A certificate issued by the Department to a facility that authorizes tattooing at that facility subject to the provisions of this regulation.

U. Licensee. The individual, corporation, partnership, organization, or public entity that has been issued a license to provide tattoo services and with whom rests the ultimate responsibility for compliance with this regulation.

V. Micropigmentation or Application of Permanent Cosmetics. A medical procedure performed above the jaw line and anterior to the ear and frontal hairline in which color or pigment is applied with a needle or electronic machine to produce a permanent mark visible through the skin. The procedure includes, but is not limited to, the application of eyeliner; eye shadow; and lip, eyebrow, or cheek color for purposes of enhanced aesthetics; scar concealment; and/or repigmentation of areas involving reconstructive surgery or trauma. Micropigmentation shall not include placing on the body any pictures, images, numbers, signs, letters of the alphabet, or designs. Medical micropigmentation shall not be construed to be included in the definition of tattooing as provided in Section 100.NN.

W. Minor. A person who has not attained eighteen (18) years of age.

X. Mobile Unit. A vehicle, trailer, or portable unit from which tattooing is performed.

Y. Picture Identification. A valid driver's license from any state or an official photographic identification card issued by the South Carolina Department of Revenue, a federal or state law enforcement agency, an agency of the United States Department of Defense, or the United States Department of State, such as a military ID or passport.

Z. Playground. A place, other than grounds at a private dwelling, that is provided by the public or members of a community for recreation.

AA. Release. The point at which the client's active involvement with a facility is terminated and the facility no longer maintains active responsibility for the client.

BB. Repeat Violation. The recurrence of any violation cited under the same section of the regulation within a thirty-six (36) month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

CC. Revocation of License. An action by the Department to cancel or annul a license by recalling, withdrawing, or rescinding the facility's authority to operate.

DD. Sanitized or Sanitization. A procedure that reduces the level of microbial contamination so that the item or surface is considered safe.

EE. School. An establishment, other than a private dwelling, where the customary processes of education are conducted.

FF. Sharps. Any objects, sterile or contaminated, that may purposefully or accidentally cut or penetrate the skin including, but not limited to, pre-sterilized, single-use needles, scalpel blades and razor blades.

GG. Single-use. An item that is used one (1) time on one (1) client and then is properly disposed of by appropriate measures.

HH. Staff Member. An individual who is a compensated employee of the facility on either a full or part-time basis.

II. Sterile. The condition of an object when it is free of live bacteria, spores or other microorganisms, including pathogens, usually achieved by heat or chemical means.

JJ. Sterilize or Sterilization. The approved procedure of making an object free of live bacteria, spores, or other microorganisms including pathogens, usually by heat or chemical means.

KK. Suspension of License. An action by the Department requiring a licensee to cease operation for a period of time until such time as the Department rescinds that restriction.

LL. Tattoo Artist. A staff member twenty-one (21) years of age or older who practices body tattooing at the tattoo facility and who meets the requirements of this regulation, including both experienced tattoo artists and tattoo artist trainees.

MM. Tattoo Artist Trainee. A staff member under the supervision and instruction of an experienced tattoo artist who is in the process of acquiring one thousand (1000) hours of tattoo procedure training as required in Section 603.B.

NN. Tattoo or Tattooing. To indelibly mark or color the skin by subcutaneous introduction of nontoxic dyes or pigments. The practice of tattooing does not include the removal of tattoos, the practice of branding, cutting, scarification, skin braiding, or the mutilation of any part of the body.

OO. Tattoo Procedures Training. Training that includes hands-on tattooing performed on clients and other tattooing-related activities including sterilization techniques.

PP. Temporary Location. A short-term fixed location at which tattooing is licensed and performed for a specified period of not more than fourteen (14) days.

QQ. Work Station. A work area where tattoo procedures are performed and that meets the requirements as set forth in Section 1602.

SECTION 200—LICENSE REQUIREMENTS

201. Scope of Licensure (II)

A. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself, including advertising or marketing, as a tattoo facility in South Carolina without first obtaining a license from the Department. Facilities that perform tattooing prior to the effective date of licensure are in violation of S.C. Code Sections 44–34–10, *et seq*.

B. When it has been determined by the Department that tattooing is being performed at a location, and the owner has not been issued a license from the Department to perform such procedures, the owner shall cease operation immediately.

C. Current or previous violations of the South Carolina Code of Laws and/or Department regulations may jeopardize the issuance of a license for the facility or the licensing of any other facility or addition to an existing facility that is owned or operated by the licensee. The facility shall provide only the procedures or services it is permitted to provide pursuant to the definition in Section 100.T of this regulation.

202. License Application

A. Applicants for a tattoo facility license shall submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes both the applicant's oath assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two (2) of its officers. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in the event his or her address is different from that of the facility, and the name(s) of the person(s) in control of the facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with this regulation. Corporations or partnerships shall be registered with the South Carolina Office of the Secretary of State. Other required application information includes:

1. Copy of the business license, as applicable;

2. Licensing fee and certification fee, if applicable;

3. Certified copy of local ordinance authorizing tattooing within its jurisdiction, or a letter signed by the city or county manager or administrator with authority to represent the city or county stating that tattooing is authorized within its jurisdiction;

4. Written acknowledgement of compliance with applicable federal Office of Safety and Health Administration (OSHA) requirements and certificates attesting to completion by tattoo artists of courses in bloodborne pathogens, tattoo infection control, American Red Cross First Aid, and adult cardiopulmonary resuscitation (CPR);

5. Written evidence that the individual(s) performing tattooing procedures is an experienced tattoo artist in accordance with Section 100.LL, or a tattoo artist trainee in accordance with Section 100.MM;

6. Description of the disposal methods of dyes, inks, and pigments, including written authorization for disposal from the local wastewater treatment plant or statement from landfill that disposal is in accordance with its waste acceptance plan; and

7. Legible facility floor plan, drawn to scale, including location(s) of work station(s) and identification of sterilization equipment.

B. Prospective licensees shall provide to the Department a written statement verifying that the applicant has advertised his or her intent to apply for a tattoo facility license in the legal section of the newspaper nearest to the location of the proposed facility at least once a week for three (3) consecutive weeks in accordance with S.C. Code Section 44–34–110(C).

C. A license shall not be granted to a facility, nor shall a facility conduct tattooing procedures within one thousand (1,000) feet of a church, school, or playground. This distance shall be the shortest route of ordinary pedestrian or vehicular travel along public roads from the nearest point of the grounds utilized as part of the church, school, or playground. These restrictions shall not apply to the renewal of an existing license or to ownership changes for locations that are licensed at the time the application is filed with the Department.

203. Compliance

An initial license shall not be issued to a proposed facility that has not been previously and continuously licensed under Department regulations until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with this regulation. A copy of the licensing standards shall be maintained by the licensee and accessible at all times to all staff members. In the event a licensee who already has a facility or activity licensed by the Department makes application for another facility or activity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility. A licensee issued a license for a facility at a specific location shall not establish a new or additional facility without obtaining an additional license from the Department.

204. Issuance and Terms of License

A. A license is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

B. The facility shall maintain a business address and telephone number at which the facility may be reached during business hours.

C. The issuance of a license does not guarantee adequacy of individual care, treatment, procedures and/or services, personal safety, fire safety, or the well-being of any client.

D. A license is not assignable or transferable and is subject to suspension or revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this state.

E. A license shall be effective for a specific facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. Except for temporary locations, a license shall remain in effect until the facility is otherwise notified by the Department.

F. Mobile units shall have a permanent mailing address. Licenses for mobile units shall indicate the permanent mailing address and that the facility is mobile. Schedules of mobile unit locations shall be submitted to the Department three (3) months in advance and shall include written evidence that the mobile unit is in compliance with the location requirements of Section 202.C.

G. Temporary locations shall have a permanent mailing address. Licenses for temporary locations shall indicate the permanent mailing address and that the license is temporary for a specified number of work stations for a specified period of time.

H. Tattoo artists and tattoo artist trainees shall perform tattooing only in licensed facilities. (I)

I. Licensed facilities shall be allowed to continue utilizing the previously-licensed structure without building modification and shall comply with the remainder of the standards within this regulation.

205. Licensing Fees

A. Method of Payment. Licensing fees shall be made payable by check, credit card, or money order to the Department.

B. Fees include an initial and annual renewal fee of four hundred dollars ($400.00) for facilities with eight (8) or fewer work stations. Facilities with more than eight (8) work stations shall pay an additional fifty dollars ($50.00) for each additional work station. An additional amount may be charged if necessary to cover the cost of inspection or investigation.

C. Applicants for a new license shall pay an initial certification fee of fifty dollars ($50.00) to determine compliance with Section 202.C. This certification fee is not applicable to applicants seeking licensure for mobile units.

206. Late Fee

Failure to submit a renewal application or fee before the license expiration date shall result in a late fee of twenty-five percent (25%) of the licensing fee amount in addition to the licensing fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time period specified by the Department may result in an enforcement action.

207. License Renewal

To renew a license, an applicant shall file an application with the Department and pay a licensing fee. If an application is denied, a portion of the fee shall be refunded based upon the remaining months of the licensure period, or seventy-five dollars ($75.00), whichever is greater. Licenses for temporary locations shall not be renewed.

208. Change of License

A. A licensee shall request issuance of a new or amended license by application to the Department prior to any of the following circumstances:

1. Change of ownership of the facility; or
2. Change in the number of work stations in the facility.

B. Changes in facility name or address as notified by the post office shall be accomplished by application or by letter from the licensee.

C. Change of facility locations from one geographic site to another shall be by letter or application to the Department in accordance with Section 202. Mobile units shall submit written evidence of compliance with Section 202.C.

209. Exceptions to Licensing Standards

The Department has the authority to make exceptions to these standards when it is determined that the health, safety, and well-being of the clients will not be compromised and provided the standard is not specifically required by statute.

SECTION 300—ENFORCEMENT OF REGULATIONS

301. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

302. Inspections and Investigations

A. Inspections shall be conducted prior to initial licensing of a facility. The Department, at its own determination, may also conduct subsequent inspections.

B. All facilities are subject to inspection or investigation at any time without prior notice, by individuals authorized by the South Carolina Code of Laws.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records at the time of the inspection. If photocopies are made for the Department inspector(s), they shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. Physical area of inspections shall be determined by the extent to which there is potential impact or effect upon clients as determined by the inspector(s). (II)

D. A facility found noncompliant with the standards of this regulation or governing statute shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified by the Department. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences, actual and similar; and
3. The actual or expected completion dates of those actions.

E. In accordance with S.C. Code Section 44–34–40, the Department may charge a fee for licensing inspections.

SECTION 400—ENFORCEMENT ACTIONS

401. General

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of a facility, the Department, upon proper notice to the licensee, may impose a monetary penalty and/or deny, suspend, revoke, or refuse to issue or renew a license.

402. Violation Classifications

Violations of standards in regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines have a negative impact on the health, safety, or well-being of persons in the facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. Class I and II violations are indicated by notation after each applicable section, as "(I)" or "(II)." Sections not annotated in that manner denote Class III violations. A classification at the beginning of a section and/or subsection applies to all subsections following, unless otherwise indicated.

E. In arriving at a decision to take enforcement actions, the Department will consider the following factors: the number and classification of violations, including repeat violations; specific conditions and their impact or potential impact on health, safety, or well-being of the clients; efforts by the facility to correct cited violations; behavior of the licensee that would reflect negatively on the licensee's character, such as illegal or illicit activities; overall conditions of the facility; history of compliance; any other pertinent conditions that may be applicable to statutes and regulations.

F. When a decision is made to impose monetary penalties, the Department may utilize the following schedule as a guide to determine the dollar amount:

Frequency of violation of standard within a thirty-six (36) month period:

MONETARY PENALTY ACTIONS

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$500 - 1,500	$300 - 800	$100 - 300
2nd	1,000 - 3,000	500 - 1,500	300 - 800
3rd	2,000 - 5,000	1,000 - 3,000	500 - 1,500
4th	5,000	2,000 - 5,000	1,000 - 3,000
5th	5,000	5,000	2,000 - 5,000
6th and more	5,000	5,000	5,000

SECTION 500—POLICIES AND PROCEDURES

A. Policies and procedures addressing each section of this regulation regarding client procedures or services, rights, infection control, the operation of the facility, including emergency procedures in the event of an adverse reaction shall be developed and implemented by the facility, and revised as appropriate in order to accurately reflect actual facility operation. Facilities shall establish a time-period for review of all policies and procedures. These policies and procedures shall be accessible at all times and a hard copy shall be available or be readily accessible electronically.

B. By application, the licensee agrees to comply with all standards of this regulation. The policies and procedures shall describe the means by which the facility shall ensure that the standards described in this regulation are met.

C. Each facility shall conspicuously display a clearly legible notice to clients informing them of any disqualification that tattooing may confer upon a prospective blood donor according to the standards of the American Association of Blood Banks. This notice shall also appear in any informed consent or release form which a tattoo artist or trainee uses, and shall be signed by the client, and contain, at a minimum, aftercare suggestions for the specific tattoo site.

SECTION 600—STAFF AND TRAINING

601. General (II)

A. A facility shall make appropriate staff in numbers and training available at the facility to provide appropriate, safe tattooing procedures to clients and meet the demands of effective emergency on-site action that may arise. Training and qualifications for the tasks each performs shall be in compliance with all professional standards and applicable federal and state laws and regulations.

B. A tattoo artist shall be at least twenty-one (21) years of age and shall not be under the influence of any drugs, alcohol, or other substance that would impair his or her ability to perform tattooing. (I)

C. All new staff members shall be oriented to acquaint them with the organization and environment of the facility, their specific duties and responsibilities, including the necessary training to perform the duties, and client needs.

D. The facility shall maintain accurate current information regarding all staff members of the facility, to include at least address, phone number, health, work, and training background, as well as current health and education information. The facility shall assign duties and responsibilities to all staff members in writing and in accordance with the individual's capability and training.

602. Administrator

The licensee shall designate an individual to serve as administrator. The administrator shall have the authority and responsibility for the overall operation of the facility and is responsible for ensuring compliance with these regulations. An individual shall be designated, in writing, to act in the absence of the administrator. A facility tattoo artist may also serve as the administrator.

603. Inservice Training (II)

A. The following training shall be provided by appropriate resources as approved by the Department to all tattoo artists in the context of their job duties and responsibilities prior to client contact and at a frequency determined by the facility, but at least annually:

1. OSHA standards in bloodborne pathogens;
2. Tattooing infection control;
3. American Red Cross First Aid certification, American Safety and Health Institute Certification, or certification from a program that meets or exceeds the certification standards of the Red Cross First Aid or the American Safety and Health Institute; and
4. Adult cardiopulmonary resuscitation (CPR). (American Red Cross or the American Heart Association).

B. Prior to independently performing tattooing procedures, a tattoo artist trainee shall have a minimum of one thousand (1000) hours of tattoo procedure training within the last thirty-six (36) months under the direct supervision of an experienced tattoo artist who shall sign and maintain a written statement attesting to the completion of such training.

604. Health Status

No person infected with or a carrier of tuberculosis, or any other condition which may be transmitted to clients in the facility, or having boils, open or infected skin lesions shall have client contact.

SECTION 700—REPORTING

701. Accidents and/or Incidents (II)

A. The facility shall report each accident and/or incident resulting in unexpected death or serious injury to the next of kin, responsible party, or emergency contact for each affected individual at the earliest practicable hour, not to exceed twenty-four (24) hours. The licensee shall notify the Department immediately, not to exceed twenty-four (24) hours, via telephone, email, facsimile, or other method as determined by the Department. The licensee shall submit a report of the licensee's investigation of the accident and/or incident to the Department within five (5) calendar days. Accidents and/or incidents requiring reporting include, but are not limited to,:

1. Actual or suspected abuse by staff;
2. Criminal event against client(s);
3. Those resulting in hospitalization;
4. Severe lacerations; and
5. Severe hematomas.

B. Reports submitted to the Department shall contain only: facility name, license number, type of accident and/or incident, date accident and/or incident occurred and location, number of clients directly injured or affected, client age and sex, number of staff directly injured or affected, witness(es) name(s), identified cause of accident and/or incident, internal investigation results if cause unknown, a brief description of the accident and/or incident including location where occurred, treatment of injuries, identity of other agencies notified, if applicable, and date of the report. The report retained by the facility, in addition to the minimum reported to the Department, shall contain: name(s) of client(s), staff, the injuries and treatment associated with each client or staff member. Records of all accidents and/or incidents shall be retained by the facility for six (6) years after the date of the report.

702. Fire and Disasters (II)

The Department shall be notified immediately via telephone, email, facsimile, or other method as determined by the Department regarding any fire in the facility, or natural disaster, which jeopardizes the safety of any persons in the facility, followed by a complete written report, to include fire department reports, if any, to be submitted within a time period determined by the facility, but not to exceed seventy-two (72) hours from the occurrence of the fire or natural disaster.

703. Administrator Change (II)

The Department shall be notified in writing by the licensee within ten (10) days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual and effective date of the appointment.

704. Facility Closure

A. Prior to permanent closure of a facility, the licensee shall notify the Department in writing of the intent to close and the effective closure date. Within ten (10) days of closure, the facility shall notify the Department of the provisions for the maintenance of the facility records as required by regulation. On the date of closure, the current original license shall be returned to the Department.

B. In instances where a facility temporarily closes, the licensee shall notify the Department in writing within fifteen (15) days prior to temporary closure. In the event of temporary closure due to an emergency, the facility shall notify the Department in writing within twenty-four (24) hours of the closure. At a minimum this notification shall include, but not be limited to, the reason for the temporary closure, the manner in which the records are being stored, and the anticipated date for reopening. The Department shall consider, upon appropriate review, the necessity of inspecting and determining the applicability of current construction standards to the facility prior to its reopening. If the facility is closed for a period longer than one (1) year, and there is a desire to reopen, the facility shall reapply to the Department for licensure and shall be subject to all licensing requirements at the time of that application, including construction-related requirements for a new facility.

SECTION 800—CLIENT RECORDS

801. Content (II)

A. The facility shall initiate and maintain a record for every individual who has undergone tattooing. The record shall contain sufficient documented information to identify the client and verify the procedure(s) performed. All entries shall be written legibly in ink or typed, signed and dated, and shall identify the author.

B. Specific entries and/or documentation shall include at a minimum:

1. Identification of the client including a means of verification of client's identity, such as a copy of the client's photo identification;

2. Explanation of client rights in accordance with Section 1000, as evidenced by the tattoo artist's and client's signature, including a signed informed consent in accordance with Section 1001;

3. Tattoo procedure performed, to include the site of the tattoo;

4. Procedures followed if an unexpected event occurs and emergency procedures taken if there is an adverse reaction;

5. Physician or other legally authorized healthcare provider signed statement that the tattoo procedure is not contraindicated in accordance with Section 900.G, if applicable; and

6. Emergency contact information for the client in case of emergency, including name, address, phone number, and other pertinent contact information.

C. The facility shall obtain a client's signed statement attesting that he or she is not intoxicated or under the influence of any drugs or alcohol.

D. The facility shall provide clients with a release or aftercare note.

802. Record Maintenance

A. The facility shall adequately produce, protect, and store client records.

B. Client records are confidential. Records containing protected or confidential information shall be made available only to authorized individuals in accordance with state and federal laws. The facility shall have a written policy designating the persons allowed to access confidential client information. (II)

C. The facility shall maintain client records for at least six (6) years following the release of the client. Other documents required by the regulation, such as endospore testing, shall be retained at least twelve (12) months or until the next Department inspection, whichever is longer, unless otherwise specified in this regulation. The facility shall determine the medium in which information is stored. The information shall be readily available to facility staff, as needed, and for Department inspections.

SECTION 900—CLIENT PROCEDURES AND SERVICES (I)

A. A facility shall only provide tattooing and shall not engage in any other retail business including, but not limited to, the sale of goods or performing any form of body piercing, other than tattooing. The sale of specific tattoo aftercare goods and services is permitted.

B. A tattoo artist shall verify by means of a picture identification that a client is at least eighteen (18) years of age and shall not perform or offer to perform tattooing upon a person under the age of eighteen (18).

C. The facility shall perform tattooing only for those persons for which the facility can provide the appropriate accommodations and services.

D. Tattooing shall not be performed upon a person impaired by drugs or alcohol. A person impaired by drugs or alcohol is considered incapable of consenting to tattooing and incapable of understanding tattoo procedures and aftercare suggestions.

E. Tattooing shall not be performed on skin surfaces having rash, pimples, boils, keloids, sunburn, open lesions, infections, or that manifest any evidence of unhealthy conditions.

F. A tattoo artist shall not tattoo any part of the head, face, or neck of another person.

G. Prior to performing a procedure on a client, the tattoo artist shall obtain information from the client regarding any existing condition(s) that could affect the healing process, such as allergies to medications, tattoo dyes or inks, or to latex, or taking medications such as anticoagulants that thin the blood and/or interfere with blood clotting. If a client indicates the presence of such a condition, the facility shall obtain documentation from a physician or other legally authorized healthcare provider that the procedure is not contraindicated prior to the tattooing procedure.

H. Inks, dyes or pigments used in tattooing shall be nontoxic, obtained from a commercial supplier or manufacturer and specifically manufactured for tattooing, and shall be used in accordance with manufacturer's instructions and standard professional practice. Products banned or restricted by the Food and Drug Administration (FDA) shall not be used.

I. The facility shall provide aftercare recommendations to the client to include but not be limited to:

1. Instructions for care following service;
2. Possible side effects;
3. Restrictions; and
4. Infection control information.

J. Clients shall be given the opportunity to participate in aftercare programs if offered by the facility. (II)

K. During all operating hours, tattooing shall not be performed unless there is an experienced tattoo artist present in the facility.

L. The tattoo artist is not authorized to remove a tattoo(s) or perform micropigmentation or permanent cosmetic procedures. Tattoo removal, micropigmentation or permanent cosmetic procedures shall be provided only by physicians or other legally authorized healthcare providers.

SECTION 1000—CLIENT RIGHTS

1001. Informed Consent (II)

A. The facility shall inform the client of the potential for any risks, and/or adverse effects or consequences regarding the tattoo procedure(s) to be performed. In all instances of tattooing, the client must voluntarily choose, in writing, to receive the procedure.

B. The informed consent process shall include information relating to disqualification that tattooing may confer upon a prospective blood donor in accordance with Section 500.C.

1002. Grievances and Complaints (II)

The facility shall inform the client or responsible party in writing of the grievance procedure should the client consider one or more of his or her rights violated. The facility shall include the address and phone number of the Department in the grievance procedure.

1003. Procedures and Charges

Tattooing procedures performed by the facility and the charges for such procedures, whether a flat fee or hourly rate, shall be stated in writing, and the client shall be made aware of such charges and procedures as verified by his or her signature, prior to the procedure. For facilities charging an hourly rate, it is acceptable to have the hourly rate in writing as opposed to a total fee.

SECTION 1100—MAINTENANCE (II)

A. A facility shall keep the structure, component parts, amenities, and equipment in good repair and operating condition to perform the functions for which they were designed.

B. The physical plant shall be maintained free of fire hazards or impediments to fire prevention. (I)

SECTION 1200—INFECTION CONTROL AND ENVIRONMENT

1201. Staff Practices (I)

Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances and for the sanitization of surfaces with an appropriate sanitizing solution. These preventive measures or practices shall be in compliance with applicable regulations and guidelines of the Occupational Safety and Health Administration (OSHA), for example, the Bloodborne Pathogens Standards; the Centers for Disease Control and Prevention; Regulation 61–105, Infectious Waste Management; and other applicable federal, state, and local laws and regulations.

1202. Hepatitis B Vaccination (I)

A. All tattoo artists shall have the hepatitis B vaccination series unless the vaccine is contraindicated or an individual is offered the series and declines. In either case, the decision shall be documented.

B. Each tattoo artist who elects to have the series shall have completed the initial dose of the three (3) dose series within thirty (30) days of employment.

1203. Infection Control (I)

A. A tattoo artist shall utilize the following infection control measures:

1. Before and after each tattoo procedure, wash his or her hands thoroughly for a minimum of twenty (20) seconds with water and a liquid germicidal solution, used in accordance with the manufacturer's directions, and dried with single-use disposable paper towels or electric air dryer;

2. When necessary to perform a procedure on individuals who must undergo shaving of hair, utilize a single-use disposable razor;

3. The site of the tattoo shall be cleaned in a sterile surgical manner with a liquid germicidal solution approved by the Department and used in accordance with the manufacturer's direction and then swabbed with a disinfectant before tattooing;

4. Utilize single-use sterile disposable gloves when setting up equipment and performing procedures on a client and immediately replace upon notice of a tear, any contamination, or other defect;

5. Prior to any direct contact with the client, place in a sterile manner all sterile instruments and sterile tattoo items on a sterile disposable towel or drape to be used as a single sterile field throughout the procedure;

6. When conducting a procedure, use single-use disposable needles and injection equipment which are designated and sterilely packaged as single-use only; these needles and injection equipment shall not be cleaned or reused in any manner on another client;

7. Re-gloving with single-use sterile disposable surgical gloves must occur prior to initiation of the procedure, which is to be performed using aseptic techniques. Any contamination of the instruments or field shall immediately result in cessation of the procedure and nonuse of sterilized equipment until re-sterilized;

8. At all times when preparing the skin and while applying the actual tattoo, the tattoo artist shall wear single-use sterile disposable surgical gloves, which must be discarded upon completion of the tattoo;

9. After use, all single-use needles, razors, and other sharps shall be immediately disposed of in approved sharps containers; these used containers shall be labeled with the Universal Biohazard

Symbol and the word "biohazard" and be disposed of in a manner prescribed by the Department; and

10. The work station shall be supplied with an adequate supply of paper or plastic barrier film to protect equipment and any other item that must be protected to prevent cross-contamination.

B. The use of gauze, alum, styptic pencils, or medical supplies deemed necessary to control bleeding is permissible provided that a separate disposable single-use sterile item is used on each client.

C. Single-service individual containers of ink or dye shall be used for each client and the container shall be discarded immediately after completing the procedure. Any dye or ink in which the needles were dipped shall be discarded and not used on another person.

D. If pens and/or stencils are used, only clean disposable single-use pens and stencils for transferring the design to the skin shall be used.

E. If any type of ointment is used, a single-use ointment tube or applicator shall be used.

F. All tattoo artists shall wear clean outer garments while performing tattooing procedures, maintain a high degree of personal cleanliness, and conform to hygienic practices. If lap cloths or lap towels are used, they shall be single-use only.

G. Food, drink, and the use of tobacco products in the procedure and disinfection or sterilization areas shall be prohibited. Food and/or drink is permitted in the procedure room(s) for clients with conditions which may require food and/or drink.

H. Live animals shall not be permitted in the procedure and disinfection or sterilization areas.

EXCEPTION: This standard does not apply to patrol dogs accompanying security or police officers, guide dogs, or other service animals accompanying individuals with a disability into the procedure area.

1204. Sterilization of Equipment (I)

A. All used equipment intended for reuse, such as tubes or grips, shall be properly scrubbed clean of visible materials and soaked for a minimum of twenty (20) minutes in a liquid germicidal solution approved by the Department, which shall be used in accordance with the manufacturer's direction. The equipment shall then be immediately placed in a mechanical ultrasonic cleanser for at least twenty-five (25) minutes prior to being re-sterilized by autoclave. The ultrasonic cleanser shall be clearly labeled as "biohazardous" and shall be located as far as possible from the autoclave within the disinfection or sterilization area.

B. A facility utilizing single-use or disposable equipment and/or instruments shall not be required to re-sterilize by autoclave those single-use and/or disposable items provided they are utilized and disposed of in accordance with the manufacturer's direction and not reused in any manner on another client.

C. Facilities shall properly package and sterilize by autoclave those instruments, equipment, and other tattoo items other than inks and electrical instruments that are not single-use or disposable, shall include a sterile indicator, and shall include a label with the date of sterilization. Sterile items shall not be used if the package integrity has been breached.

D. Each facility shall keep a current written log for the previous two (2) years of autoclave use, including, but not limited to, the date and time of use and results of sterilization spore test strip tests.

E. The effectiveness of the autoclave in killing bacterial endospores shall be tested at least once each month.

1205. Housekeeping (II)

The interior and exterior of the facility shall be uncluttered, clean, free of safety hazards, and free of vermin and offensive odors.

A. Interior housekeeping of the facility shall, at a minimum, include:

1. Cleaning each specific area of the facility;

2. Cleaning and disinfection, as needed, of equipment and supplies used and/or maintained in each area, appropriate to the area and purpose or use of the equipment or supplies; and

3. Safe storage and use of chemicals indicated as harmful on the product label, cleaning materials, and supplies in cabinets or well-lighted closets and/or rooms, inaccessible to clients.

B. Exterior housekeeping at a facility shall, at a minimum, include:

1. Cleaning of all exterior areas, such as porches and ramps, and removal of safety impediments such as snow or ice; and

2. Keeping the facility grounds reasonably free of weeds, rubbish, overgrown landscaping, and other potential breeding sources of vermin.

C. The discharge of dyes, inks, and pigments shall be accomplished in a safe manner with written consent prior to discharge from the local wastewater treatment plant. Where the treatment for discharge of dyes, inks, or pigments is performed by the facility, or where there is direct discharge into the environment, such actions shall be in compliance with Regulation 61–67, Standards for Wastewater Facility Construction, and/or Regulation 61–9, Water Pollution Control Permits. The discharge of dyes, inks, or pigments into a septic tank system is prohibited.

1206. Refuse Disposal

A. A facility shall deposit all garbage and refuse in suitable watertight containers. A facility shall dispose of rubbish and garbage in accordance with local requirements.

B. A facility shall cover and store refuse containers outside on an approved platform constructed of concrete, wood, or asphalt and secured in such a manner so as to prevent overturning by animals, the entrance of flies, or the creation of a nuisance. A facility shall thoroughly clean garbage and trash containers as necessary to prevent the creation of a nuisance.

1207. Infectious Waste (I)

Accumulated waste, including all contaminated sharps, dressings, pathological, and/or similar infectious waste, shall be disposed of in a manner compliant with OSHA Bloodborne Pathogens Standards and R.61–105.

SECTION 1300—EMERGENCY PROCEDURES

1301. Emergency Call Numbers (I)

A facility shall post emergency call data in a conspicuous place and shall include at least the telephone numbers of fire and police departments, ambulance service, and the poison control center. Other emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

1302. Medical Emergencies (I)

Medical emergencies shall be managed in a manner to ensure the health, safety and well-being of clients and staff.

SECTION 1400—FIRE PREVENTION AND PROTECTION

1401. Arrangements for Fire Department Response (I)

Facilities located outside of a service area or range of a public fire department shall arrange, by written agreement, for the nearest fire department to respond in case of fire. A copy of the agreement shall be kept on file in the facility and a copy shall be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department.

1402. Inspections (I)

A facility shall maintain and test fire protection systems in accordance with the applicable provisions of the codes officially adopted by the South Carolina State Fire Marshal.

1403. Fire Response Training (I)

A. A facility shall provide fire response training for each staff member within forty-eight (48) hours of his or her first day of employment in the facility and at least annually thereafter. A new facility seeking initial licensing shall provide the Department with evidence of fire response training for each staff member prior to the initial licensing inspection. Fire response training shall address, at a minimum, the following:

1. Fire plan, including the training of staff members;
2. Reporting a fire;
3. Use of the fire alarm system, if applicable;

4. Location and use of fire-fighting equipment;

5. Methods of fire containment;

6. Specific responsibilities, tasks, and/or duties of each staff member; and

7. Fire evacuation plan, including routes and procedures.

B. A facility shall establish a plan for the evacuation of clients and staff members to include procedures and evacuation routes out of the facility, in case of fire or other emergencies, and the plan shall be posted in conspicuous public areas throughout the facility.

SECTION 1500—DESIGN AND CONSTRUCTION

1501. General (II)

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each client.

1502. Adopted Codes and Standards (II)

Facility design and construction shall comply with applicable provisions of this regulation and the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal.

SECTION 1600—FACILITY ACCOMMODATIONS

1601. General (II)

A. A facility shall include an area for the purpose of disinfecting and sterilization of equipment that shall be physically separate from the area used for tattoo procedures to avoid cross-contamination of equipment. These areas shall be separated from each other and from waiting clients by a door, divider, or wall. A facility shall not store or otherwise keep supplies or equipment not utilized for disinfection or sterilization in this area.

B. All rooms shall have sufficient ventilation to keep them free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes.

C. Adequate potable water for the needs of the facility shall be provided from an approved source and shall be available and accessible to clients.

D. Adequate artificial lighting shall be provided in the procedure rooms and disinfection or sterilization areas.

E. Emergency electrical service shall be provided for work station lighting, corridor egress, and exit sign lighting.

1602. Work Stations

A. The work station shall be sized to accommodate necessary equipment or supplies, staff, and procedure table, but not less than sixty-four (64) square feet of floor space, exclusive of fixed cabinets or shelves. The work station shall be utilized exclusively for tattooing. Multiple work stations shall be separated by dividers, curtains, walls, or partitions measuring at least four (4) feet in height.

1. Wall and floor surfaces of the work stations and disinfection or sterilization rooms shall be nonporous and easily cleanable.

2. A separate, properly identified sink, with hot and cold running water, used for disinfection practices only shall be located in the disinfection or sterilization area.

3. At least one (1) sink, with hot and cold running water, shall be provided for every five (5) work stations for hand washing. There shall be a wall-mounted single-use paper dispenser or electric air dryer adjacent to each sink. Restroom sinks are included in this calculation.

B. Procedure tables shall be constructed of a nonporous, sanitizable material.

C. Work stations shall be separated from client waiting areas by door, divider, curtain, wall, or partition.

1603. Supplies and Medications

A. A standard first aid kit or equivalent first aid supplies shall be readily accessible in the facility and shall contain at a minimum:

1. 4″ × 4″ gauze pads;
2. Benzalkonium swabs;
3. 2″ × 2″ gauze pads;
4. Gauze roller bandage;
5. Cardiopulmonary resuscitation (CPR) mouth barrier device; and
6. Eyewash solution.

B. A facility shall properly store and safeguard topical and oral medications to prevent access by unauthorized persons. Medication storage areas shall be secured and of sufficient size for clean and orderly storage. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life. Expired or discontinued medications and supplies shall be removed from the facility and destroyed. (I)

1604. Restrooms (II)

A. There shall be an appropriate number of restrooms in the facility, to accommodate clients, staff, and visitors. The minimum requirement is one (1) toilet fixture for every five (5) tattoo work stations.

B. The restrooms shall be accessible during all operating hours of the facility.

C. A restroom(s) shall be equipped with at least one (1) toilet fixture, toilet paper installed in a holder, a sink supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a covered waste receptacle. Equipment and supplies used in the course of tattoo procedures or disinfection and sterilization procedures shall not be stored or utilized in the restroom.

D. Restroom floor areas shall be no less than fifteen (15) square feet.

E. There shall be at least one (1) sink for every two (2) toilet fixtures located within a restroom.

F. Privacy shall be provided at toilet fixtures and urinals.

G. Restrooms for persons with disabilities shall be provided as required by codes whether or not any of the staff or clients are disabled.

H. All restroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surfaces to the highest level of splash.

1605. Location

A. Transportation. The facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. Parking. The facility shall have a parking area to reasonably satisfy the needs of clients, staff members, and visitors.

C. Access to firefighting equipment. Facilities shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

SECTION 1700—FIRE PROTECTION EQUIPMENT AND SYSTEMS

1701. Firefighting Equipment (I)

Firefighting equipment such as fire extinguishers, standpipes and automatic sprinklers shall be provided as required by the applicable codes in Section 1502.

1702. Flammable Liquids (I)

The storage and handling of flammable liquids shall be in accordance with the applicable codes in Section 1502.

1703. Furnishings and Equipment (I)

A. The physical plant shall be maintained free of fire hazards and impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted at the facility.

C. Wastebaskets, window dressings, portable partitions and dividers, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant. Window blinds shall not require flame treatments or documentation thereof.

SECTION 1800—MOBILE UNITS AND TEMPORARY LOCATIONS

All mobile units and temporary locations shall meet the standards of this regulation. Mobile units shall meet the standards of the state, federal, and local departments of transportation for the permitting and safe operation of the unit. Mobile units and temporary locations shall not be located within one thousand (1,000) feet of a church, school, or playground in accordance with Section 202.C.

SECTION 1900—SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

SECTION 2000—GENERAL

Conditions which have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Added by State Register Volume 30, Issue No. 3, eff March 24, 2006. Amended by State Register Volume 40, Issue No. 5, Doc. No. 4568, eff May 27, 2016.

61–112. Implementation of Emergency Health Powers Act.

(Statutory Authority: 2002 SC Code Ann. §§ 44–1–140; 44–4–100 et seq. (Supp. 2003). Related Authority: SC Code Ann. § 25–1–440 (Supp. 2003))

Section 1. Scope and Purpose

This regulation provides procedures for responding to the occurrence or imminent risk of a Qualifying Health Condition in a manner which is consistent with the authorities of S.C. Code Ann. Sections 44–1–110 through -140, the Emergency Health Powers Act (S.C. Code Ann. Section 44–4–10 *et seq*.), S.C. Code Ann. Sections 44–29–10 through –50, Regulations 61–16 and 61–20, and the State Emergency Response Plan with its supporting annexes, appendices, and Standard Operating Procedures. The regulation is intended to provide for timely recognition of sources or potential sources of disease, identification of victims or potential victims, delivery of health care, application of appropriate public health measures, and assurance of due process and personal privacy commensurate with the public health threat.

Section 2. Definitions

Unless otherwise defined below, terms in this regulation have the definitions set forth in S.C. Code Ann. Section 44–4–130, S.C. Code Ann. Section 44–29–10(C), and S.C. Code Ann. Regulation 61–20.

"Administer" — the direct application of a drug or device pursuant to a lawful order of a practitioner to the body of a patient by injection, inhalation, ingestion, topical application, or any other means.

"Commissioner" — the commissioner of the Department of Health and Environmental Control (DHEC) or his designee.

"Dispense" — the transfer of possession of one or more doses of a drug or device by a licensed pharmacist or person permitted by law, to the ultimate consumer or his agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. As an element of dispensing, the dispenser shall, before the actual physical transfer, interpret and assess the prescription order for potential adverse reactions or side effects, interactions, allergies, dosage, and regimen the dispenser considers appropriate in the exercise of his professional judgment, and the dispenser shall determine that the drug or device called for by the prescription is ready for dispensing. The dispenser shall also provide counseling on proper drug usage, either orally or in writing, as provided in this chapter. The actual sales transaction and delivery of a drug or device is not considered dispensing and the administration is not.

"Distribute" — the delivery of a drug or device other than by administering or dispensing

"Emergency medical services" — the arrangement of personnel, facilities, and equipment for the delivery of health care services under emergency conditions.

"First Responder" — a health care worker, disaster relief worker, public safety officer, mortuary staff, or other individuals directly engaged in examining, treating or directing persons or animals during a Public Health Emergency.

"Initiating Event" — 1) the release of contaminants or infectious agents, 2) the spread of communicable disease, or 3) an accumulation of observations which lead to the conclusion that contamination may have been released, or that a communicable disease has begun to spread by either a natural or intentional event, with the potential for widespread public health impact. The existence of an Initiating Event may be inferred, based upon data and observations, and need not be a discrete event localized in time or place.

"Medical Supplies" — antitoxins, serums, vaccines, immunizing agents, antibiotics, and other pharmaceutical agents or medical supplies

"Official List of Reportable Diseases" — the list published pursuant to S.C. Code Ann. Regulation 61–20 as amended from time to time.

"Route of Transmission" — the pathway by which an individual may be exposed to an infectious or communicable disease, or chemical or radiological contamination; includes consideration of physical pathways (aerosol, droplet, vapor, blood-borne, body fluids, or direct contact), biological pathways (human to human, animal to human, or other biological vectors), and receptor route (inhalation, ingestion, skin absorption).

"Strategic National Stockpile" or "SNS" — a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration, airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and re-supply state and local public health agencies in the event of a national emergency anywhere and at anytime within the U.S. or its territories.

Section 3. Declaration of Public Health Emergency; Roles of Agencies

A. The Governor, in consultation with the Public Health Emergency Plan Committee, has the authority to declare a state of Public Health Emergency. DHEC will provide information and advice to the Committee and to the Governor before and after declaration of a state of Public Health Emergency.

B. It is inherent in the nature of public health emergencies that some actions must be taken before the declaration of a state of Public Health Emergency. Nothing in this regulation shall be construed to limit DHEC's authority or obligation, before the declaration of a state of Public Health Emergency, to undertake such investigations or to take such actions pursuant to Code Sections 13–7–40 and –50, 44–1–80 and 44–1–140, 44–55–60, and 44–56–50 as may be necessary to detect, identify, and control the spread of communicable diseases or of biological, chemical, or radiological agents capable of causing disease or injury.

C. DHEC shall request the assistance of public safety agencies, coroners, medical examiners, professional licensing boards, professional associations, health care facilities, and vendors delivering goods and services to health care facilities and medical professionals to implement this regulation. Where specifically provided for by statute or regulation, such requests shall have the force of law.

Section 4. Personal and public health information

A. Medical Information

i. Upon declaration of a state of Public Health Emergency DHEC may by order amend the Official List of Reportable Conditions to include specific diseases or diagnostic criteria. DHEC may designate whether such reports are "Report Immediately" or "Urgently Reportable" and may provide telephone hot line numbers, electronic notification (email) addresses or other means of reporting as may be appropriate.

ii. Before declaration of a state of Public Health Emergency DHEC may by order amend the Official List of Reportable Conditions to include specific diseases or diagnostic criteria. DHEC may designate whether such reports are "Report Immediately" or "Urgently Reportable" and may provide telephone hot line numbers, electronic notification (email) addresses or other means of reporting as may be appropriate. Within twenty four hours of such order DHEC will provide the Governor and the Public Health Emergency Plan Committee with information upon which such order was based.

B. Non-Medical Information

If the Commissioner determines that individuals who have been in certain facilities, or at specific events, or in contact with certain individuals, objects, animals, or categories of individuals, have been or may have been exposed to contaminants or communicable diseases, he may by order require reports to be submitted to DHEC, which may include but not be limited to: passenger manifests; attendance rosters; lists of patrons of events, activities, or venues; and the like. The order shall include as much specificity as is reasonably available to limit the scope of the report.

C. Use and safeguarding

i. In order to investigate the causes and spread of communicable or epidemic disease, to prevent or control the spread of contamination or infectious diseases, and to protect the public health, the Commissioner may by order require collection of contact tracing information from individuals who have or may have been exposed to contaminants, infectious agents, or communicable diseases. To the extent that such information may be Protected Health Information, individuals carrying out such orders and collecting contact tracing information shall be deemed to be acting in accordance with the authority of Code Sections 44–1–80 and 44–4–560 for purposes of having access to such information.

ii. Other than in accordance with subsection (i) above, access to DHEC records containing protected health information of persons who have participated in medical testing, treatment, vaccination, isolation, or quarantine programs or efforts by DHEC during a public health emergency is limited to those persons having a legitimate need to provide treatment to the individual who is the subject of the health information; or to conduct epidemiological research; or to investigate the causes of transmission.

iii. Pursuant to Code Section 44–4–560(B)(3), protected health information otherwise exempt from disclosure by Section 44–4–560(A) may be included in petitions and other court documents required pursuant to Section 44–4–540.

iv. Pursuant to Code Section 44–4–560(B)(3) and (B)(5), DHEC may seek an *ex parte* court order for permission to disclose otherwise protected health information if necessary to locate individuals to limit the spread of contagion or to offer medical treatment. DHEC will include with the John Doe petition for such order a sealed affidavit stating with particularity the basis for believing that location of the specific individuals is necessary to protect the public health or the health of the individual and why disclosure of the identity or the protected health information is necessary.

Section 5. Use of Real Property

A. Use of Health Care Facilities

i. Coordination of assets

Upon declaration of a Public Health Emergency DHEC may require health care facilities to provide current information on patient census, available patient beds, and potential expansion capacity. Potential expansion capacity shall include vacant beds, rooms constructed but not placed into operation in accordance with a Certificate of Need, and rooms which could be adapted for multiple occupancy pursuant to subsection ii below. Health care facilities shall include such potential expansion capacity as separate line items in reports submitted for inclusion in the Regional Mass Casualty Response Plans. The means of reporting bed availability, facility problems, emergency department diversion, hospital pharmaceutical supplies, equipment, decontamination capability and other information necessary to coordinate a regional mass casualty response will be determined by DHEC and may include software or web page reporting mechanisms in current use and provided by DHEC. Hospitals may be required to report information with a predetermined frequency, or as requested within each hospital preparedness planning district.

ii. Suspension of hospital licensure requirements

Upon declaration of a state of Public Health Emergency, DHEC may by order suspend for the duration of the PHE so much of Regulations 61–15 and 61–16 as (1) restricts use of unlicensed beds or space; (2) restricts the conversion of single and double occupancy patient rooms to higher capacity (consistent with medically appropriate criteria); or (3) restricts establishment of wards, dormitories, or other spaces not designated as patient rooms.

B. Use of other real property

i. Upon declaration of a Public Health Emergency, DHEC may identify and notify public and private facilities to include but not be limited to hospitals, clinics, emergency medical services,

outpatient treatment facilities, mortuaries, laboratories, and refrigerated storage facilities, that use of such facilities will be needed for the duration of the PHE to protect the public health.

ii. Operation of such facilities by the owners and operators is preferred. However, upon refusal by the owners or operators, or upon refusal to respond to DHEC's notification within a reasonable time not to exceed forty-eight hours, DHEC may apply for an *ex parte* court order authorizing DHEC, or its designee, to enter into said facility and take control for purposes of responding to the Public Health Emergency. Upon presentation, any public safety agency may execute such order. DHEC may apply for any such order to provide that designees operating facilities pursuant to court order shall be held harmless as to the owners or operators. After notice and opportunity for a hearing, DHEC may apply for an order continuing the *ex parte* order and setting the compensation, if any, due the owners and operators for such period of displacement.

C. Decontamination and sealing

i. DHEC may order decontamination of facilities to prevent the transmission of communicable diseases or to remove or neutralize biological, chemical, or radiological contaminants; such orders may include standard infection control techniques or other specific techniques as appropriate. DHEC may order decontamination of part or all of a facility or may order the sealing of part or all of a facility in lieu of decontamination. Sealed facilities shall be flagged or placarded in accordance with Regulation 61–20, Section 6; Regulation 61–20, Sections 8 and 9 apply.

ii. Orders requiring the sealing of facilities shall be reviewed regularly on a schedule commensurate with the nature of the contaminant, the scope and extent of the Public Health Emergency, and available resources.

Section 6. Personal property

A. DHEC may order decontamination, sealing, or destruction of equipment, foodstuffs, personal property, or any other material to limit the spread of communicable disease or contaminating agents. Such orders may apply to specific items or to classes of items.

B. Destruction may be ordered when decontamination is not practical or when exigent action is necessary to control the spread of contamination or communicable disease.

i. A petition for an order of destruction based on impracticality of decontamination shall be accompanied by one or more affidavits stating (1) the basis for determining the material to be contaminated; (2) if contamination cannot be confirmed by tests, the basis for believing the material to be contaminated or potentially contaminated; (3) the risk to the public health if the material is neither decontaminated or destroyed; (4) alternatives such as decontamination or isolation which have been considered and the reasons they are not adequately protective of the public health.

ii. Nothing herein shall be construed to prohibit the immediate destruction without court order of a source of contamination or communicable disease when, in the professional judgment of DHEC staff, such action is necessary to prevent or limit the spread of contamination or disease. To the extent practicable, staff will record a description of the affected property, the location, and the basis for ordering immediate destruction.

C. If material can be sealed to eliminate it as a source of communicable disease or contamination with the possibility of decontamination after the Public Health Emergency abates, DHEC may order this as an option. Orders requiring sealing of material shall be reviewed regularly on a schedule commensurate with the nature of the contaminant, the scope and extent of the Public Health Emergency, and available resources.

D. Failure to comply with an order requiring decontamination or sealing of material may be grounds for seeking a court order requiring destruction of such material.

E. Animals

i. In consultation with the State Veterinarian, DHEC may issue orders requiring isolation, quarantine, or destruction of animals. Unless there is a clear medical or public health necessity, no animal shall be destroyed except by court order.

ii. Domestic pets: DHEC may by order allow persons to be accompanied by their pets in communal isolation or quarantine facilities, depending on the nature of the threat and the capacity of the facility. Alternatively DHEC may order establishment of pet holding areas or forbid pets in isolation or quarantine facilities.

iii. Non-domestic animals; farm animals; large animals: DHEC may by order allow owners or their representatives access to isolated animals for feeding or other necessary care; such access shall be upon such conditions as DHEC shall order.

Section 7. Response equipment and supplies

A. Possession and distribution

i. Pursuant to Code Section 44–4–330, DHEC may purchase antitoxins, serums, vaccines, immunizing agents, antibiotics, and other pharmaceutical agents or medical supplies ("Medical Supplies"). After declaration of a Public Health Emergency, and in accordance with Code Section 11–35–1570, the Commissioner or his designee may authorize others to make emergency procurements; provided, that such emergency procurements shall be made with as much competition as is practicable under the circumstances. A written determination of the basis for the emergency and for the selection of the particular contractor shall be included in the contract file.

ii. Strategic National Stockpile

a. DHEC has been designated as the entity responsible for distribution of SNS materials after transfer of SNS materials from CDC. DHEC shall name a consultant pharmacist to be responsible for establishing appropriate policies and procedures for the receipt, storage, dispensing, and distribution of drugs from the SNS and for supervising a record-keeping system for those drugs. DHEC shall submit these policies, procedures, and record-keeping systems to the Board of Pharmacy for review and approval.

b. Upon notification that SNS materials are being sent to South Carolina and the declaration of a Public Health Emergency, DHEC shall notify the SC Board of Pharmacy and the SC Department of Labor, Licensing and Regulation of the impending arrival, distribution, and dispensing of SNS materials.

c. Provided that the Board of Pharmacy has approved the submitted policies, procedures and record-keeping systems, DHEC may proceed to distribute and dispense SNS materials.

d. Records with respect to receipt, storage, distribution and dispensing of SNS materials shall be retained for two years and shall be readily available for audit by the Board of Pharmacy, the Department of Labor, Licensing and Regulation, the DHEC Bureau of Drug Control, or a responsible Federal agency.

iii. DHEC may distribute, administer or dispense Medical Supplies either through its own employees, by instructions to wholesalers, or by allocation to health care providers for redistribution in accordance with directives issued by DHEC. In allocating Medical Supplies, DHEC will consider the amount on hand, the amount reasonably anticipated from other sources, and the population at risk. DHEC may allocate or deny Medical Supplies based on age, proximity to an initiating event or route of transmission, whether the individual is a First Responder, whether alternative personal protective measures are readily available, or other criteria of epidemiological significance.

iv. In allocating Medical Supplies to First Responders, DHEC may consider proximity to an initiating event or route of transmission in addition to other risk factors.

B. Orders affecting wholesale distribution

i. After declaration of a Public Health Emergency, DHEC may order manufacturers and distributors doing business in South Carolina to provide information on the amount, location and availability of Medical Supplies in South Carolina or in distribution chains serving South Carolina.

ii. In consultation with public health officials in neighboring states and with Federal officials, DHEC may direct distribution of Medical Supplies to designated health care providers. DHEC may direct designated health care providers to distribute or dispense Medical Supplies in accordance with criteria established by DHEC, which may include age, proximity to an initiating event or route of transmission, or other criteria of epidemiological significance.

C. Orders affecting retail distribution

DHEC may issue guidelines defining diagnostic criteria, risk factors and contraindications for the guidance of health care providers. The Commissioner may by order identify categories of individuals to whom Medical Supplies shall not be given.

Section 8. Qualified health care providers

A. Authorization to practice

i. Authorization of otherwise qualified health care professionals who are not licensed in South Carolina to render professional services during a public health emergency is the responsibility of the respective licensing board or entity. This may include students or interns as may be recommended by their faculty and approved by the respective licensing board.

ii. DHEC will consult with the Board of Medical Examiners, Board of Nursing, Board of Pharmacy, the State EMT Coordinator, and other licensing boards to determine what credentials will be required of otherwise qualified, but unlicensed, individuals before assignment in a response role. Upon declaration of a Public Health Emergency, DHEC may assign individuals after review of individual credentials but before confirmation from the professional licensing boards.

B. Conditions of licensure

i. If, during a Public Health Emergency, an individual health care provider unreasonably fails or refuses to perform vaccinations, treatment, examination, or testing of individuals, DHEC may submit evidence of such refusal to the appropriate licensing board for consideration in subsequent licensing decisions.

ii. DHEC may consider evidence of failure or refusal to allow vaccinations, treatment, examination or testing of individuals as a basis for revoking or denying renewal of facility licenses issued by DHEC. Revocation or denial of a license based in whole or in part on such grounds may be challenged as a contested case.

Section 9. Quarantine; Restrictions on travel and public assembly

A. Upon declaration of a Public Health Emergency in which there is a substantial likelihood of person-to-person transmission of disease or spread of contamination, DHEC may recommend to law enforcement authorities orders placing restrictions on public gatherings. Such recommendations shall be reasonably tailored to address the risk and may include limits on the number or age of individuals, restrictions on location, or restrictions on non-essential gatherings.

B. Upon declaration of a Public Health Emergency, DHEC may order closure of primary or secondary schools.

C. Quarantine and isolation

i. DHEC will provide notice to individuals in quarantine or isolation sufficient to inform them of (1) the basis for the order of quarantine or isolation; (2) the restrictions imposed by the order; (3) procedures for obtaining judicial review of the order; (3) notice of any hearings, appointment of counsel, or other court proceedings; (4) the findings of the court after any review of the order; (5) any testing, treatment or vaccination which is planned or available; (6) the location and hours of operation of facilities for the delivery of mail, food, fuel, medical treatment or supplies, and other necessaries.

ii. (1) DHEC will by order establish criteria for allowing entry into and departure from quarantine or isolation facilities, which may include prohibitions against departure. The Commissioner may designate medical professionals to assist law enforcement personnel assigned to implement the quarantine order. (2) If quarantine has been established by geographical area, criteria for departure may include procedures for documenting that travelers have permission to enter the intended destination.

iii. DHEC will offer the reviewing court information, including best professional judgment, concerning risk of disease transmission and possible prophylactic measures for the court's consideration in establishing procedures for allowing quarantined or isolated individuals access to counsel and access to court proceedings consistent with public health and due process.

Section 10. Human remains

A. Upon declaration of a Public Health Emergency, DHEC will notify coroners, medical examiners, and funeral directors of specific procedures to be followed in handling and disposing of remains of individuals known or presumed to have died from or been exposed to contamination or communicable disease. This may include individuals determined to have died as a result of other causes, such as trauma, but who had been exposed prior to death.

B. Prior to disposal

i. Every person in charge of disposing of any human remains must maintain a written record of each set of human remains and all available information to identify the decedent and the circumstances of death and disposal. If the human remains cannot be identified, prior to disposal, a qualified person must, to the extent possible, take fingerprints and one or more photographs of the human remains, and collect a DNA specimen. The Commissioner may by order require collection of specific tissue samples or performance of specific tests. All information gathered under this paragraph must be promptly forwarded to DHEC. Identification must be handled by the agencies that have laboratories suitable for DNA identification.

ii. All human remains of a person who has died from an infectious disease must be clearly labeled with all available information to identify the decedent and the circumstances of death. Any human remains of a deceased person with an infectious disease must have an external, clearly visible tag indicating that the human remains are infected and, if known, the infectious disease. The person in charge of disposing of such human remains shall report to DHEC the identifying information and the date, means and place of disposal.

C. If DHEC concludes that there is no public health reason to require disposal within twenty-four hours of human remains of persons who have died of an infectious disease, DHEC shall so notify coroners, medical examiners, and funeral directors.

D. Mass graves: In the event of mass casualties in excess of the provisions of the State Emergency Operations Plan to provide for disposal, mass graves shall

i. not be located in floodways, wetlands, karst formations, or in unstable terrain;

ii. have at least two feet vertical separation above groundwater;

iii. be at least two hundred feet from the nearest property line, potable well, or irrigation well, and one hundred feet from surface waters (including ephemeral or seasonal streams);

iv. provided with daily cover to control vectors, hydrated lime, and absorbent material;

v. provided with adequate final cover, fencing and venting to minimize the need for long-term care.

vi. The corners of mass graves shall be marked with permanent monuments and the location recorded where title to real property is recorded.

vii. A permanent record of the names or other identifying information of all human remains shall be kept.

Section 11. Severability

Should any section, paragraph or other part of these regulations be declared invalid for any reason, the remainder shall not be affected.

HISTORY: Added by State Register Volume 30, Issue No. 3, eff March 24, 2006.

61–113. Groundwater Use and Reporting.

(Statutory Authority: 1976 Code Ann. § 49–5–10 et seq., as amended)

A. Purpose and Scope

Regulation 61–113, *et seq*. is promulgated pursuant to the Groundwater Use and Reporting Act, S.C. Code Ann. Sections 49–5–10 *et seq*. (1976 Code of Laws, as amended), and is known as the Groundwater Use and Reporting Regulation. The Department finds the standards and procedures prescribed are necessary to maintain, conserve and protect the groundwater resources of the State. Designation of capacity use areas shall be in accordance with the Groundwater Use and Reporting Act, S.C. Code Ann. Sections 49–5–60 (1976 Code of Laws, as amended).

B. Definitions

Unless the context otherwise requires, as used in this regulation:

1. "Abandoned well" means a well where the pump has been disconnected for reasons other than repair or replacement and whose use has been discontinued for a period of one year, or has been pronounced as abandoned by the owner or operator.

2. "Annular space" means the space between the well casing and the formation or the space between the outer casing and the inner casing in a well where two or more casings are used.

3. "Aquifer" means a geologic formation, group of these formations, or part of a formation that contains sufficient saturated permeable material to yield significant quantities of groundwater to wells and springs.

4. "Aquifer storage and recovery (ASR)" means a water well which allows potable water to be injected into a subsurface aquifer to be recovered by pumping at a later date.

5. "Artificial filter or gravel-pack" means specially graded filter material that is placed in the annular space to increase the effective diameter of the well and to prevent fine-grained sediments from entering the well.

6. "Artificial-filter or gravel-packed well" means a screened well that is constructed with artificially emplaced filter material in the annular space between the well screen(s) and borehole wall.

7. "Available precipitation" for water use calculations means the annual average precipitation less annual average evapotranspiration.

8. "Bedrock" means the competent parent solid rock formation (crystalline, metamorphic, limestone) underlying weathered rock, soil, and sediments.

9. "Best Management Plan" means a document that supports the design, installation, maintenance, and management of water conveyance systems and/or water withdrawal systems (water supply, commercial, industrial, agricultural, etc.), which promotes water conservation, and protects water quality.

10. "Board" means the Board of the S.C. Department of Health and Environmental Control.

11. "Capacity Use Area" means an area, designated by the Board, where excessive groundwater withdrawal presents potential adverse effects to the natural resource or poses a threat to public health, safety, or economic welfare or where conditions pose a significant threat to the long-term integrity of a groundwater source, including saltwater intrusion.

12. "Certified Well Driller" means any person duly and currently registered by the S.C. Department of Labor, Licensing, and Regulation to practice as a well driller in South Carolina.

13. "Coastal Plain" means:

a. All of Aiken, Allendale, Bamberg, Barnwell, Beaufort, Berkeley, Calhoun, Charleston, Clarendon, Colleton, Darlington, Dillon, Dorchester, Florence, Georgetown, Hampton, Horry, Jasper, Lee, Marion, Marlboro, Orangeburg, Sumter, and Williamsburg counties; and

b. Those portions of Chesterfield, Edgefield, Kershaw, Lexington, Richland, and Saluda counties east or southeast of the fall line as identified on the best available geologic map.

14. "Cone of depression" means the deviation of the hydraulic gradient from the normal path of groundwater flow (potentiometric surface) converging towards a pumping well or system of wells.

15. "Confining bed" means a strata of relatively impermeable material having distinctly lower hydraulic conductivity stratigraphically adjacent to one or more aquifers.

16. "Consumptive use" means any use of withdrawn groundwater other than a non-consumptive use, as defined in this section.

17. "Department" means the S.C. Department of Health and Environmental Control, including personnel thereof authorized and empowered by the Board to act on behalf of the Department or Board.

18. "Dewatering operation" means an operation that is withdrawing groundwater from an aquifer for the purpose of draining an excavation or preventing or retarding groundwater flow into an excavation. This operation includes, but is not limited to, mining, water and sewer line construction, and excavating for a building foundation.

19. "Domestic well" means an individual residential or irrigation well intended to supply water to a single family dwelling for routine household purposes, lawns, or gardens.

20. "Drawdown" means the difference in levels between the static water level in a well and the surface of the depressed water level that occurs when the well is pumped.

21. "Effluent" means water conveyed out of a wastewater treatment facility or other works used for the purpose of treating, stabilizing, or holding wastewater.

22. ''Emergency withdrawal'' means the withdrawal of groundwater, for a period not exceeding thirty calendar days, for the purpose of fire fighting, hazardous substance or waste spill response, or both, or other emergency withdrawal of groundwater as determined by the Department.

23. ''Evapotranspiration'' means a collective term that includes water discharged to the atmosphere as a result of evaporation from the soil and surface water bodies and as a result of plant transpiration.

24. ''Flowing well'' means a well releasing groundwater under such pressure that pumping is not necessary to bring it above the ground surface.

25. ''Geophysical log'' means a continuous record from an instrument that measures physical, chemical, electrical, or radioactive properties of subsurface geological formations or groundwater contained in these formations.

26. ''Groundwater'' means subsurface water found in the void spaces of geologic materials within the zone of saturation.

27. ''Groundwater withdrawal permit'' means a permit issued by the Department to groundwater withdrawers in designated Capacity Use Areas for the withdrawal of groundwater.

28. ''Groundwater withdrawer'' means a person withdrawing groundwater in excess of three million gallons during any one month from a single well or from multiple wells under common ownership within a one-mile radius from any one existing or proposed well.

29. ''Industrial Well'' means a well used for supplying water to an industrial or commercial operation or establishment whose ultimate use of the water is for processing, manufacturing, cooling, or similar industrial process.

30. ''Irrigation requirement'' means the total amount of water required at the field to produce a specific crop or maintain a healthy, functional turf or landscape.

31. ''Irrigation well'' includes, but is not limited to, a well used for supplying water for agricultural, commercial or aesthetic irrigation, and livestock operations.

32. ''Limestone'' means a sedimentary formation composed chiefly of calcium carbonate, consolidated or unconsolidated, which may be in the form of shell pieces or calcareous muds or sands.

33. ''Marl'' means calcareous clays. In South Carolina, the term is mostly applied to the Cooper Marl of Eocene Age, characterized by its dark greenish drab to grayish green color.

34. ''Non-consumptive use'' means the use of water from an aquifer that is returned to the aquifer from which it was withdrawn, at or near the point from which it was withdrawn, without substantial diminution in quantity or quality.

35. ''Permit to construct'' means a permit for well construction issued by the Department after consideration of, among other things, proposed well location, depth, rated capacity, withdrawal rate, and existing water withdrawals.

36. ''Permittee'' means a person having obtained a permit to construct or a groundwater withdrawal permit issued in accordance with these regulations.

37. ''Person'' means an individual, firm, partnership, association, public or private institution, municipality or political subdivision, local, state, or federal government agency, department, or instrumentality, public water system, or a private or public corporation organized under the laws of this State or any other state or county.

38. ''Public water system'' means a water system as defined in the State Safe Drinking Water Act, S.C. Code Ann. Section 44–55–20 (1976 Code of Laws, as amended).

39. ''Pumping water level'' means the distance, usually measured in feet, from the land surface or other permanent specified datum to the water surface (water level) in a well being pumped.

40. ''Rated capacity'' means the amount, in gallons per minute (gpm), of groundwater that is withdrawn or capable of being withdrawn from the completed well with the pump installed.

41. ''Saltwater'' means water containing concentrations of chloride and total dissolved solids in excess of standards as defined in S.C. R.61–58, State Primary Drinking Water Regulation.

42. ''Saltwater intrusion'' means the movement of saltwater into a freshwater aquifer.

43. "Surface water" means all water that is open to the atmosphere and subject to surface runoff, which includes lakes, streams, ponds, and reservoirs.

44. "Static water level" means the distance, usually measured in feet, from the land surface or other permanent specified datum to the water surface (water level) in a non-pumping well.

45. "Well" means an excavation that is cored, bored, drilled, jetted, dug hole, driven shaft, or otherwise constructed whose depth is greater than the largest surface dimension from which water is extracted or injected for the purpose of locating, testing, or withdrawing groundwater or for evaluating, testing, developing, draining, or recharging a groundwater reservoir or aquifer, or that may control, divert, or otherwise cause the movement of groundwater from or into an aquifer. Wells typically fall into one of the following types of construction:

a. Type I, open hole wells completed in crystalline bedrock aquifers;

b. Type II, screened, natural filter wells completed in unconsolidated aquifers;

c. Type III, screened, gravel-packed wells completed in unconsolidated aquifers;

d. Type IV, open hole wells completed in consolidated limestone aquifers; and

e. Type V, bored or dug well having large diameter.

46. "Well interference" means the instance where cones of depression from two or more wells overlap creating an additive drawdown in the affected area.

C. Applicability of Regulations

The standards contained herein apply to all persons who withdraw or are capable of withdrawing groundwater in excess of three million gallons in any given month from a well or multiple wells under common ownership within a one-mile radius from any one existing or proposed well in South Carolina. These regulations do not change or modify previous Capacity Use Area designations.

D. Permits and Registrations Required

1. Before a groundwater withdrawer or proposed groundwater withdrawer in a designated capacity use area can construct a new well or increase the rated capacity of an existing well, an application for a permit to construct shall be made to, and a permit to construct obtained from, the Department unless exempt pursuant to Section J.

2. Before a person may become a groundwater withdrawer in a designated capacity use area, an application for a groundwater withdrawal permit shall be made to, and a groundwater withdrawal permit obtained from, the Department unless exempt pursuant to Section J.

3. Before a groundwater withdrawer or proposed groundwater withdrawer outside a designated capacity use area in the Coastal Plain can construct a new well or increase the rated capacity of an existing well, a Notice of Intent shall be made to the Department at least thirty days prior to initiating the action, unless exempt pursuant to Section J.

4. All groundwater withdrawers in the State shall register their groundwater withdrawal and subsequent use with the Department.

5. A groundwater withdrawer outside a designated capacity use area shall register all new wells with the Department within thirty days after initiating use of the wells.

E. Permit Application

1. A person who is required to obtain a Groundwater Withdrawal Permit for an existing or proposed groundwater withdrawal or use under Section D shall submit a permit application on forms, furnished upon request, by the Department. The applicant shall furnish the Department, as determined by the Department, with sufficient documented evidence as described in Section E to aid in evaluating the effect of the existing or proposed groundwater withdrawal or use on the water resources of the Capacity Use Area.

2. Sufficient documented evidence shall include, but not be limited to, the following:

a. Name, address, and phone number of applicant who shall be the owner and his applicable agent, professional engineer or professional geologist, as appropriate;

b. Location of all existing and/or proposed wells, properly identified, for which the permit is requested, marked on the best available map, which may be a portion or copy of a United States Geological Survey 7 ½ (seven and one-half) minute quadrangle map, latest county highway map,

or more detailed map or aerial photography, where required by the Department, provided the map or aerial photography submitted is clearly identified;

c. The latitude and longitude of all wells, obtained from the location map or by acceptable Global Positioning System (GPS) instrumentation;

d. As-built construction details of all wells to include, but not limited to, the following;

1. Name of driller;

2. Date of drilling;

3. Total depth of well (in feet);

4. Diameter of drilled hole;

5. Diameter, depth, and type of casing;

6. Depth (length) of grouting;

7. Depth and diameter of well screen(s), if used, and the material, type, and diameter of screen openings;

8. Type of pump, size (horsepower), and performance curves;

9. Static water level and pumping water level; and

10. Number of hours per day the well(s) is pumped.

e. A completed SCDHEC Water Well Record or other approved form and driller's logs, if available;

f. Copy of geophysical/mechanical logs, if available;

g. The ground elevation of the well(s), if available;

h. The location of all abandoned or unused well(s) owned or under the control of the applicant;

i. The proposed amount of groundwater withdrawal (in million gallons) per year;

j. A "Best Management Plan" for water use and water conservation designed to protect water quality and reduce water consumption to include, but not limited to, the following, as applicable;

1. Reasonable and appropriate conservation techniques, application processes, and alternate sources of water, including but not limited to, surface water(s) and/or availability of treated effluent, to minimize or eliminate groundwater sources;

2. Based on the current and/or proposed withdrawal rates, provide reasonable and appropriate documentation that the proposed water use is necessary to the anticipated needs of the applicant to include, but not limited to, the following;

a. Public Water Supply- by system, population served, anticipated growth, annual water use statistics (e.g., monthly average, peak summer/winter consumption);

b. Industrial Water Supply- by industry type, anticipated growth, and annual water use statistics (e.g., monthly average, peak summer/winter consumption);

c. Irrigation Water Supply- irrigated acreage, major crops (with irrigated acreage for each crop), water use by crop (per acre), calculated irrigation requirement (including available precipitation), critical period growth requirements, growing season, and nutrient and pest management strategy;

d. Golf Course Irrigation Water Supply- irrigated acreage (differentiating actual golf course areas and aesthetic landscaping), water use per acre, calculated irrigation requirement (including available precipitation), annual water use statistics (e.g., monthly average, peak summer/winter consumption), and nutrient and pest management strategy;

e. Aquaculture Water Supply- pond capacity (acre-feet), make-up water requirement, drain-fill periodicity, (e.g., monthly average, peak summer/winter consumption).

3. Maintenance schedule to preserve the integrity and efficient operation of water conveyance system(s); and

4. A statement specifying the beneficial use of the groundwater being withdrawn as necessary to meet the reasonable needs of the applicant.

k. Historical water use information;

l. Availability of alternate water sources;

m. Any present or anticipated unreasonable adverse or potential adverse effects on other water uses or users, including, but not limited to, adverse effects on public use; and

n. Permitted effluent discharges in accordance with a valid NPDES Discharge Permit.

3. In addition to the information required under Section E.2. above, applicants proposing new well construction or increasing the rated capacity of an existing well or wells shall provide proposed well construction details and technical specifications or pump specifications, including, but not limited to, the following:

a. Name of driller, if known;

b. Date of drilling, if known;

c. Total depth of well (in feet);

d. Diameter of drilled hole;

e. Diameter, depth, and type of casing;

f. Depth of grouting - the minimum length of grout to protect the aquifer utilized, unless demonstrated that an alternate grout length is as protective, shall be;

1. Type II and III, the first confining bed (clay, marl, etc.) immediately above the aquifer being utilized or to within ten (10) feet of the uppermost screen when no confining bed is encountered;

2. Type IV, twenty (20) feet into firm limestone or firm marl, whichever is less.

g. Depth and diameter of the open hole or well screen(s), if used, and the material, type, and diameter of screen openings. The open hole or screen setting(s) shall not connect aquifers or zones with documented differences in water quality or result in or create the potential for contamination of any aquifer or zone or cause depletion or significant loss of head in any aquifer or zone;

h. Type of pump, size (horsepower), and performance curves;

i. Deep well airline of steel, iron, or heavy gauge copper material, or an access port not less than one-half inch in diameter, with screw cap for water-level measurements; and

j. Filling, plugging, and sealing procedures for any well(s) that are to be abandoned in accordance with Section N.

4. In addition to the information and standards required under Section E.2 and Section E.3 above, applicants proposing new well construction must comply with requirements established in S.C. R.61–44, South Carolina Individual Residential Well & Irrigation Permitting, and, at a minimum, comply with the S.C. R.61–71, South Carolina Well Standards, as appropriate.

F. Department Actions on Permit Applications, Modifications, Revocation and Denials

1. In considering all permit applications, modifications, and revocations, the Department shall consider, but not be limited to, the following:

a. The number of persons using an aquifer and the object, extent, and necessity of their respective withdrawals or uses;

b. The nature and size of the aquifer;

c. The physical and chemical nature of any impairment of the aquifer adversely affecting its availability or viability for other water uses, including public use;

d. The severity and duration of such impairment under foreseeable conditions;

e. The injury to public health, safety, or welfare which may result if such impairment were not prevented or abated;

f. The kinds of businesses or activities to which the various uses are related;

g. The relative importance and necessity of uses claimed by permit holders and permit applicants, or of the water use of the area, and the extent of injury or detriment caused or reasonably expected to be caused to other water uses, including public use;

h. Diversion from or reduction of flows in surface water or other aquifers;

i. Information provided by the applicant in accordance with Section E;

j. An approved local or regional Groundwater Management Strategy; and

k. Any other relevant factors, such as, but not limited to, public comments and best available geologic and hydrologic information on the aquifer or aquifers of the area.

2. In each case where an applicant for a Groundwater Withdrawal Permit demonstrates to the Department's satisfaction that the groundwater withdrawal is reasonable and necessary to meet the applicant's requirements and where there are no unreasonable adverse effects on other water users, including public use, and including potential as well as current use, a Groundwater Withdrawal Permit may be issued by the Department and contain, but not be limited to, the following conditions:

a. Amount of groundwater to be withdrawn or used;

b. Well(s) to be utilized;

c. Aquifer(s) to be utilized;

d. Well spacing to minimize well interference; and

e. Monitoring well(s) to be installed for monitoring groundwater levels and water quality.

3. Groundwater withdrawn under any permit shall be used only for the purposes set forth in the permit.

4. The Department may grant a temporary Groundwater Withdrawal Permit for up to one hundred eighty days or until a final decision is made on the application if an imminent hazard to public health exists or if an applicant demonstrates that physical or financial damage has occurred, or will occur, if a temporary permit is not granted. The issuance of a temporary permit does not guarantee the issuance of a final Groundwater Withdrawal Permit.

5. The Department may:

a. Revoke a construction permit or a Groundwater Withdrawal Permit if it determines information in the permit application is false or misleading, the permittee fails to comply with the conditions set forth in the permit, or when there is found to be an unreasonable adverse effect upon the water uses or water users in the area, including public use, and including potential as well as current use, based upon considerations set forth in Section F;

b. Deny a permit if the application therefore or the effect of the water use proposed or described therein upon the water resources of the area is found to be contrary to the public interest or general welfare, based upon considerations in Section F; and

c. Revoke a temporary Groundwater Withdrawal Permit if the permittee fails to comply with the conditions of the temporary permit or provide timely response to requests for actions for information made pursuant to the application review.

6. The Department's denial or revocation of any permit shall be final unless a request for a contested case hearing is filed in accordance with the Administrative Procedures Act and the Rules of the Administrative Law Court.

7. A Groundwater Withdrawal Permit shall not be transferred to any other person or user except by modification of the permit in accordance with Section G.

8. Public notices shall be required for an:

a. Initial application for a Groundwater Withdrawal Permit in an existing capacity use area;

b. Application to modify an existing Groundwater Withdrawal Permit where an increase in the permitted withdrawal limit is requested;

c. Application to modify an existing Groundwater Withdrawal Permit where construction of a new well or wells, with concurrent increase in the permitted withdrawal limit, is requested; and

d. Application to renew an existing Groundwater Withdrawal Permit, where no increase in the permitted withdrawal limit is requested, only if the Department determines there is sufficient public interest on the proposed groundwater withdrawal.

9. Wording for public notices will be provided to the applicant by the Department and shall contain, but not be limited to, the following:

a. Applicant's name and mailing address;

b. Location of the well or wells;

c. Aquifers to be utilized;

d. Proposed withdrawal limit(s); and

e. Notice of thirty day comment period.

10. The applicant will publish the public notice, for one day, in a newspaper of general circulation in the area of the proposed withdrawal.

11. The applicant will provide an affidavit of publication from the newspaper to the Department within fifteen days of initial publication and a copy of the published notice.

12. The Department will notify currently permitted groundwater withdrawers of newly proposed groundwater withdrawal within a one-mile radius of the proposed well location. This notification will be provided at least thirty days prior to issuance of the final permit.

G. Permit Modifications

1. An application to modify a Groundwater Withdrawal Permit shall be required when:

a. The permittee desires to increase the permitted groundwater withdrawal limit;

b. The permittee desires to increase the rated capacity of a well or wells;

c. The permittee desires to construct a new well, unless exempt pursuant to Section J; or

d. There is a proposed change or transfer of ownership of the permitted entity.

2. Applications to modify a Groundwater Withdrawal Permit shall be made in compliance with the provisions in Section E. The Department may modify a permit after consideration of factors pursuant to Section F. If the Department determines that no modification will be granted, this determination shall be final unless a request for a contested case hearing is filed in accordance with the Administrative Procedures Act and the Rules of the Administrative Law Court.

H. Duration of Permits and Renewal

1. No permit shall be issued for a period longer than the following:

a. Five (5) years;

b. The period found by the Department necessary to conserve and protect the resource, prevent waste, and to provide and maintain conditions which are conducive to the development and use of water resources; or

c. The temporary period as specified in Section F.

2. A Groundwater Withdrawal Permit shall be renewed by filing a completed application in compliance with Section E at least ninety days prior to its expiration. A Groundwater Withdrawal Permit that expires, with a completed application in compliance with Section E received by the Department at least ninety days prior to the expiration date, will continue to be valid until a decision is reached on the permit renewal application.

I. Groundwater Use Reports

1. Every permitted and registered groundwater withdrawer in the State shall annually, before January 30th, file with the Department a water use report on forms furnished by the Department or approved by the Department of the quantities of groundwater withdrawn. Failure to provide a groundwater use report is grounds for revocation of a permit.

2. Water use reports shall include, but not be limited to, the following:

a. Name of permit holder and permit number;

b. Use of the groundwater being withdrawn;

c. Source of groundwater, identifying the well or wells utilized;

d. Monthly quantity of water withdrawn from each well; and

e. How the withdrawal was measured.

3. The quantity of groundwater withdrawn must be determined by one of the following:

a. Flow meters accurate to within ten percent of calibration;

b. Rated capacity of the pump in conjunction with the use of an hour meter, electric meter, or log;

c. The rated capacity of a cooling system;

d. Any standard or method employed by the United States Geological Survey in determining such quantities; or

e. Any other method approved by the Department, which will provide reliable groundwater withdrawal data.

4. The groundwater withdrawer is not required to submit the groundwater withdrawal report required by Section I if the monthly quantity withdrawn from each well is being reported to the Department as a result of another environmental program reporting requirement, permit condition, or consent agreement.

J. Exemptions

1. The following are exempt from this regulation:

a. Emergency withdrawal of groundwater;

b. Any person withdrawing groundwater for non-consumptive uses;

c. A person withdrawing groundwater for the sole purpose of wildlife habitat management; or

d. A person withdrawing groundwater at a single-family residence or household for noncommercial use.

2. The following are exempt from the permitting of Section D and public notification requirements of Section F:

a. Dewatering operations at mines;

b. All other dewatering operations;

c. Type I wells installed into crystalline bedrock in a designated capacity use area; or

d. Groundwater withdrawer constructing a new well to replace an existing well with no increase in capacity or withdrawal amount.

3. Aquifer Storage and Recovery (ASR) wells are exempt from the requirements of this regulation if:

a. A permit pursuant to S.C. R.61–87, Underground Injection Control Regulations, is obtained from the Department; and

b. The amount of water withdrawn does not exceed the amount of water injected.

K. Saltwater Intrusion

1. To protect against or abate saltwater intrusion, the Department shall consider the best available information on the geologic and hydrologic characteristics of the aquifer or aquifers and the groundwater withdrawals of the area, and shall require water users to take such action as the Department deems necessary for its control.

2. Types of control measures the Department may require applicants, permit holders, and groundwater withdrawers to take may include, but not be limited to, the following:

a. Pumping arrangements to reduce groundwater withdrawal in areas of concentrated pumping;

b. Location of wells to eliminate or reduce groundwater withdrawals near zones of saltwater intrusion;

c. Requirement of selective withdrawal from other available freshwater aquifers than those currently used;

d. Selective curtailment or reduction of groundwater withdrawals where it is found to be in the public interest or general welfare or to protect the water resource;

e. Conjunctive use of freshwater or saltwater aquifers, or waters of less desirable quality where water quality of a specific character is not essential;

f. Construction and use of observation or monitor wells, drilled into freshwater aquifers between areas of groundwater withdrawal (or proposed areas of groundwater withdrawal) and sources of saltwater;

g. Construction and use of wells, drilled into areas of intrusion, to intercept saltwater moving towards the center of excessive groundwater withdrawal;

h. Construction and use of wells, drilled into the saltwater aquifer, to relieve hydraulic pressure causing saltwater intrusion in the aquifer;

i. Abandonment of wells, in accordance with Section N, that have penetrated saltwater zones or zones of undesirable water quality and are determined by the Department to be causing contamination of freshwater aquifers;

j. Prohibiting the hydraulic connection of saltwater and freshwater aquifers that could result in deterioration of water quality in a freshwater aquifer(s);

k. Abandonment of wells, not covered under Section K.2.i., in accordance with Section N; and

l. Such other necessary and appropriate control or abatement techniques as are technically feasible and have proven to be successful in other areas.

L. Unreasonable Adverse Effects on Other Water Users

1. To protect against or abate unreasonable adverse or potential unreasonable adverse effects on other water users within a designated capacity use area, including but not limited to adverse effects on public use, the Department shall consider the best available information on the geologic and hydrologic characteristics of the aquifer or aquifers and the groundwater withdrawals of the area, and shall require groundwater users to take such action as the Department deems necessary and appropriate for its control.

2. Types of control measures which the Department may require applicants, permit holders, and groundwater withdrawers to take may include, but not be limited to, the following:

a. Requirement of selective withdrawal from other available freshwater aquifers than those currently used;

b. Pumping arrangements to reduce groundwater withdrawal in areas of concentrated pumping;

c. Selective curtailment or reduction of groundwater withdrawals where it is found to be in the public interest or general welfare or to protect the water resource;

d. Conjunctive use of aquifers, or waters of less desirable quality where water quality of a specific character is not essential;

e. Construction and use of observation or monitor wells;

f. Abandonment of wells, in accordance with Section N, that have penetrated zones of undesirable water quality where such wells are determined by the Department to be causing contamination of freshwater aquifers;

g. Prohibiting the hydraulic connection of aquifers that could result in deterioration of water quality in a freshwater aquifer(s);

h. Abandonment of wells, not covered under Section L.2.f., in accordance with Section N below;

i. Require the applicants, permit holders, and groundwater withdrawers to cooperate with the Department and other groundwater users in the affected area, in determining and implementing reasonable and practical methods to conserve and protect the water resources and to avoid or minimize adverse effects of the quantity and quality of water available to persons whose water supply has been materially reduced or impaired as a result of groundwater withdrawals; and

j. Such other necessary and appropriate control or abatement techniques as are technically feasible and have proven to be successful in other areas.

M. Hydrologic and Geologic Information

1. The Department may gather and/or require the submission of hydrologic and geologic information on the aquifer or aquifers in and adjacent to a designated capacity use area for the purpose of evaluating and managing the groundwater resource.

2. Required information may include, but not be limited to, the following:

a. Surface and/or subsurface geologic mapping;

b. Areas of groundwater recharge and amount of recharge;

c. Drilled well cuttings and/or drilled well cores;

d. Geophysical logs;

e. Pumping test to establish hydraulic characteristics of an aquifer(s);

f. Static and pumping water levels of wells;

g. Groundwater availability and flow;

h. Water quality analyses;

i. Amount of groundwater withdrawal from the aquifer(s); and

j. Drill test, monitor or observation wells.

3. All persons who are required to obtain a Groundwater Withdrawal Permit under this regulation shall furnish the Department such additional geologic and hydrologic information and well construction data as the Department requires which may include, but not be limited to, the following:

a. Collection of drill cuttings at ten foot intervals and/or at lithological changes of the stratigraphy, showing depth, in feet, below ground surface, at which the cuttings were collected;

b. Geophysical logs, where the Department finds additional information on the geology, hydrology or well construction is required;

c. Data on all water bearing zones encountered;

d. Drill stem or packer tests;

e. Pumping test data;

f. Water quality analyses; and

g. Completed DHEC Water Well Record or other approved reporting form.

4. Any person drilling a test or exploration well for the purpose of obtaining geologic and/or hydrologic information on water or mineral resources in a designated capacity use area shall apply for a permit to construct in accordance with Section E from the Department to drill such well and shall submit to the Department the information identified in this Section; provided that no person shall be required to disclose any secret formula, process or methods used in any manufacturing operation or any confidential information concerning business activities carried on by him or under his supervision; provided, however, if the information is necessary for the Department to make a determination on a permit application or modification, the Department may deny such permit on the grounds that the applicant failed to provide the necessary information. In addition to the information required under Section E the following information shall be submitted on forms provided by or approved by the Department prior to the drilling of a test, exploration, or observation well:

a. Name and address of applicant who shall be the owner and his applicable agent, professional engineer, or professional geologist, as appropriate;

b. Intended purpose of the well(s);

c. Name and address of owner(s) of property on which the proposed test, exploration, or observation well(s) is to be located;

d. Proposed location(s) of all test, exploration, or observation well(s), identified by number, for which the permit is requested, marked on the best available map;

e. Proposed depth(s) of all test, exploration, or observation well(s), the diameter(s), and proposed method of drilling and construction;

f. Type of casing, screen, and other materials to be used in construction of the well(s);

g. Type of borehole logs, including geophysical logs, to be run on the well(s); and

h. Proposed method of abandonment.

5. Upon completion of the test, exploration, or observation well(s) the following information shall be submitted to the Department:

a. A completed SCDHEC Water Well Record or other approved form;

b. As-built construction diagram of the completed well, showing hole sizes and depths, casing sizes, and screen (if applicable), grout location, and construction materials;

c. Elevation data;

d. Aquifer test or pumping test data;

e. Driller's log, geologist's or engineer's log;

f. Geophysical logs; and

g. Method of abandonment (if applicable).

6. All test, exploratory, and observation well(s) drilled and not developed for groundwater withdrawal shall be filled, plugged, and sealed in accordance with Section N.

7. Wells without pumps which are declared not to be abandoned shall be fitted with a secure cap when they are not being used as observation wells or for other purposes.

N. Abandoned Wells

1. Where the Department finds any existing well(s) of groundwater withdrawers or any test, exploratory, or observation well(s) have been abandoned and are no longer put to beneficial use and which are deemed by the Department to have an unreasonable adverse or potential unreasonable adverse effect on other water users or uses, or which result, or may result, in physical or chemical impairment of the aquifer(s), shall require the well owner to fill, plug, and seal the well in a manner acceptable to and approved by the Department.

2. Where the Department finds an abandoned well to be a contributor, or may in the future become a contributor to saltwater intrusion or contamination or to be having an unreasonable adverse impact on groundwater users or freshwater aquifers, shall require the well owner to fill, plug, and seal the well in a manner acceptable to and approved by the Department.

3. Upon completion of abandonment the well owner or his agent shall submit a completed SCDHEC Water Well Record or other approved form to the Department.

O. Wells Not Requiring Pumps

Wells that are flowing by releasing groundwater under such pressure that pumping is not necessary to bring it above the ground surface at a rate of greater than five thousand gallons a day at any time are an unreasonable use of groundwater constituting waste and are prohibited, except that the water from these wells may be utilized to the extent actually necessary for a specific use. These wells must be fitted with a mechanism to restrict the flow of water if the flow is in excess of that necessary for the specific use. The Department may promulgate additional regulations to govern use of these wells in this State.

P. Severability

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

HISTORY: Added by State Register Volume 30, Issue No. 6, eff June 23, 2006.

61–114. South Carolina Birth Defects Program.

(Statutory Authority: 1976 Code §§ 44–44–10 through 44–44–160)

Section A: Purpose and Scope

Section B: Definitions

Section C: Public Health Surveillance and Monitoring of Birth Defects

Section D: Data Usage

Section E: Referral

Section F: Confidentiality

Section G: Severability

Section A: Purpose and Scope

This regulation establishes standards for implementing provisions of Sections 44–44–10 through 44–44–160 of the South Carolina Code of Laws, 1976, as amended, regarding the public health monitoring of birth defects identified in children up to two years of age in South Carolina. The Birth Defects Act of 2004 established the South Carolina Birth Defects Program (SCBDP) within the Department of Health and Environmental Control. The Department has been given the legislative mandate to promulgate regulations for public health monitoring of birth defects and to ensure compliance with the public health monitoring of children born in South Carolina. The responsibilities of the various agencies, institutions and persons involved in public health surveillance and monitoring of birth defects are defined. Procedures for public health surveillance and monitoring, use of data, and maintenance of confidentiality are included.

Section B: Definitions

1. "Birth defect" is defined as a structural malformation, deformation, or disruption, present at birth, as determined before or after birth.

2. "Department" means the South Carolina Department of Health and Environmental Control.

3. "Child" is defined as a child up to two years of age.

4. "Identifying Information" is defined as the child's legal name, aliases, birth date, time of birth, place of birth, birth weight, race, ethnicity, parent's or legal guardian's complete name, complete address and telephone number; mother's Social Security number and other information as deemed necessary by Department.

5. "ICD-9-CM diagnostic code categories" is the International Classification of Disease which assigns code numbers to each of the birth defects or any subsequent method of classification as may be adopted from time to time.

6. "Active surveillance system" is the process that is used to identify cases and collect data about children with birth defects. An active surveillance system utilizes case abstractors to conduct on-site visits to medical facilities to abstract information directly from medical records and other sources.

Section C: Public Health Surveillance and Monitoring of Birth Defects

1. The Department shall conduct statewide monitoring of all major structural birth defects using active surveillance methods to ascertain cases. This monitoring may be both prenatal and postnatal (up to two years of age) and shall include live births and fetal deaths occurring in South Carolina. South Carolina Birth Defects Program Nurse Abstractors will conduct active surveillance at all hospitals in South Carolina that provide obstetrical or pediatric care for case identification and abstraction. Hospitals and other medical facilities will provide, upon request, access to medical records containing ICD-9-CM diagnostic code categories in the range of birth defects codes recommended by the Centers for Disease Control (CDC) and the National Birth Defects Prevention Network (NBDPN) for surveillance. The categories of ICD-9-CM codes for birth defects includes, but is not limited to, the following:

a. Central nervous system disorders

b. Eye and ear disorders

c. Cardiovascular disorders

d. Orofacial disorders

e. Gastrointestinal disorders

f. Genitourinary disorders

g. Musculoskeletal disorders

h. Chromosomal disorders

i. Other disorders to include Fetal Alcohol Syndrome and Amniotic bands

j. ICD-9-CM codes regarding known or suspected fetal abnormality affecting management of mother.

2. The birth defects surveillance system will be implemented by phasing in additional birth defect categories until all CDC recommended types of birth defects are monitored.

3. Birth defects case abstraction information will include demographic data on the child, mother and father, if available.

4. The Department shall maintain a central database of all birth defects data gathered from hospitals, specialty clinics and other facilities, regarding births, pregnancies, stillbirths, and pediatric deaths through age two, throughout the state, including border regions.

5. The Department may enter into agreements with other states, health care facilities, and other entities in order to conduct monitoring of birth defects.

6. Monitoring

a. Upon request, the Department shall have access to all records of parent(s), child, and siblings if necessary, for the purpose of identifying birth defects, including vital records, hospital medical records, physician office medical records, specialty clinic records, and discharge data, in order to identify birth defect cases. The Department shall verify the cases through records review and may include review by a physician geneticist.

b. For the purpose of surveillance and identification of birth defects, all laboratories, universities, and other sources of birth defects information shall provide the Department access to all health, medical, or other records, upon request.

c. Access to all records described herein may be granted in hard copy or electronically.

Section D: Data Usage

1. Unless otherwise provided by law, all reports generated by the Department containing birth defects data will be publicly disclosed in aggregate form only. No identifying information will be publicly released by the Department.

2. Birth defect data may be used by the Department, its agents, partners and contractors, to facilitate optimal treatment services for affected children and families.

3. Any entity or person wishing to conduct research using this data must comply with the Department's procedures, including review by the Institutional Review Board (IRB).

4. The Department may negotiate and enter into agreements and contracts with state and federal agencies, other states, universities, genetic centers and other parties, as appropriate, in order to facilitate operation of the program. These agreements and contracts may include the release of identifying data to enable the other entity to offer families assistance for prevention of recurrence of birth defects.

Section E: Referral

1. The Department may contact a family whose child is identified as having a structural birth defect either directly or through the child's health care provider in order to offer services. Family acceptance of referrals is voluntary. Referrals shall be made in accordance with the Department guidelines and recommendations.

2. South Carolina Birth Defects Program nurse abstractors will conduct surveillance activities, to include review of medical records for documentation of physician, social work or discharge planner referral for follow-up of children with birth defects. When there is no documented evidence of follow-up, South Carolina Birth Defects Program staff may access other appropriate health and developmental systems or organizations for referral for early intervention, such as Babynet. Babynet will provide regular feedback, as requested, to South Carolina Birth Defects Program on status of birth defects cases referred.

Section F: Confidentiality

These records will be kept confidential and used and released pursuant to the provisions of S.C. Code Ann. Section 44–44–140 only.

Section G: Severability

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining

portions of this regulation, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

HISTORY: Added by State Register, Volume 32, Issue No. 5, eff May 23, 2005.

61–115. Environmental Electronic Reporting Requirements.

(Statutory Authority: Atomic Energy and Radiation Control Act, S.C. Code Ann. §§ 13–7–10 et seq.; Uniform Electronic Transactions Act, S.C. Code Ann. §§ 26–6–10 et seq.; DHEC Enabling Act, S.C. Code Ann. §§ 44–1–10 et seq.; State Underground Petroleum Environmental Response Bank Act, S.C. Code Ann. §§ 44–2–10 et seq.; Safe Drinking Water Act, S.C. Code Ann. §§ 44–55–10 et seq.; State Recreational Waters Act, S.C. Code Ann. §§ 44–55–50 et seq.; Hazardous Waste Management Act, S.C. Code Ann. §§ 44–56–10 et seq.; Infectious Waste Management Act, S.C. Code Ann. §§ 44–93–10 et seq.; Solid Waste Policy and Management Act, S.C. Code Ann. §§ 44–96–10 et seq.; Pollution Control Act, S.C. Code Ann. §§ 48–1–10 et seq.; Environmental Protection Fund Act, S.C. Code Ann. §§ 48–2–10 et seq.; Pollution Control Facilities, S.C. Code Ann. §§ 48–3–10 et seq.; Water Quality Revolving Fund Authority Act, S.C. Code Ann. §§ 48–5–10 et seq.; Stormwater Management and Sediment Reduction Act, S.C. Code Ann. §§ 48–14–10 et seq.; Erosion and Sediment Reduction Act, S.C. Code Ann. §§ 48–18–10 et seq.; S.C. Mining Act, S.C. Code Ann. §§ 48–20–10 et seq.; Coastal Zone Management Act, S.C. Code Ann. §§ 48–39–10 et seq.; Oil and Gas Exploration, Drilling, Transportation and Production Act, S.C. Code Ann. §§ 48–43–10 et seq.)

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SECTION I. PURPOSE

The purpose of this regulation is to provide the framework by which the South Carolina Department of Health and Environmental Control (Department) will accept, manage, and enforce electronic record submissions from the regulated community. The Department has been authorized to implement these requirements for environmental programs that the United States Environmental Protection Agency (EPA) has delegated, authorized, or approved the Department to administer as referenced in EPA's Cross-Media Electronic Reporting Rule (CROMERR) as published in the October 13, 2005, issue of the Federal Register (70 FR 59848–59889). Additionally, under the Uniform Electronic Transactions Act (UETA) of 2004, S.C. Code Ann. Sections 26–6–10 et seq. the Department is also authorized to include UETA requirements for federally-authorized and state-only programs.

SECTION II. DEFINITIONS

The following words and terms, when used in this section, have the following meanings:

(a) Authorized program—A federal program that the EPA has delegated, authorized, or approved the State of South Carolina to administer, or a program that the EPA has delegated, authorized, or approved the State of South Carolina to administer in lieu of a federal program, under provisions of Title 40 of the Code of Federal Regulations (CFR) and such delegation, authorization, or approval has not been withdrawn or expired.

(b) Copy of record—A true and correct copy of an electronic document received by an electronic document receiving system, which can be viewed in a human-readable format that clearly and accurately associates all of the information provided in the electronic document with descriptions or labeling of the information. A copy of record includes:

(1) all electronic signatures contained in or associated with that document;

(2) the date and time of receipt; and

(3) any other information used to record the meaning of the document or the circumstances of its receipt.

(c) Electronic document—Any information that is submitted in digital form to satisfy requirements of authorized federal or state programs. Information may include data, text, sounds, codes, computer programs, software, or databases.

(d) Electronic document receiving system—A set of apparatus, procedures, software, or records used to receive electronic documents.

(e) Electronic signature—Any information in digital form that is included in, or associated with, an electronic document for the purpose of expressing the same meaning and intention as would a handwritten signature if affixed to an equivalent paper document with the same reference to the same content.

(f) Electronic signature agreement—An agreement drafted by the Department and signed by an individual with respect to an electronic signature device that the individual will use to create his or her electronic signature. The agreement will require such individual to protect the electronic signature device from compromise; to promptly report to the agency or agencies relying on the electronic signatures created any evidence discovered that the device has been compromised; and to be held as legally bound, obligated, or responsible by the electronic signature created as by a handwritten signature.

(g) Electronic signature device—A code or other mechanism that is used to create electronic signatures.

(h) Federal program—Any program administered by the EPA under any provision of 40 Code of Federal Regulations and delegated to the State of South Carolina by the EPA.

(i) Handwritten signature—The scripted name or legal mark of an individual, made by that individual with a marking or writing instrument such as a pen or stylus and executed or adopted with the present intention to authenticate writing in a permanent form.

(j) Person—An individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, governmental agency, public corporation, or other legal or commercial entity.

(k) Signatory—An individual authorized to and who signs a document using a format acceptable to the Department.

(*l*) State program—Any program that is established by state legislation and implemented by the Department under state law, including but not limited to: The Atomic Energy and Radiation Control Act, S.C. Code Ann. Sections 13–7–10 et seq.; Uniform Electronic Transactions Act, S.C. Code Ann. Sections 26–6–10 et seq.; DHEC Enabling Act, S.C. Code Ann. Sections 44–1–10 et seq.; State Underground Petroleum Environmental Response Bank Act, S.C. Code Ann. Sections 44–2–10 et seq.; Safe Drinking Water Act, S.C. Code Ann. Sections 44–55–10 et seq.; State Recreational Waters Act, S.C. Code Ann. Sections 44–55–50 et seq.; Hazardous Waste Management Act, S.C. Code Ann. Sections 44–56–10 et seq.; Infectious Waste Management Act, S.C. Code Ann. Sections 44–93–10 et seq.; Solid Waste Policy and Management Act, S.C. Code Ann. Sections 44–96–10 et seq.; Pollution Control Act, S.C. Code Ann. Sections 48–1–10 et seq.; Environmental Protection Fund Act, S.C. Code Ann. Sections 48–2–10 et seq.; Pollution Control Facilities, S.C. Code Ann. Sections 48–3–10 et seq.; Water Quality Revolving Fund Authority Act, S.C. Code Ann. Sections 48–5–10 et seq.; Stormwater Management and Sediment Reduction Act, S.C. Code Ann. Sections 48–14–10 et seq.; Erosion and Sediment Reduction Act, S.C. Code Ann. Sections 48–18–10 et seq.; S.C. Mining Act, S.C. Code Ann. Sections 48–20–10 et seq.; Coastal Zone Management Act, S.C. Code Ann. Sections 48–39–10 et seq.; Oil and Gas Exploration, Drilling, Transportation and Production Act, S.C. Code Ann. Sections 48–43–10 et seq.

SECTION III. APPLICABILITY

(a) This section applies to:

(1) persons and signatories who submit official, final electronic documents to the Department to satisfy requirements of:

(A) authorized programs for which the Department has announced it is accepting specified electronic documents; or

(B) state programs for which the Department has announced it is accepting specified electronic documents;

(2) the Department's electronic document receiving system and other software applications implemented, revised, or modified as announced by the Department; and

(3) authorized programs and state programs for which the Department has announced it is accepting specified electronic documents.

(b) This section does not apply to:

(1) documents submitted via facsimile; or

(2) electronic documents submitted via magnetic or optical media such as diskette, compact disc, digital video disc, or tape; or

(3) state programs specifically listed in Section 26–6–30 of the South Carolina Code of Laws Annotated, Chapter 6, Uniform Electronic Transactions Act.

SECTION IV. USE OF ELECTRONIC DOCUMENT RECEIVING SYSTEM

(a) When the Department has announced that it is accepting specified electronic documents, persons who submit electronic documents to the Department to satisfy requirements of a federal or state program must use the electronic document receiving system and associated procedures designated by the Department.

(b) Persons desiring to use an electronic signature device must execute an electronic signature agreement with handwritten wet ink signature or by using an electronic identity verification system utilized by the Department.

(c) An electronic signature device is compromised if the code or mechanism is available for use by any other individual.

(d) An electronic document must bear the valid electronic signature of a signatory if that signatory is required under the federal or state program to sign the paper document for which the electronic document substitutes.

(e) An electronic signature on an electronic document is valid if it has been created with an electronic signature device that the identified signatory is uniquely entitled to use for signing that document; the device has not been compromised; and the signatory is an individual who is authorized to sign the document by virtue of his or her legal status and/or his or her relationship to the entity on whose behalf the signature is executed.

(f) The presence of an electronic signature on an electronic document submitted to the Department establishes that the signatory intended to sign the electronic document and submit it to the Department to fulfill the purpose of the electronic document.

SECTION V. RESPONSIBILITIES OF AN AUTHORIZED ELECTRONIC SIGNATORY

(a) When the electronic signature device is used to create an individual's electronic signature, the signatory must ensure that the code or mechanism is unique to that individual at the time the signature is created, and the signatory must be uniquely entitled to use it. Approved signatories shall:

(1) protect the electronic signature device from compromise;

(2) report to the Department any evidence that the device has been compromised, within one business day of the discovery; and,

(3) prohibit any other individual from using the electronic signature device unique to his or her signature.

SECTION VI. ENFORCEMENT

(a) An electronic signature on an electronic document submitted to the Department is the legal equivalent of a handwritten signature on a paper document submitted to the Department.

(b) Persons and signatories are subject to penalties and other remedies under Department rules or applicable statutes for failure to comply with a reporting requirement of the Department if the person or signatory reports electronically and fails to comply with the applicable provisions of this chapter, applicable statutes, Department regulations, and the electronic participation agreement.

(c) Nothing in this chapter limits the use of an electronic document, copy of record, or information derived from electronic documents as evidence in enforcement proceedings.

(d) The Department may, without advance warning, terminate use of electronic document receiving systems for individuals if, in the Department's sole determination, the use of the electronic document receiving system is performed in a manner contrary to applicable rules and regulations.

SECTION VII. SEVERABILITY

In the event that any portion of this regulation is construed by a court of competent jurisdiction to be invalid or otherwise unenforceable, such determination shall in no manner affect the remaining portions of this regulation, which, in such case, shall remain in effect as if such invalid portions were not originally a part of this regulation.

HISTORY: Added by State Register Volume 32, Issue No. 5, eff May 23, 2008.

61–116. South Carolina Trauma Care Systems.

(Statutory Authority: S.C. Code Sections 44–61–510 et seq.)

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SECTION 100—DEFINITIONS

A. Bypass. A medical protocol or request for the transport of an EMS patient past a normally used EMS receiving facility to an alternate medical facility for the purpose of accessing more readily available or appropriate medical care.

B. Certificate. A document issued by the Department to a hospital that denotes the trauma designation level thereof, as determined by the Department subject to the provisions of this regulation.

C. Certificate Holder. The hospital that has received a certificate to provide trauma care from the Department and with whom rests the ultimate responsibility for compliance with this regulation.

D. Department. The South Carolina Department of Health and Environmental Control (DHEC).

E. Designation. The formal determination by the Department that a hospital is capable of providing a specified level of trauma care services.

F. Emergency Department. The area of a licensed general acute care hospital that customarily receives patients in need of emergency medical evaluation and/or care.

G. Emergency Medical Services (EMS). The treatment and transport of patients in crisis health situations, occurring from a medical emergency or from an accident, natural disaster, or similar situation, that may be life threatening, through a system of coordinated response and emergency medical care.

H. Emergency Medical Services Advisory Council. Emergency Medical Services council created pursuant to S.C. Code Section 44–61–30(C).

I. Facility. A trauma center having a certificate of designation by the Department.

J. Field Triage. Classification of patients according to medical need at the scene of an injury or onset of an illness.

K. Glasgow Coma Scale. A standardized system for assessing response to stimuli in a neurologically impaired patient by assessing eye opening, verbal responsiveness, and motor ability.

L. Hospital. A facility licensed by the Department and organized and administered to provide medical or surgical care or nursing care of illness, injury, or infirmity and in which all diagnoses, treatment, or care is administered by or under the direction of persons currently licensed to practice medicine, surgery, or osteopathy.

M. Injury. The result of an act that damages, harms, or hurts; unintentional or intentional damage to the body resulting from acute exposure to thermal, mechanical, electrical or chemical energy or from the absence of such essentials as heat or oxygen.

N. Injury Prevention. Efforts to reduce or prevent incidents that might result in injuries.

O. Level I. Hospitals that have met the requirements for Level I as stated in Section 204 of this regulation and are designated by the Department.

P. Level I Pediatric. Hospitals that have met the Level I criteria along with the required pediatric criteria, and are designated as "Level I Pediatric" by the Department.

Q. Level II. Hospitals that have met the requirements for Level II as stated in Section 204 of this regulation and are designated by the Department.

R. Level II Pediatric. Hospitals that have met the Level II criteria along with the required pediatric criteria, and are designated as "Level II Pediatric" by the Department.

S. Level III. Hospitals that have met the requirements for Level III as stated in Section 204 of this regulation and are designated as "Level III" by the Department.

T. Level IV. Hospitals that have met the requirements for Level IV and are designated as "Level IV" by the Department.

U. Licensed Nurse. An individual licensed by the South Carolina Board of Nursing as a registered nurse or licensed practical nurse.

V. Medical Control. On-line or off-line physician direction over pre-hospital activities to ensure efficient and proficient trauma triage, transportation, and care, as well as ongoing quality assurance.

W. Participating Providers. Those providers who have been approved by the Department for participation in the trauma system and include, but are not limited to, designated trauma centers, designated rehabilitation facilities, and designated fee-for-service physicians who provide trauma care within a designated facility.

X. Performance Improvement (PI) Programs. A method of monitoring, evaluating and improving processes of patient care that emphasizes a multidisciplinary approach to problem solving. These activities are concordant with the Institute of Medicines six (6) quality aims for patient care: safe, effective, patient-centered, timely, efficient, and equitable. (ACS P.114).

Y. Physician. An individual currently licensed as such by the South Carolina Board of Medical Examiners.

Z. Rehabilitation. Services that seek to return a trauma patient to the fullest physical, psychological, social, vocational, and educational level of functioning of which he or she is capable, consistent with physiological or anatomical impairments and environmental limitations.

AA. Repeat Violation. The recurrence of any violation cited under the same section of the regulation.

BB. Revocation of Certificate and Designation. An action by the Department to cancel or annul a certificate and designation by recalling, withdrawing, or rescinding its authority to operate.

CC. South Carolina Trauma Plan. An organized plan developed by the Department pursuant to legislative directive that sets out a comprehensive system of prevention, management, and rehabilitation of traumatic injuries.

DD. State Medical Director (or "State Medical Control Physician"). A South Carolina board-certified physician responsible for providing medical oversight to the Department.

EE. State Trauma Advisory Council (or "TAC"). The Department's advisory committee regarding trauma related issues.

FF. State Trauma Registry. A statewide database of information collected by the Department including, but not limited to, the incidence, severity, and causes of trauma and the care and outcomes.

GG. Suspension of Certificate and Designation. An action by the Department terminating the certificate holder's authority to provide trauma care services for a period of time until such time as the Department rescinds that restriction.

HH. Traumatic Injury. Injury or wound to a person caused by the application of an external force or by violence and requiring medical or surgical intervention to prevent death or disability. For the purposes of this regulation, the definition of "trauma" shall be determined by current national medical standards including, but not limited to, injury severity scales.

II. Trauma Care Facility (or "trauma center"). A hospital designated by the Department to provide trauma care services at a particular level.

JJ. Trauma Care Region. A geographic area of the state formally organized in accordance with standards promulgated by the Department and is coterminous with the Department EMS regions.

KK. Trauma Care System. An organized statewide and regional system of care for the trauma patient, including the Department, emergency medical service providers, hospitals, in-patient rehabilitation providers, and other providers who have agreed to participate in and coordinate with and who have been accepted by the Department in an organized statewide system.

LL. Trauma Patient. A patient who presents with acute bodily injuries secondary to an external force requiring immediate intervention deemed necessary to preserve life and limb.

MM. Trauma Program. An administrative unit that includes the trauma service and coordinates other trauma-related activities, including, but not limited to, injury prevention and public education.

NN. Trauma Program Manager. A designated individual with responsibility for coordination of all activities of the trauma program who works in collaboration with the trauma medical director.

OO. Trauma Medical Director. A physician designated by the facility and medical staff to coordinate trauma care.

PP. Trauma System Fund. The separate fund established pursuant to this regulation for the Department to create and administer the State Trauma System.

QQ. Trauma Team. A group of health care professionals organized to provide coordinated and timely care to the trauma patient.

RR. Triage. The process of sorting injured patients on the basis of the actual or perceived degree of injury and assigning them to the most effective and efficient regional care resources in order to insure optimal care and the best chance of survival.

SS. Verification. The inspection of a participating facility in order to determine whether the facility is capable of providing a designated level of trauma care.

SECTION 200—DESIGNATION PROCESS

201. Eligibility for Designation (II)

A. Any South Carolina licensed hospital with a functioning emergency service may apply for trauma center designation.

B. Any South Carolina licensed hospital applying for initial designation or renewal designation after July 1, 2018, shall obtain an American College of Surgeons (ACS) verification.

202. Application Process

A. A facility seeking designation shall submit to the Department a completed application and Pre-Review Questionnaire (PRQ). The application shall include the applicant's oath assuring that the contents of the application and PRQ are accurate and true and that the applicant will comply with this regulation. The application shall be authenticated as follows:

1. The application shall be signed by the owner(s) if an individual or partnership;

2. If the applicant is a corporation, the application shall be signed by two (2) of its officers;

3. If the applicant is a governmental unit, the application shall be signed by the head of the governmental unit having jurisdiction.

B. The application shall set forth the full name and address of the facility for which the designation is sought, the name and address of the owner of the facility in the event that his or her address is different from that of the facility, and a list of essential program personnel. In the event of a change in the owner of the facility and/or essential program personnel, the Department shall be notified in writing within forty-eight (48) hours of the change.

C. The Department may require additional information evidencing the applicant's ability to comply with this regulation. Corporations or partnerships shall be registered with the South Carolina Office of the Secretary of State. Other required information may also include, but is not limited to, written affirmation of compliance with all applicable federal Occupational Safety and Health Association (OSHA) requirements or guidelines.

D. The application shall be property of the Department and shall be considered public information at the end of the designation process, subject to state and federal laws. The PRQ shall be confidential in accordance with S.C. Code Section 44–61–520.

E. All applicants prior to July 1, 2018, shall select either a state or ACS site visit. All applicants after July 1, 2018, shall undergo a site visit by an ACS team accompanied by a Department representative.

203. Designation Renewal

A. Prior to July 1, 2018, unless directed otherwise by the Department, all designations shall be renewed every five (5) years by application in accordance with Section 202.

B. After July 1, 2018, the trauma center shall renew their designation requirements at timeframes as required by the ACS and in accordance with Section 202.

C. Any facility designated prior to July 1, 2018, shall be designated for a period of five (5) years.

204. Categories of Designation

A. The designations available are the adult and pediatric designations listed in Chapter 2 of the 2014 ACS "Resources for Optimal Care of the Injured Patient."

B. Until July 1, 2018, a trauma center may be granted full designation or provisional designation. Designation levels are granted based on the factors prescribed in the 2014 ACS "Resources for Optimal Care of the Injured Patient."

C. Prior to July 1, 2018, applicants may obtain provisional designation at any of the levels prescribed in Section 204.A. To receive provisional designation status, a hospital shall have no more than one (1) Type I deficiency and/or no more than five (5) Type II deficiencies.

1. Provisional designation may be granted for a period not to exceed one (1) year except as granted by the Department. The Trauma Advisory Council shall provide oversight during the provisional period.

2. Provisional trauma centers shall have a written work plan of objectives to rectify deficiencies and to demonstrate progress on the work plan throughout the one (1) year designation period.

3. At the end of the provisional designation period, the Department may grant full designation, extend the provisional period, or suspend the trauma center for cause.

D. A hospital may submit an Application for Request of a Waiver prior to the state site visit.

205. Designation

The designation processes delineated herein are the same regardless of designation level sought, including pediatric.

A. Prior to July 1, 2018, after receipt and acceptance of the application, the Department shall provide a Pre-Review Questionnaire (PRQ) to the hospital seeking designation which shall be completed and returned to the Department in accordance with Section 205.C. The information in the PRQ shall be reviewed by the Department and team prior to the site visit, and the information provided in the PRQ by the hospital shall be verified by the site review team. Any misrepresentation and/or false information provided by the hospital in the PRQ is grounds for denial of designation.

B. After July 1, 2018, any new hospital that wishes to become a trauma center, and any existing trauma center wishing to renew its designation, shall be required to provide to the Department an American College of Surgeons (ACS) verification notice. The hospital shall notify the Department prior to the associated ACS visit. A Department representative shall conduct a state verification simultaneously.

C. The PRQ shall be submitted no later than thirty (30) days prior to the scheduled site visit.

206. Site Review

A. The Department will work with the hospital requesting designation to establish a date for a designation site visit. All costs associated with the site visit and team expenses, excluding costs associated with Department personnel, are the responsibility of the applicant.

B. The onsite review for designation shall be conducted by the review team verifying the requirements for designation.

C. Any facility wishing to become a trauma center, or remain a trauma center after July 1, 2018, shall undergo the ACS verification process. Centers current as of July 1, 2018, shall obtain ACS verification prior to the expiration of their state designation. No extensions shall be granted for failure to schedule appropriately.

207. Review Team Composition

A. The review team shall include, but not be limited to:

1. Two (2) general surgeons (at least one (1) pediatric surgeon for pediatric facilities), who do not live or work in the same state as the applicant and who currently work in a designated trauma center and who are a FACS or member of the ACS; and

2. A Department representative.

3. Prior to July 1, 2018, additional members may be assigned at the discretion of the Department or request of the facility. Any additional cost(s), with the exception of costs for Department representative(s), shall be the responsibility of the facility.

B. The composition of site visit teams, if required for follow up on facilities with provisional designation, shall be determined by the Department with consideration of recommendations made by the TAC.

C. There shall be no demonstrable conflict of interest between any inspection team member and the hospital for which the team member has been selected. The hospital applying for designation shall be provided with the reviewer's information. The hospital shall notify the Department in writing within three (3) business days of any conflict or if they wish to reject a reviewer. After 5:00 p.m. on the third (3rd) day, the team shall be secured and no objections may be submitted.

D. The cost of the team shall be the responsibility of the applying facility and includes meals, lodging, transportation, and honorarium.

E. Prior to July 1, 2018, hospitals applying for designation may, at its own discretion and its own expense, request a verification site inspection by representatives of the American College of Surgeons or any other national organization having standards that are, at a minimum, equal to the criteria set forth in this regulation. The composition of the site visit team, if other than the state, shall be subject to the discretion of the entity utilized. If a hospital wishes to use an outside agency and intends to submit their recommendation to the state for designation, a Department representative shall be present for the entire visit. The Department may accept the findings of the verification site visit or may request additional information as necessary to ensure that the hospital meets the criteria set forth in this regulation.

208. Protocol for Inspections

The applicant's administration, faculty, medical staff, employees and representatives shall not have any contact with any onsite review team member in regards to the designation process after the announcement of the team members and prior to the onsite review, except as authorized by the Department. A violation of this provision may be grounds for denying the applicant's proposal as determined by the Department. If a review team member contacts the facility representative directly for information, the facility may respond as requested and shall notify the Department.

209. Content of Inspection

The onsite review team shall evaluate the appropriateness and capabilities of the applicant to provide trauma care services and validate the hospital's ability to meet the responsibilities, equipment, and performance standards for the level of designation sought and to meet the overall needs of the trauma system in that region. Any evidence of inadequate performance or trauma patient care shall be presented to the TAC and this alone is grounds for denial of designation or re-designation.

210. Designation Criteria

A. The Department shall use the designation criteria of the 2014 ACS "Resources for Optimal Care of the Injured Patient" for each trauma center level. These provisions apply to all designation levels, including pediatric.

B. As part of the designation process and site review, the review team shall perform a comprehensive chart review. At least ten (10) charts shall be reviewed by the site review team. All site team members shall review charts.

C. The charts reviewed by the review team shall be in accordance with the latest ACS Review Agenda.

211. Designation Process

A. Prior to completion of the site visit, the team shall meet and develop a draft report and provide feedback to the facility. The format shall be the same as the official written report.

B. On completion of the site visit, the team shall have ninety (90) days to submit a written report of their recommendation to the Department. The report shall include deficiencies listed by criteria number, opportunities (shall not be counted as deficiencies and shall not be used in consideration of designation status), strengths, and recommendations.

C. Within thirty (30) days of receipt of the written report from the site review team, the report shall be forwarded to the TAC, or appropriate subcommittee, to review for the purpose of providing the Department a recommendation. The final report shall also be forward to the facility at the same time. The report shall be sent to the hospital Trauma Program Manager, Trauma Medical Director, and Administrator as identified on the application.

D. As soon as practical, but no later than ninety (90) days after receipt of the onsite report document, the TAC, or subcommittee of the TAC, shall make written recommendations to the Department regarding trauma center designation based on:

1. Evaluation of the pre-review questionnaire;

2. Evaluation of deficiencies, including deficiencies in trauma patient care, and supporting statements from the onsite review team; and

3. The ability of each hospital to demonstrate compliance with the designation criteria at the level of designation they are seeking.

E. The Department shall make the final determination of designation regarding each application and shall consider all pertinent facts, the final survey report, and the recommendation of the TAC.

F. After July 1, 2018, a hospital requesting designation shall submit to the Department a letter of verification from the American College of Surgeons. Any hospital not obtaining ACS verification shall be denied South Carolina designation. Hospitals denied designation or whose designation was suspended or revoked shall wait a period of no less than six (6) months after the written decision prior to resubmitting an application. However, there is no waiting period if the hospital seeks a designation level lower than the denied, suspended, or revoked designation.

G. With the recommendation of the State Trauma Advisory Council, the Department shall notify the hospital of its decision regarding designation at the level requested by the hospital.

H. Prior to July 1, 2018, trauma centers requesting an ACS consultation or verification visit shall include a Department representative to participate in the site visit, as written in this regulation. The Department may utilize the visit and final report to designate the trauma center based on these regulations for state designation.

212. Process of Re-designation

A. Scheduled re-designation inspections of currently designated trauma centers shall occur in an interval no greater than five (5) years. After July 1, 2018, the designation interval shall coincide with the ACS verification cycle and shall not exceed three (3) years.

B. Designated trauma centers shall be notified by the Department within six (6) months of the trauma center's scheduled date for the submission of the application for re-designation.

C. The hospital shall follow the application procedure outlined in Section 202.

D. All hospitals requesting re-designation shall follow the designation procedures outlined in Section 211.

E. If a change in the designated trauma center's staffing or resource capabilities occurs at any time during the trauma center's designation period, an inspection may be conducted by the Department as needed to ensure compliance with the regulatory requirements. If such inspection reveals that the trauma center may not be meeting regulatory requirements, the Department may require that the trauma center undergo a complete trauma center re-designation verification inspection prior to the next scheduled re-designation date.

213. Change in Trauma Center Designation Status

A. A designated trauma center shall have the right to withdraw as a trauma center or to request a designation lower than its current designation level by giving a ninety (90) day written notice to the Department.

B. A designated trauma center shall: (II)

1. Notify the Department within ten (10) calendar days if it is unable to provide the level of care or services for its level of designation, the reasons, and plans to correct;

2. Notify the Department if it chooses to no longer provide trauma services commensurate with its designation level.

C. If the trauma center chooses to apply for a lower level of designation, they shall follow the procedures listed in the application and designation process in accordance with this regulation, and may have an onsite visit upon recommendation by the TAC.

214. Public Notification of Trauma Center Designation Status

A. At the time of designation, revocation of designation, or of any change in the status of a hospital's designation as a trauma center, the Department shall report such changes to the public by means of public record within thirty (30) days of the change of said hospital's trauma center designation status. The Department shall also notify licensed emergency medical service providers of the change of trauma center designation status.

B. The Department, Trauma Advisory Council, and the members of the onsite inspection team shall maintain confidentiality of information, records, and reports developed pursuant to onsite reviews as permitted by state and federal laws.

SECTION 300—CERTIFICATE OF DESIGNATION REQUIREMENTS

301. Certification Requirements (II)

A. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or market itself or represent itself as a trauma center or use similar terminology, for example, "trauma hospital" or "trauma facility," in South Carolina without first obtaining a certificate of designation from the Department. When it has been determined by the Department that an entity claims, advertises, or represents itself as a trauma center and is not designated by the Department, the entity shall be ordered by the Department to cease operation immediately. False representation as a trauma center may result in monetary penalties as determined by the Department.

B. A certificate of designation shall not be issued to an entity until the owner and/or operator of that entity has demonstrated to the Department that the facility is in substantial compliance with these standards through the designation process.

C. No provider that has been issued a certificate for a trauma center at a specific address shall relocate or establish a new trauma center without first obtaining authorization from the Department.

D. No trauma center shall, in any manner, advertise or publicly assert that its trauma designation affects the hospital's care for non-trauma patients or that the designation would influence the referral of non-trauma system patients.

302. Issuance and Terms of the Certificate of Designation (II)

A. A certificate shall be issued by the Department and shall be displayed in a conspicuous place in a public area in the trauma center.

B. The issuance of a certificate does not guarantee adequacy of individual care, treatment, procedures, and/or services, personal safety, fire safety or the well-being of any patient.

C. A certificate is not assignable or transferable and is subject to revocation at any time by the Department for the provider's failure to comply with the laws and regulations of this State.

D. A certificate shall be effective for a specific trauma center, at a specific physical location, for a period of up to five (5) years following the date of issue. A certificate shall remain in effect until the Department notifies the certificate holder of a change in that status or until the expiration of such certificate. Certificates issued after July 1, 2018, shall expire on the date of expiration of the ACS verification.

303. Exceptions to the Standards

The Department has the authority to make exceptions to these standards when it is determined that the health, safety, and well-being of the patients will not be compromised and provided such standard is not specifically required by statute.

SECTION 400—ENFORCEMENT OF REGULATIONS

401. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a hospital trauma center in order to enforce this regulation. Such areas of review may include, but not be limited to, trauma patient records, hospital trauma registry data, trauma process improvement plans, educational records, committee minutes, and physical facilities.

402. Inspections and Investigations

A. An onsite inspection shall be conducted prior to designation of a hospital trauma center in accordance with Sections 207 and 208. Subsequent inspections may be conducted as deemed appropriate by the Department.

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted unobstructed access to all properties and areas, objects, and records. If photocopies are made for the Department, they shall be used only for purposes of enforcement of regulations and/or ensuring compliance with designation criteria, and confidentiality shall be maintained as permitted by state and federal laws. The physical area of inspections shall be determined by the extent to which there is potential impact or effect upon patients as determined by the Department.

D. A facility found noncompliant with this regulation shall submit a written plan of correction to the Department, signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe:

1. The actions to correct each cited deficiency;
2. The proposed actions to prevent similar recurrences; and
3. The actual or expected completion dates of those actions.

E. Information received by the Department through filed reports, inspections, or as otherwise authorized under this regulation shall not be disclosed publicly in such a manner as to identify hospitals or other participating providers except in proceedings involving the denial, change, or revocation of a trauma center designation or type.

F. The Department, members of the onsite inspection team, and the TAC shall maintain confidentiality of information, records, and reports developed pursuant to onsite reviews as permitted by state and federal laws.

403. Investigation Procedures

A. Any person or entity may communicate a complaint or knowledge of an incident of any alleged violation of these regulations to the Department. Complaints shall be submitted in written form to the Department. The Department may begin an investigation without a written complaint if there is sufficient cause.

B. All designated trauma centers and EMS providers are subject to investigation at any time without prior notice by individuals authorized by the Department.

C. An authorized representative of the Department, upon presentation of valid identification, shall be permitted to examine equipment, vehicles, physical plant, and records. Any other requests shall be complied with so long as it is pertinent to the care of trauma patients and consistent with the requirements within the applicable regulations.

D. At the conclusion of the Department's investigation, the Department shall report its findings to the trauma center in writing, including any requirements for corrective action.

SECTION 500—ENFORCEMENT ACTIONS

501. General

A. When the Department determines that a designated trauma center is in violation of any statutory provision, rule, or regulation relating to the duties therein, the Department may, upon proper notice to that entity, impose a monetary penalty and/or deny, suspend, and/or revoke its certificate of designation. This includes failure to comply with designation criteria and/or failing to comply with previously approved corrective plans.

B. The Department may impose monetary penalties on any licensed emergency medical service provider found noncompliant with this or other related statute or regulations.

502. Violation Classifications

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of any persons or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of this time may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety or well-being of persons in the facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations. The citation of a Class III violation may specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. In arriving at a decision to take enforcement action, the Department will consider the following factors:

1. The number and classification of violations, including repeat violations;

2. The specific conditions and their impact or potential impact on health, safety or well-being of the patients;

3. The efforts by the facility to correct cited violations;

4. The overall conditions of the facility;

5. The failure or refusal to comply with the provisions or requirements of this regulation;

6. The misrepresentation of a material fact about facility capabilities or other pertinent circumstances in any record or in a matter under investigation for any purposes connected with this chapter;

7. The prevention, interference with, or any attempts to impede the work of a representative of the Department in implementing or enforcing these regulations or the statute;

8. The use of false, fraudulent, or misleading advertising, or any public claims regarding the hospital's ability to care for non-trauma patients based on its trauma center designation status;

9. The misrepresentation of the facility's ability to care for trauma patients based on its designation status;

10. The failure to provide data to the Trauma Registry;

11. Any other pertinent conditions that may be applicable to statutes and regulations.

E. When a decision is made to impose monetary penalties, the Department may utilize the following schedule as a guide to determine the dollar amount:

Frequency of violation of standard within a thirty-six (36) month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1st	$500–1500	$300–800	$100–300
2nd	1000–3000	500–1500	300–800
3rd	2000–5000	1000–3000	500–1500
4th	5000	2000–5000	1000–3000
5th	7500	5000	2000–5000
6th and more	10000	7500	5000

SECTION 600—STAFFING (I)

A. Trauma centers shall have adequate staff, to include physicians, a Trauma Program Manager, Registrar, and other staff necessary to meet criteria for designation as outlined in the 2014 edition of "Resources for Optimal Care of the Injured Patient," by the American College of Surgeons.

B. Detailed components of support services and medical, nursing, and ancillary staffing for each level shall, at a minimum, meet the criteria for the applicable designation as outlined in the 2014 edition of "Resources for Optimal Care of the Injured Patient," by the American College of Surgeons.

SECTION 700—FACILITY, EQUIPMENT, AND CARE REQUIREMENTS

701. Physical Facilities (II)

Environment, equipment, supplies, and procedures utilized in the care of trauma patients shall meet the criteria outlined in the 2014 edition of "Resources for Optimal Care of the Injured Patient," by the American College of Surgeons unless required otherwise by these regulations.

702. Trauma Care of the Patient (Transfers) (II)

Trauma patients arriving at non-designated trauma centers shall be transferred to the appropriate level of trauma center. Patients arriving at a designated trauma center and having care needs exceeding the capabilities of that center shall be transferred to a higher level of care. Each hospital providing trauma care services shall establish and implement a written plan that outlines the process, providers, and methods of providing risk-appropriate stabilization and transfer of any patient requiring specialized services as well as reciprocal transfer of those patients when specialized services are no longer required. These plans shall be developed in collaboration with the receiving trauma centers and may include specific crew configuration for transport. The plan shall outline the following:

A. Communication between referring hospitals (must be physician to physician), transport teams, medical control, patients, and families;

B. Indications for both acute phase and reciprocal transfer between trauma centers, to include essential contact persons and telephone numbers for referrals and transfers; and

C. A list of all medical record copies and additional materials to accompany each patient in transport.

703. Trauma Care Services (I)

A. Each trauma care facility shall provide adequate staffing and equipment to meet criteria established by the Department, guided by the recommendations outlined in the 2014 edition of "Resources for Optimal Care of the Injured Patient," by the American College of Surgeons.

B. No person, regardless of his ability to pay or location of residence, may be denied trauma care if a member of the admitting hospital's medical staff or, in the case of a transfer, a member of the accepting hospital's staff determines that the person is in need of trauma care services.

C. If the care required for any patient is not available at the facility, arrangements shall be made for transfer to a more appropriate facility. Prior to the transfer of a patient to another facility, the receiving trauma center shall be notified of the impending transfer.

SECTION 800—TRAUMA TRIAGE AND TRANSPORT GUIDELINES (I)

801. Purpose

The Department, with the advice of the Trauma Advisory Council, shall establish Trauma Triage and Transport Guidelines to improve the quality of trauma care being provided to patients by ensuring that EMS providers transport patients to the appropriate level of trauma care. Such guidelines shall be established using the 2011 version of the Center for Disease Control's "Guidelines for Field Triage of Injured Patients."

802. Required Participation.

All licensed Emergency Medical Services (EMS) providers shall, at a minimum, use the Department's trauma triage and transport guidelines that shall be based on the guidelines established by the 2011 version of the Center for Disease Control's "Guidelines for Field Triage of Injured Patients." The EMS providers may edit the guidelines to identify the local trauma centers, but must use the Department-approved policy otherwise.

803. Required Transport

Emergency medical service personnel shall transport a trauma patient directly to a trauma center that is qualified to provide appropriate care, unless one (1) or more of the following exceptions apply:

A. It is medically necessary to transport the patient to another hospital for initial assessment and stabilization before transfer to a trauma center;

B. It is unsafe or medically inappropriate to transport the patient directly to a trauma center due to adverse weather or ground conditions;

C. Transporting the patient to a trauma center would cause a shortage of local emergency medical service resources (defined as no resources available for longer than thirty (30) minutes in a reasonable response area) and air transport is unavailable;

D. No appropriate trauma center is able to receive and provide trauma care to the trauma patient without undue delay; or

E. Before transport of a patient begins, the patient requests to be taken to a particular hospital that is not a trauma center or, if the patient is less than eighteen (18) years of age or is not able to communicate, such a request is made by an adult member of the patient's family or a legal representative of the patient.

804. Triage Tag System

All 911 EMS providers shall utilize a universal triage tag recommended by the Department. Such a tag shall have a barcode to scan for patient tracking and shall have the ability to show only one (1) color of triage category at any given time. The initial supply of these tags shall be provided by the Department and requests shall be granted on a first come first served basis. It shall be the responsibility of each agency to replenish their supply as necessary. Any other emergency response agencies, such as law enforcement, fire, and private EMS, may also request issuance of such tags to participate in the system and ensure consistency.

SECTION 900—PATIENT RIGHTS (III)

901. General

The facility shall comply with all relevant federal, state, and local laws and regulations concerning discrimination, for example, Title VII, Section 601 of the Civil Rights Act of 1964.

902. Grievances and Complaints

A. The facility shall establish a written grievance and complaint procedure and make this procedure available to patients upon request.

B. Upon receipt of a complaint by the Department, the Department shall:

1. Notify the hospital of the complaint;

2. Initiate a review of the complaint which may consist of an onsite review by the Department;

3. Develop a written report of the review; and

4. Notify the hospital of the results and provide a copy of the final report.

SECTION 1000—STATEWIDE TRAUMA REGISTRY (II)

1001. Purpose of Trauma Registry

A. The Department shall establish a trauma data collection and evaluation system, known as the "Trauma Registry." The Trauma Registry shall be designed to include, but not be limited to, trauma studies, patient care and outcomes, compliance with standards of verification, and types and severity of injuries in the state. The data elements collected in the state registry shall be determined by the Department with collaboration from the TAC and defined in the data dictionary.

B. The Department may collect, as considered necessary and appropriate, data and information regarding trauma patients admitted to a facility through the emergency service, through a trauma center, or directly to a special care unit. Data and information shall be collected in a manner that protects and maintains the confidential nature of patient and staff identifying information.

C. Any South Carolina hospital may participate in submitting to the Trauma Registry.

D. The Department shall establish and maintain a current data dictionary and provide it to all trauma centers to define required data points.

1002. Requirement to Submit Data

A. Each designated trauma center shall participate in the System Trauma Registry by:

1. Identifying a person to be responsible for coordination of trauma registry activities;

2. Participating in and submitting data to the National Trauma Data Bank (NTDB); and

3. Downloading required trauma data as stipulated by the Department in the state data dictionary. Each trauma center designated by the Department shall provide data to the Department at least quarterly as listed below. The trauma center shall provide the data to the Department no later than ninety (90) days following the end of each quarter. The trauma center shall establish measures to ensure that the data entered in the trauma registry is accurate and complete.

Admission Period	Due Date
January - March	July 1
April - June	October 1
July - September	January 1
October - December	April 1

B. Only patient care records that are included in the hospital's trauma registry may be requested for review by site inspection teams at the time of initial designation and re-designation or by the Department for focused reviews during any time of the hospital's designation period.

1003. Inclusion and Exclusion Criteria

Patient inclusion and exclusion criteria shall be established by the Department under the guidance of the Trauma Advisory Council and maintained in the state data dictionary. Such data shall include, at a minimum, the information and data points required by the National Trauma Data Bank.

1004. Confidentiality Protection of Data and Reports

Information that identifies individual patients shall not be disclosed publicly without the patient's consent. Reports that do not contain protected health information or any identifiable information may be generated and distributed. Such reports shall show only general information and shall not identify any protected information or hospital information.

SECTION 1100—HOSPITAL RESOURCES DATA BASE (II)

1101. Purpose

A. The Hospital Resources Data Base shall be used to monitor hospital resources on a continuous basis, disseminate information throughout South Carolina's healthcare system, and inform users of the clinical services offered, laboratory capabilities, and bed capacity.

B. The Department shall manage the Hospital Resources Data Base for South Carolina participants.

1102. Required Participation

All trauma centers designated by the Department shall utilize the Hospital Resources Data Base. Information shall be updated on a daily basis, which shall include, but not be limited to: hospital bed availability, specialty service capability, and disaster resources.

SECTION 1200—TRAUMA CARE FUND

1201. Eligible Recipients of Fund

Trauma centers, rehabilitation centers, physicians, Emergency Medical Services providers licensed by the Department, Regional EMS Councils, Regional Trauma Councils, and the Division of EMS and Trauma are eligible to receive trauma care funds appropriated by the South Carolina General Assembly.

1202. Allocation of Fund

The Department may authorize and allocate the distribution of funds as directed by the General Assembly in the Appropriations Act to trauma centers, rehabilitation centers, physicians, Emergency Medical Services providers licensed by the Department, air ambulance providers licensed by the Department that always use a certified paramedic on all flights and maintain a licensed South Carolina medical director on staff, Regional Trauma Councils, and Regional EMS Councils. The Department, with the advice of the Trauma Advisory Council and its subcommittees and/or workgroups, shall determine the priority of distributions after Department operating expenses, as well as a distribution formula.

SECTION 1300—PERFORMANCE IMPROVEMENT PROGRAMS

1301. General

Performance improvement (PI) programs shall be developed, maintained, and executed.

1302. Statewide Trauma System Performance Improvement Plan

The Department shall develop and maintain a Statewide Trauma System PI Plan with input from the state Trauma Advisory Council and its subcommittees or workgroups. This plan shall, at a minimum, report:

A. Summary statistics and trends for demographic and related information about trauma care for the state Trauma Advisory Council; and

B. Outcome measures for evaluation of clinical care and system-wide quality assurance and performance improvement programs.

1303. Trauma Center Performance Improvement Plan (II)

Each trauma center shall have in place an ongoing performance improvement process consistent with the designation requirements. Performance improvement records must be available for inspection by the Department upon request. Records shall include the process for identification and review, documentation or disposition of issues found, and summaries of changes implemented to include, but not be limited to, patient care practice, policies, and/or operating procedures.

1304. Performance Improvement and Feedback

Each trauma center shall develop functional relationships with all potential referring facilities and is required to provide feedback. Any process issues shall be identified and a written cooperative plan shall be established when needed. Sufficient documentation of other lesser process issues shall be maintained and available for review upon request.

SECTION 1400—ADVISORY COMMITTEES

1401. State Trauma Advisory Council

A. The State Trauma Advisory Council shall act as an advisory body for trauma care system development and provide technical support to the Department in areas of trauma care system design, trauma standards, data collection and evaluation, performance improvement, trauma system funding, and evaluation of the trauma care system and trauma care programs.

B. The State Trauma Advisory Council (TAC), the State EMS Advisory Council, and the Department shall adopt similar guidelines for its operations. These guidelines shall include attendance, maintenance of minutes, and other guidelines necessary to ensure the orderly conduct of business. The TAC shall have other functions as follows:

1. Review and comment on the Department's regulations, policies, and standards for trauma;

2. Advise the Department regarding trauma system needs and progress throughout the state;

3. Review state and local pre-hospital trauma triage guidelines; and

4. Advise the Department on injury prevention and public information and/or educational programs.

1402. Medical Control Committee

A. The Medical Control Committee is a subcommittee of the Trauma Advisory Council and the EMS Advisory Council composed of medical control physicians from each of the state's four (4) EMS regions, physician members of the EMS and Trauma Advisory Councils, and the State Medical Control Physician.

B. The Medical Control Committee is an advisory board responsible for the establishment of approved pre-hospital equipment and skills, the State EMS Formulary and other issues pertaining to EMS and trauma care.

SECTION 1500—TRAUMA SYSTEM PLANS

1501. General

A. The Department shall establish and maintain a state trauma system plan with input from the TAC and its working groups.

B. The Department shall use the state trauma system plan as the basis for establishing a statewide inclusive trauma system.

C. In developing the state trauma system plan, the Department shall consider any available federal model trauma plans.

D. The Department shall provide technical assistance and support to the TAC, the Medical Control Committee, hospitals or other healthcare facilities, and EMS providers as necessary to carry out the State Trauma Plan.

1502. Trauma Center Internal Disaster Plan (II)

Each designated trauma center shall develop an internal disaster plan that is based on data supplied by the trauma registry and other sources and shall provide for the ongoing assessment and improvement of performances of the trauma center. Such plan shall be made available to the site survey team at the time of their visit.

SECTION 1600—SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

SECTION 1700—GENERAL

Conditions which have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Added by State Register Volume 33, Issue No. 4, eff April 24, 2009; Amended by State Register Volume 40, Issue No. 5, Doc. No. 4578, eff May 27, 2016.

61–117. Access to Restricted Information.

(Statutory Authority: Section 30–4–45, S.C. Code of Laws, 1976, as amended)

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A. Purpose and Scope.

This regulation applies to information that has been designated pursuant to Code Section 30–4–45(A) or (B) for release.

B. Definitions.

1. "Department" means the Department of Health and Environmental Control.

2. "Governmental functions" means the official activities of a state, federal, or local governmental entity.

3. "Department's Headquarters" means the Department's office at 2600 Bull Street, Columbia, South Carolina.

4. "Requestor" means the individual or entity requesting access to Restricted Information.

5. "Restricted Information" means any information in the possession of the Department that is designated and identified by the Department in the written notification to the Attorney General pursuant to S.C. Code Section 30–4–45(B).

6. "Vulnerable zone" means a circle, the center of which is within the boundaries of a facility possessing hazardous, toxic, flammable, radioactive, or infectious materials subject to S.C. Code Section 30–4–45 and the radius of which is that distance a hazardous, toxic, flammable, radioactive, or infectious cloud, overpressure, radiation, or radiant heat would travel before dissipating to the point it no longer threatens serious short-term harm to people or the environment.

C. Release of Restricted Information.

1. Restricted Information, if not otherwise exempt from disclosure pursuant to applicable law, may be released to state, federal, and local authorities as required to carry out official governmental functions, as follows:

a. The requestor must appear in person at the Department's Headquarters and must sign a register and show photographic identification issued by a state, federal or local government agency; and

b. The requestor must provide a written statement that: describes the intended use of the Restricted Information being requested; describes the format and medium for access to the requested information; attests that the requested information will be for official use only; and certifies that the requested information will not be released further except as required to carry out official governmental functions and in accordance with Code Section 30–4–40(c).

2. If copies are requested, the requestor must pick them up at the Department's Headquarters in person, or by official courier. Copies will not be mailed, faxed, e-mailed, or sent by delivery service. An official courier who picks up requested copies must appear in person at the Department's Headquarters and must sign a register and show photographic identification issued by a state, federal, or local governmental agency.

3. The Department may provide state, federal or local government officials or their authorized representatives access to Restricted Information that is maintained on an electronic data system provided such access is controlled (eg. password protected) and the information is necessary to carry out official governmental functions.

D. Disclosure in Vulnerable Zone.

1. Persons living or working within a vulnerable zone will be provided Restricted Information as follows:

a. The requestor must provide written verification of the location and address of his/her home or place of business along with a photographic identification.

b. The Department will determine whether the location lies within the vulnerable zone of any facility for which Department records are requested.

c. If the location for which the Restricted Information is sought does not lie within the vulnerable zone of any facility, the Department will so notify the requestor and will deny the request.

d. If the location lies within the vulnerable zone of any facility or facilities, the requestor will be provided an opportunity to review the Restricted Information that identifies the facility, shows the vulnerable zone on a local area map, and identifies the nature of the event for which the vulnerable zone was determined.

2. The requestor may review the Restricted Information at the Department's Headquarters and may take written notes, but will not be provided with copies or be allowed to make copies, scans, photographs, or otherwise duplicate the information.

E. Special Requests.

1. Restricted Information, if not otherwise exempt from disclosure pursuant to applicable law, may be released in response to a special request, as follows:

a. The requestor must demonstrate to the satisfaction of the Department that the Restricted Information, if released, will be used solely for the purpose of conducting academic or scientific research, advance knowledge about South Carolina's environment, or otherwise be of benefit to the state;

b. The requestor must appear in person at the Department's Headquarters and must sign a register and show photographic identification issued by the agency or organization for which the requestor is conducting research; and

c. The requestor must provide a written statement that: describes the intended use of the Restricted Information being requested; describes the format and medium for access to the requested information; provides that the requested information will be for research purposes only; and certifies that the requested information will not be released further.

2. If copies are requested, the requestor must pick them up at the Department's Headquarters in person, or by official courier. Copies will not be mailed, faxed, e-mailed, or sent by delivery service. An official courier who picks up requested copies must appear in person at the Department's Headquarters and must sign a register and show photographic identification issued by the agency or organization for which the requestor is conducting research.

F. Requests for Restricted and Unrestricted Information.

1. Upon receipt of a request that seeks both Restricted Information and unrestricted information, the Department will segregate restricted and unrestricted information in response to the request.

2. Those documents containing only unrestricted information will be provided in accordance with normal Department procedures. So much of the request as seeks Restricted Information will be responded to in accordance with Code Section 30–4–40(c) and this regulation.

G. Customary Charges for Copies.

The Department's customary charges authorized in S.C. Code Section 30–4–30 for searching and making copies of records are applicable to requests for release of Restricted Information covered by this regulation.

HISTORY: Added by State Register Volume 36, Issue No. 5, eff May 25, 2012.

61–118. South Carolina Stroke Care System.

(Statutory Authority: 1976 Code §§ 44–61–610 et seq.)

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SOUTH CAROLINA STROKE CARE SYSTEM

SECTION 100

DEFINITIONS

A. Acute Care Hospital. A hospital licensed by the Department that has facilities, medical staff and all necessary personnel to provide diagnosis, care, and treatment of a wide range of acute conditions, including injuries.

B. Acute Stroke Ready Hospital (''ASRH''). Disease-specific certification by the Joint Commission or other nationally recognized organization at the level of Acute Stroke Ready Hospital and recognized by the Department.

C. Certificate of Recognition. A document issued by the Department to an Acute Care Hospital indicating the Department has recognized the Acute Care Hospital as a Stroke Center at a stroke Recognition level appearing in Section 204 of this regulation.

D. Certificate Holder. An Acute Care Hospital with a current Certificate of Recognition from the Department and with whom rests the ultimate responsibility for compliance with this regulation.

E. Comprehensive Stroke Center (''CSC''). Disease-specific certification by the Joint Commission or other nationally recognized organization at the level of Comprehensive Stroke Center, and recognized by the Department.

F. Department. The South Carolina Department of Health and Environmental Control (''DHEC'').

G. Emergency Medical Services (''EMS''). The treatment and transport of patients in crisis health situations occurring from a medical emergency or from an accident, natural disaster, or similar life-threatening situation, through a system of coordinated response and emergency medical care.

H. Primary Stroke Center (''PSC''). Disease-specific certification by the Joint Commission or other nationally recognized organization at the level of Primary Stroke Center, and recognized by the Department.

I. Recognition. The formal determination by the Department that an Acute Care Hospital is certified or accredited to provide a particular level of stroke care services.

J. State Stroke Registry Database. The stroke data collection and evaluation system, also known as ''Get With The Guidelines-Stroke,'' designed to include, but not be limited to, stroke studies, patient care and outcomes, and severity of illness in the State. The data elements collected in the State Stroke Registry Database are determined by the Department with collaboration from the Stroke Advisory Council.

K. Stroke Advisory Council (''SAC''). Stroke System of Care Advisory Council created pursuant to S.C. Code Section 44–61–650(A).

L. Stroke Care System. An organized statewide system of care for the Stroke Patient, including the Department, EMS providers, hospitals, inpatient rehabilitation providers, and other providers who have agreed to participate in coordinating stroke care services and who have been recognized by the Department in an organized statewide system.

M. Stroke Center. A hospital recognized by the Department as certified or accredited by the Joint Commission or another nationally recognized organization that provides disease-specific certification or accreditation for stroke care.

N. Stroke Patient. An individual being treated for a sudden brain dysfunction due to a disturbance of cerebral circulation. The resulting impairments include, but are not limited to, paralysis, slurred speech, and/or vision loss. Strokes can be classified as either ischemic or hemorrhagic.

O. Telemedicine-Enabled Stroke Center. A center utilizing interactive audio, video, and other electronic media for the purpose of diagnosis, consultation, or treatment of acute stroke. Telemedicine-Enabled Stroke Centers offer telemedicine services for stroke on a twenty-four (24) hour, seven (7) day per week basis, have a transfer plan in place with at least one (1) PSC or CSC, and report a minimum of four (4) performance measures of their choosing, at least two (2) of which are clinical measures related to clinical practice guidelines, quarterly to the State Stroke Registry Database.

P. Thrombectomy-Capable Stroke Center ("TSC"). Disease-specific certification by the Joint Commission or other nationally recognized organization at the level of Thrombectomy-Capable Stroke Center, and recognized by the Department.

SECTION 200

RECOGNITION PROCESS

201. Eligibility for Recognition

A. Any Acute Care Hospital certified or accredited as a stroke center by the Joint Commission or other nationally recognized organization that provides disease-specific certification or accreditation for stroke care may apply to the Department for Recognition.

B. In order to maintain Department Recognition, an Acute Care Hospital shall maintain certification or accreditation as a stroke center by the Joint Commission or from an equivalent process by another nationally recognized organization that provides disease-specific certification or accreditation for stroke care.

C. Any facility that no longer meets nationally recognized, evidence-based standards as a stroke center, or no longer possesses disease-specific certification or accreditation for stroke care, shall notify the Department within thirty (30) business days as required by S.C. Code Section 44–61–640(D), and surrender the Certificate of Recognition to the Department.

202. Application Process

A. An Acute Care Hospital seeking Recognition shall submit to the Department a completed application. The application shall include the applicant's attestation assuring that the contents of the application and other requested documents are accurate and true. The application shall be authenticated as follows:

1. If the applicant is an individual or a partnership, the application shall be signed by the owner(s);

2. If the applicant is a corporation, nonprofit organization, or limited liability company, the application shall be signed by two (2) of its officers;

3. If the applicant is a governmental unit, the application shall be signed by the head of the governmental unit having jurisdiction.

B. The application shall set forth the full name and address of the Acute Care Hospital for which the Recognition is sought, and the name and address of the owner of the facility in the event that his or her address is different from that of the facility. In the event of a change in ownership of the Acute Care Hospital, the Department shall be notified in writing within forty-eight (48) hours of the change.

C. The application shall include a copy of the full accreditation report by the Joint Commission or other nationally recognized organization at the level of Recognition requested.

D. The application shall include signed copies of agreements to allow the Department to access data submitted to the State Stroke Registry Database.

203. Recognition Renewal

A. Recognition shall expire upon expiration of current disease-specific certification or accreditation for stroke care by the Joint Commission or other nationally recognized organization.

B. To maintain Recognition, an Acute Care Hospital shall renew its recognition upon renewal of current disease-specific certification or accreditation for stroke care as required by the Joint Commission or other nationally recognized organization.

C. The application process for renewal shall follow the same process outlined in Section 202.

204. Recognition Levels

A. Recognition Levels by the Department for Stroke Centers include Acute Stroke Ready Hospital (''ASRH''), Primary Stroke Center (''PSC''), Thrombectomy-Capable Stroke Center (''TSC''), and Comprehensive Stroke Center (''CSC'').

B. As nationally recognized, disease-specific certification or accreditation programs become available at more comprehensive and less comprehensive levels, the Department may adopt and recognize those hospitals that have achieved the certification or accreditation.

205. Recognition

A. Recognition is based upon Department review and verification of the application and its supporting documents, as indicated in Section 202. Failure to meet recognition requirements, misrepresentation, and/or false information provided by the hospital is grounds for denial.

B. Upon approval, the Department will issue a Certificate of Recognition to the hospital denoting the Recognition level. The Department will also place the name of the hospital and its corresponding Recognition level on the Department's website.

206. Process of Re-recognition

An Acute Care Hospital seeking Recognition after previously, but no longer, being a Certificate Holder shall follow the Recognition procedures outlined in Section 202.

SECTION 300

ISSUANCE AND TERMS OF THE CERTIFICATE OF RECOGNITION

A. The issuance of a Certificate of Recognition does not guarantee adequacy of individual care, treatment, procedures, and/or services, personal safety, fire safety, or the well-being of any patient.

B. A Certificate of Recognition is not assignable or transferable.

C. A Certificate of Recognition shall be effective for a specific Stroke Center at a specific physical location. A Certificate of Recognition shall remain in effect until expiration of current disease-specific certification or accreditation.

SECTION 400

STATEWIDE SYSTEM OF STROKE CARE

A. Licensed EMS providers shall establish a stroke assessment and triage system that incorporates the South Carolina Stroke Assessment and Triage tool identified by the Department and located in the SC EMS Protocol ''Suspected Stroke.''

B. After July 1, 2019, licensed EMS providers shall utilize SC EMS Protocol ''Adult Stroke Patient Destination Determination by Stroke Center Capability'' for transport of acute Stroke Patients to the closest Stroke Center within a specified timeframe of onset of symptoms unless one (1) or more of the following exceptions apply:

1. It is medically necessary to transport the patient to another hospital;

2. It is unsafe or medically inappropriate to transport the patient directly to a Stroke Center due to adverse weather or ground conditions;

3. Transporting the patient to a Stroke Center would cause a shortage of local EMS resources (defined as no resources available for longer than thirty (30) minutes in a reasonable response area) and air transport is unavailable;

4. No appropriate Stroke Center is able to receive and provide stroke care to the Stroke Patient without undue delay; or

5. Before transport of a patient begins, the patient requests to be taken to a particular hospital that is not a Stroke Center or, if the patient is less than eighteen (18) years of age or is not able to

communicate, such request is made by an adult member of the patient's family or a legal representative of the patient.

SECTION 500

STATE STROKE REGISTRY DATABASE

501. Data Submission

A. All Certificate Holders shall participate in the State Stroke Registry Database by:

1. Submitting data identified by the Department to the State Stroke Registry Database; and

2. Signing and completing agreements to allow the Department to access data submitted to the State Stroke Registry Database.

B. The Certificate Holder shall ensure that all data is submitted to the State Stroke Registry Database quarterly, as outline below. The Certificate Holder shall ensure that the data entered in the State Stroke Registry Database is accurate and complete.

Admission Period	Due Date
January - March	July 1
April - June	October 1
July - September	January 1
October - December	April 1

502. Inclusion and Exclusion Criteria

Patient inclusion and exclusion criteria shall be established by the Department under the guidance of the Stroke Advisory Council and maintained in the State Stroke Registry Guidelines.

503. Confidentiality Protection of Data and Reports

Information that identifies individual patients shall not be disclosed. Reports that do not contain protected health information or any identifiable information may be generated and distributed. Such reports shall not identify any protected information or hospital information.

HISTORY: Added by SCSR 42–5 Doc. No. 4760, eff May 25, 2018.

61–119. Surface Water Withdrawal, Permitting, Use, and Reporting.

Statutory Authority: Sections 49–4–10 et seq., S.C. Code of Laws, 1976, as amended

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A. PURPOSE AND SCOPE.

1. Implementation Provision.

This regulation implements The South Carolina Surface Water Withdrawal, Permitting, Use, and Reporting Act, Section 49–4–10 et seq., S.C. Code of Laws, 1976, as amended. It establishes a system and rules for permitting and registering the withdrawal and use of surface water from within the state of South Carolina and those surface waters shared with adjacent states. The permitting, registration, use, and reporting requirements for the regulated surface water withdrawals are outlined in this regulation. This regulation applies to any person withdrawing surface water in excess of three million (3,000,000) gallons during any one (1) month.

2. Right to Withdraw.

A permit issued under this regulation confers upon a permittee a right to withdraw and use surface water pursuant to the terms and conditions of the permit. The permit does not convey a property right to the permittee nor does it relieve the permittee from being required to obtain and comply with any other permits or approvals that may be required under other existing laws. Nothing in this regulation shall be construed to diminish the Department's authority to regulate facilities under any other applicable laws.

3. South Carolina Drought Act Provision.

Nothing in this regulation limits or precludes any action authorized by the South Carolina Drought Response Act, Section 49–23–10 et seq., S.C. Code of Laws, 1976, as amended, hereafter referred to as the S.C. Drought Response Act. In the event that an action authorized by the S.C. Drought Response Act conflicts with requirements of this regulation or a permitted use, the action taken pursuant to the S.C. Drought Response Act supersedes any actions taken pursuant to this regulation or the permit.

B. DEFINITIONS.

Definitions as used in this regulation are as follows:

1. 'Administratively complete' means a determination by the Department that all elements of an application, as specified in the applicable regulation and including but not limited to all required signatures and tender of the application fee, where required, have been received.

2. 'Affected area' means that portion of a county or counties within a river basin that, under the circumstances, are determined by the Department to likely be affected by a proposed surface water withdrawal.

3. 'Agricultural use' means:

a. plowing, tilling, or preparing the soil at an agricultural facility;

b. planting, growing, fertilizing, or harvesting crops, ornamental horticulture, floriculture, and turf grasses;

c. application of pesticides, herbicides, or other chemicals, compounds, or substances to crops, weeds, or soil in connection with the production of crops, livestock, animals, or poultry;

d. breeding, hatching, raising, producing, feeding, keeping, slaughtering, or processing livestock, hogs, aquatic animals, equines, chickens, turkeys, poultry, or other fowl normally raised for food, mules, cattle, sheep, goats, rabbits, or similar farm animals for commercial purposes;

e. producing and keeping honeybees, producing honeybee products, and honeybee processing facilities;

f. producing, processing, or packaging eggs or egg products;

g. manufacturing feed for poultry or livestock;

h. rotation of crops;

i. commercial aquaculture;

j. application of existing, changed, or new technology, practices, processes, or procedures to an agricultural use;

k. the operation of a roadside market; and

l. silviculture.

4. 'Agriculture facility' means any land, building, structure, pond, impoundment, appurtenance, machinery, or equipment which is used for the commercial production or processing of crops, trees, livestock, animals, poultry, honeybees, honeybee products, livestock products, poultry products, or products which are used in commercial aquaculture.

5. 'Consumptive use' means any use of water which is not a nonconsumptive use.

6. 'Department' means the Department of Health and Environmental Control.

7. 'Diffuse surface water' means water on the surface of the earth not located in defined courses, streams, or water bodies.

8. 'Drought contingency pond' means a pond or lake designated solely as a supplemental water source in a surface water withdrawer's operational and contingency plan.

9. 'Emergency withdrawal' means the withdrawal of water, for a period not exceeding thirty days, for the purpose of firefighting, hazardous substance waste spill response, or both, or other emergency withdrawal of water as determined by the Department.

10. 'Existing surface water withdrawer' means a surface water withdrawer withdrawing surface water as of January 1, 2011, or a proposed surface water withdrawer with its intakes under construction before January 1, 2011, or with all necessary applications for its intake permits deemed administratively complete before January 1, 2011.

11. 'Farm pond' means a pond completely situated on private property that is only used for providing water for agricultural uses.

12. 'Gaging station' means a site on a stream, canal, lake or reservoir where systematic observations of stage, discharge, or other hydrologic data are obtained. Gaging stations may be part of the United States Geological Survey (USGS) monitoring network or other Department approved measuring devices established by or at the direction of or approved by the Department, after consultation with the South Carolina Department of Natural Resources (SCDNR), utilizing appropriate, Department approved measuring devices.

13. 'Impoundment' means a dam, dike, natural structure, or any combination thereof that is designed to hold an accumulation of surface water or impede the flow of surface water.

14. 'Interbasin transfer' means the withdrawal of surface water from a river basin and the movement of that water to a river basin different from the source of the withdrawal.

15. 'Licensed or otherwise flow controlled impoundment' means an impoundment or waterbody for which approval to construct and/or operate has been given by an appropriate governmental authority or agency with said approval including regulated releases with required flows from the impoundment. Licensing agencies include, but are not limited to, the United States Army Corps of Engineers and the Federal Energy Regulatory Commission, which incorporate in such federal licensing and permitting decisions the State of South Carolina water quality certification under Section 401 of the Clean Water Act.

16. 'Mean annual daily flow' means the arithmetic mean of individual daily mean discharges (stream flow) for a period representative of the historic stream flow records, using flow measurements published by USGS or as determined by other Department approved, hydrologically valid data.

17. 'Minimal changes in water quantity' means that greater than ninety (90) percent of the water withdrawn by a surface water withdrawer, based upon the previous twenty-four (24) months of

historical data, is returned to the waters of origin; provided, that either the amount of water not returned to the water source does not:

a. exceed three million (3,000,000) gallons during any one (1) month; or

b. significantly reduce the safe yield at the withdrawal point.

18. 'Minimum instream flow' means the flow that provides an adequate supply of water at the surface water withdrawal point to maintain the biological, chemical, and physical integrity of the stream taking into account the needs of downstream users, recreation, and navigation and that flow is set at forty (40) percent of the mean annual daily flow for the months of January, February, March, and April; thirty (30) percent of the mean annual daily flow for the months of May, June, and December; and twenty (20) percent of the mean annual daily flow for the months of July through November for surface water withdrawers as described in Section 49-4-150(A)(1). For surface water withdrawal points located on a surface water segment downstream of and influenced by a licensed or otherwise flow controlled impoundment, 'minimum instream flow' means the flow that provides an adequate supply of water at the surface water withdrawal point to maintain the biological, chemical, and physical integrity of the stream taking into account the needs of downstream users, recreation, and navigation and that flow is set in Section 49-4-150(A)(3).

19. 'Minimum water level' means the water level in an impoundment necessary to maintain the biological, chemical, and physical integrity of the surface water in the impoundment taking into account downstream uses, withdrawals from the impoundment, and recreational and navigational needs as established by an existing federal regulatory process or established through consultation between the Department and the operator of the impoundment.

20. 'Nonconsumptive use' means a use of surface water withdrawn in such a manner that it is returned to its waters of origin within the boundaries of contiguous property owned by the surface water withdrawer with no or minimal changes in water quantity.

21. 'Permit' or 'surface water withdrawal permit' means a written authorization issued to a person by the Department that allows the person to hold and exercise a water right to withdraw surface water pursuant to the terms of the permit and this regulation.

22. 'Permitted surface water withdrawer' means a person withdrawing surface water pursuant to a surface water withdrawal permit.

23. 'Permittee' means a person authorized to make withdrawals of surface water pursuant to a surface water withdrawal permit issued by the Department.

24. 'Person' means an individual, firm, partnership, trust, estate, association, public or private institution, municipality, or political subdivision, governmental agency, public water system, or a private or public corporation or other legal entity organized under the laws of this State or any other state or county.

25. 'Proposed registered surface water withdrawer' means a proposed surface water withdrawer whose planned operations would result in his withdrawals being subject to the reporting but not the permitting requirements of this regulation.

26. 'Public water system' means a water system as defined in Section 44–55–20 of the State Safe Drinking Water Act, Section 44–55–10 et seq., S.C. Code of Laws, 1976 as amended.

27. 'Registered surface water withdrawer' means a person who makes surface water withdrawals for agricultural uses at an agricultural facility that is filing a report pursuant to Section 49–4–50.

28. 'River basin' means the area drained by a river and its tributaries or through a specified point on a river, as determined in Section 49-4-80(K)(2).

29. 'Safe yield' means the amount of water available for withdrawal from a particular surface water source in excess of the minimum instream flow or minimum water level for that surface water source. Safe yield is determined by comparing the natural and artificial replenishment of the surface water to the existing or planned consumptive and nonconsumptive uses.

30. 'Supplemental water source' means a source of water different from the source of permitted withdrawal that will be used when an adequate amount of water is unavailable for withdrawal from the permitted source, including, but not limited to, ground water wells, aquifer storage and recovery projects, water storage facilities, drought contingency ponds, and connections to other water providers.

31. 'Surface water' means all water that is wholly or partially within the State, including the Savannah River, or within its jurisdiction, which is open to the atmosphere and subject to surface runoff, including, but not limited to, lakes, streams, ponds, rivers, creeks, runs, springs, and reservoirs, but not including water and wastewater treatment impoundments, off-stream supplemental operations related impoundments, or water storage structures constructed by the surface water withdrawer to provide adequate supplies of surface water during low flow conditions.

32. 'Surface water withdrawer' means a person withdrawing surface water in excess of three million (3,000,000) gallons during any one (1) month from a single intake or multiple intakes under common ownership within a one (1) mile radius from any one (1) existing or proposed intake.

33. 'Water Supply Only Reservoir' means a reservoir from which no permitted or registered consumptive withdrawals other than for public drinking water supply are allowed.

34. 'Withdrawal' means to remove surface water from its natural course or location, or exercising physical control over surface water in its natural course or location, regardless of whether the water is returned to its waters of origin, consumed, transferred to another river basin, or discharged elsewhere.

C. EXEMPTIONS.

1. Exempt Surface Water Withdrawals.

Surface water withdrawals for the following purposes are exempt from the permitting, registering, and reporting requirements provided for in this regulation:

a. withdrawals associated with active instream dredging or sand mining operations or other nonconsumptive instream mining operations undertaken pursuant to the South Carolina Mining Act, Section 48–20–10 et seq., S.C. Code of Laws, 1976, as amended;

b. emergency withdrawals;

c. withdrawals from farm ponds that are only used for providing water for agricultural purposes:

i. owned or leased by the person making the withdrawal; or

ii. situated on two or more separately owned parcels of private property if each property owner agrees to the withdrawal;

d. a person withdrawing surface water from any pond completely situated on private property and which is supplied only by diffuse surface water, or supplied by springs completely situated on the private property, or supplied by groundwater withdrawals;

e. naturally occurring evaporation from impoundments;

f. a person withdrawing, using, or discharging surface water for the purpose of wildlife habitat management; and

g. a special purpose district withdrawing surface water from any pond completely situated on property owned by a special purpose district and which is supplied only by diffuse surface water or springs completely situated on the special purpose district's property.

2. Hydropower Reporting Requirements.

Hydropower generation, including pumped storage, is exempt from the permitting requirements of this regulation but not the reporting requirements in Section 49–4–50.

3. Provision Allowing Permitting of Exempt Withdrawals.

Nothing in this regulation prohibits an exempt surface water withdrawer from applying for and receiving a surface water withdrawal permit, consistent with applicable provisions of this regulation. Nothing in this regulation prohibits an exempt surface water withdrawer from registering a withdrawal, consistent with applicable provisions of this regulation. An exempt surface water withdrawer that obtains a permit or registers its use is entitled to all of the rights conferred upon by a permit or a registration, as the case may be.

D. PERMITS FOR EXISTING SURFACE WATER WITHDRAWERS AS OF JANUARY 1, 2011.

1. Application Requirements.

An existing surface water withdrawer must submit a permit application on a form to be provided by the Department within one hundred and eighty (180) days of the effective date of this regulation.

Any existing surface water withdrawer submitting an application more than one hundred and eighty (180) days after the effective date of this regulation will be considered a new surface water withdrawer. At a minimum, the application must contain the following information:

a. the name, address, phone number(s), principal place of business of the person applying for the permit and, if applicable, the name and address of the agent for the applicant;

b. the location of each of the applicant's intakes, including:

i. name of source waterbody;

ii. latitude and longitude of intake;

iii. a map showing the withdrawal point(s) on a 1:24,000 scale USGS quadrangle or equivalent;

iv. the county in which the intake is located;

v. type of source waterbody, such as a stream, lake or estuary;

c. the place and nature of the proposed use of the surface water withdrawn;

d. the quantity of surface water requested for withdrawal, in million gallons per month, at each relevant withdrawal point, with supporting documentation, based on whichever of the following options is greatest as identified by the person applying for the permit:

i. documented historical water use;

ii. current permitted treatment capacity;

iii. design capacity of the intake structure as of January 1, 2011;

iv. design capacity of a pending intake structure permit application deemed administratively complete as of January 1, 2011;

v. an amount necessary to recover, through the sale of water, indebtedness from an outstanding bond or revenue certificate issued prior to January 1, 2011;

vi. for a publicly owned water utility, the safe yield of the utility's existing or permitted water supply only reservoir;

e. the method that will be used to measure the quantity of water that is withdrawn;

f. the location(s) where water withdrawn pursuant to the requested permit is returned to any surface water, including latitude and longitude and notation on a 1:24,000 USGS topographic map or equivalent, and the anticipated percent of water returned at each location;

g. any information necessary for the Department to assess a request for a permit length greater than the thirty (30) year period specified in item H.1.a. of this regulation (not to exceed a total of forty (40) years) or to assess the need for an additional period (not to exceed a total of fifty (50) years) for a municipality or other governmental body to retire a bond it issued to finance the construction of waterworks as specified in item H.1.b.; and

h. the estimated ratio between water withdrawn and consumptive use of water withdrawn.

2. Requests for Additional Flow.

If an applicant requests additional withdrawal quantity over and above the quantity documented in item D.1.d above, pursuant to Section 49–4–70 B(3), the Department will evaluate the additional quantity using criteria specified in section E. below with the exception of withdrawers to be permitted pursuant to Sections 49–4–40 and 49–4–45 which will be subject to only the requirements contained in those sections. For withdrawers with multiple withdrawal points, the application must specify the additional quantity requested at each intake. The additional quantity will be specified on the permit for the specific intake. If additional quantity is approved, the withdrawer will continue to be considered an existing surface water withdrawer and permitted as such under Section 49–4–70 (B)(1) with subsequent renewals not subject to the permitting criteria in Section 49–4–80 and not subject to Section 49–4–150.

3. Operations and Contingency Plan Requirements.

Each permittee must prepare and maintain on site, available for inspection, an operational and contingency plan to promote an adequate water supply from the surface water during times when the actual flow of the surface water is less than the minimum instream flow for that particular surface

water segment. The existence of a plan is deemed to be an enforceable part of the permit under which the permittee is withdrawing surface water and shall be deemed to control a permitted surface water withdrawal in situations where the actual flow of the surface water is less than the minimum instream flow for that particular stream segment. For an existing surface water withdrawer, the operational and contingency plan will only address appropriate industry standards for water conservation. If initial permits issued under this section are expanded, contingency plans for existing surface water withdrawers must meet the requirements of section E.4 for the volume permitted over and above that of the initial permit.

4. Information to be Included in Permit.

Upon receipt of a complete application and specified fee, the Department must issue to an existing water withdrawer a permit based upon the information contained in the application and specifying the following:

a. the location of the permittee's intake facility or facilities used or constructed to make withdrawals pursuant to the permit;

b. the amount of water that may be withdrawn at each intake, based on the appropriate criteria of item D.1.d above, if appropriate, as documented by the applicant and approved by the Department;

c. the expiration date of the permit, including the period in years of the permit (not to exceed fifty (50) years) as specified in Section 49–4–100 (B);

d. the amount of water to be discharged back into the surface water body and location of the discharge; and

e. the requirement for the applicant to submit an operational and contingency plan to address applicable industry standards for water conservation.

E. PERMITS FOR NEW OR EXPANDING SURFACE WATER WITHDRAWERS AFTER JANUARY 1, 2011.

1. Requirement to Obtain Permit to Withdraw.

After the effective date of this regulation, a new surface water withdrawer must apply for and obtain a surface water withdrawal permit pursuant to this regulation before making a surface water withdrawal. A permitted surface water withdrawer that would like to increase its permitted withdrawal amount must apply to the Department for the additional amount and receive a permit modification prior to increasing the withdrawal; however, for a withdrawer seeking to increase its permitted withdrawal amount, only the proposed increase, over and above a prior permitted amount, will be evaluated under the appropriate criteria of this section, section E.

2. Application Requirements.

Applications for new permits and modification of existing permits must be made on forms to be provided by the Department. The application must contain the following information:

a. the name, address, phone number(s), principal place of business of the person applying for the permit or permit modification and, if applicable, the name and address of the agent for the applicant;

b. the location of the proposed intake(s) or the existing intake(s) to be expanded, including:

i. name of source waterbody;

ii. latitude and longitude of intake;

iii. a map showing the withdrawal point(s) on a 1:24,000 scale USGS quadrangle or equivalent;

iv. the county in which the intake is located;

v. type of source waterbody, such as stream, lake, or estuary;

c. the place and nature of the proposed use of the surface water withdrawn;

d. a declaration as to whether any portion of the water to be withdrawn pursuant to the requested permit will cross a basin boundary as defined in item F.2.d of this regulation. If water is to be transferred across basin lines, the application must include:

i. the basin, as defined in item F.2.d, to receive the transferred flow, the specific location of the transfer, the entity to which the water is being transferred and the means by which it is being transferred;

ii. the maximum quantity of water, in million gallons per month, the applicant is requesting authority to transfer during the life of the permit;

e. for a proposed new surface water withdrawal, the quantity of surface water requested for withdrawal at each relevant withdrawal point in million gallons per month, with a justification of the quantity requested;

f. for a proposed expansion of an existing surface water withdrawal, the existing permitted capacity at the specified withdrawal point and the proposed additional amount to be withdrawn in million gallons per month, along with a justification of the quantity requested;

g. the estimated ratio between water withdrawn and consumptive use of water withdrawn;

h. for a proposed new or expanding surface water withdrawal whose contingency plan will require use of a supplemental water source, the capacity of the pump(s) that will be used to refill any required supplemental water source or other drought contingency water supply vessels;

i. the method that will be used to measure the quantity of water that is withdrawn;

j. anticipated future water needs over and above the quantity being requested in the current permit application;

k. the location(s) where water withdrawn pursuant to the requested permit will be returned to any surface water, including latitude and longitude and notation on a 1:24,000 USGS topographic map or equivalent, and the anticipated percent of withdrawn water to be returned at each location;

l. a description of how applicable industry standards on the efficient use of water, if any, have been considered in determining the quantity of water being requested;

m. where applicable, a draft of the proposed withdrawer's contingency plan addressing operations during time when the actual flow of the surface water is less than or equal to the minimum instream flow plus any flow necessary to protect downstream permitted and registered withdrawals; and

n. where applicable, any information necessary for the Department to assess a request for a permit length greater than the twenty (20) year period specified in item H.2.a. (not to exceed a total of forty (40) years) or to assess the need for an additional period (not to exceed a total of fifty (50) years) for a municipality or other governmental body to retire a bond it issued to finance the construction of waterworks as specified in item H.2.b.

3. Evaluation Criteria.

a. The Department will evaluate each proposed activity requiring a new or modified surface water withdrawal permit to evaluate the reasonableness of the proposed activity, excepting those projects permitted under Section 49–4–40 or Section 49-4-45(A)(1) which will be subject to only the requirements contained in those sections. This evaluation shall address the impacts of the withdrawal on the surface water body and will make determinations in compliance with the requirements of Section 49–4–10 et seq. and this regulation. If a proposed new or expanding project is determined to be reasonable based on these criteria, a permit must be issued. Surface water withdrawals made by permitted or registered withdrawers shall be presumed to be reasonable. In assessing the reasonableness of the proposed withdrawal, the Department will address and consider the following factors.

i. The minimum instream flow or minimum water level for the surface water source at the location of the proposed surface water withdrawal will be evaluated as follows.

(A) The minimum instream flow for stream segments that are not downstream of a licensed or otherwise flow controlled impoundment or that are no longer materially influenced by a licensed or otherwise flow controlled impoundment is forty (40) percent of the mean annual daily flow for the months of January, February, March, and April; thirty (30) percent of the mean annual daily flow for the months of May, June, and December; and twenty (20) percent of the mean annual daily flow for the months of July through November. The minimum instream flow for stream segments that are not downstream of and influenced by a licensed or

otherwise flow controlled impoundment or that are no longer materially influenced by a licensed or otherwise flow controlled impoundment will be calculated as follows:

(1) an appropriate USGS or Department approved gaging station (or stations as appropriate), known as an index station, for determining the flow at the withdrawal point will be determined, considering factors such as but not limited to drainage area, flow characteristics, physiographic province, period of record, and land use;

(2) the mean annual daily flow coefficient (CFS/square mile) at the index station will be determined with adjustments as needed to address the impact of any withdrawals or discharges upstream of the gaging station;

(3) the mean annual daily flow at the proposed withdrawal site will be determined based on the appropriate gage information and the drainage area at the proposed withdrawal site; and

(4) the three seasonal minimum instream flows will be developed based on twenty (20) percent, thirty (30) percent and forty (40) percent of the calculated mean annual daily flow.

(B) The minimum instream flow for surface water withdrawal points located on a surface water segment downstream of and materially influenced by a licensed or otherwise flow controlled impoundment shall be the flow specified in the license, by the appropriate governmental agency with regulatory authority for the flow controlled impoundment, as protective of downstream uses. A withdrawal point is considered to be materially influenced by a licensed or otherwise flow controlled impoundment to the point in the stream where the Department demonstrates through flow modeling or analysis of flow data that the stream segment is no longer materially influenced by the licensed or otherwise flow controlled impoundments. The minimum instream flow below this point will be as determined in item E.3.a.i(A) above.

(C) Minimum water level for impoundments will be determined as follows.

(1) For licensed or otherwise flow controlled impoundments, the minimum water level will be the level established by an existing federal regulatory process. When a surface water withdrawal point is located on a licensed or otherwise flow controlled impoundment, a withdrawal permit may not authorize the withdrawal of surface water in an amount that would cause a reservoir:

(a) water level to drop below its minimum water level; or

(b) to be unable to release the lowest minimum flow specified in the license for that impoundment as issued by the appropriate government agency.

(2) For impoundments for which a minimum water level has not been established by an existing federal regulatory process, an appropriate minimum water level will be established through consultation between the Department and the operator of the impoundment.

(3) The requirements of E.3.a.i(A) and (B) do not apply to withdrawals from a licensed or otherwise flow controlled impoundment.

ii. The safe yield at the point of withdrawal will be evaluated as follows.

(A) For withdrawals in a stream segment not influenced by a licensed or otherwise flow controlled impoundment, the safe yield is calculated as the difference between the mean annual daily flow and twenty (20) percent of mean annual daily flow at the withdrawal point, taking into consideration natural and artificial replenishment of the surface water and affected downstream withdrawals.

(B) For withdrawals located on a stream segment materially influenced by a licensed or otherwise flow controlled impoundment, the safe yield is calculated as the difference between mean annual daily flow and the lowest designated flow in the license specified for normal conditions (non-drought), taking into consideration natural and artificial replenishment of the surface water and affected downstream withdrawals and natural attenuation of the stream flow between the licensed or otherwise flow controlled impoundment and the surface water withdrawal point.

(C) For withdrawals from a licensed or otherwise flow controlled impoundment, safe yield is calculated as the maximum amount that would not cause a reservoir water level to drop

below its minimum water level or to be able to release the lowest minimum flow specified in the license for that impoundment as issued by the appropriate governmental agency.

(D) For withdrawals from an impoundment that is not considered a licensed or otherwise flow controlled impoundment under this regulation, the safe yield is calculated as the maximum amount that would not cause the impoundment water level to drop below its minimum water level as established by the Department with input from the applicant and the owner(s) and operator(s) of the impoundment consistent with E.3.i(C)(2) above.

(E) Safe yield shall be considered as one factor in issuing a withdrawal permit as outlined in Section 49-4-80(B). Should withdrawals in excess of the safe yield be permitted, additional contingency planning shall be required of the permittee.

iii. The anticipated effect of the applicant's proposed use on existing users of the same surface water source, including, but not limited to, present agricultural, municipal, industrial, electrical generation, and instream users, will be considered by accounting for existing withdrawals from, and natural and artificial replenishment of, the waterbody in determining the safe yield of the stream and when determining operations and contingency plan requirements of section E.4 of this regulation.

iv. The reasonable foreseeable future need for the surface water including, but not limited to, agricultural, municipal, industrial, electrical generation and instream uses will be considered. Prior to issuing a permit for a new or expanding withdrawal, the Department will consider any relevant comments made during the public comment period and any other complete applications for a withdrawal from the same waterbody when considering the reasonable future needs for the surface water.

v. Whether it is reasonably foreseeable that the applicant's proposed withdrawal(s) would result in a significant, detrimental impact on navigation, fish and wildlife habitat, or recreation will be considered. As part of the review of any proposed new or expanding surface water withdrawal, the Department will solicit input from and consider any comments provided by appropriate state and federal agencies responsible for recreation, navigation, and fish and wildlife habitat, as well as the general public.

vi. The applicant's reasonably foreseeable future water needs from the surface water will be considered. As part of the application for a new or expanding surface water permit, the applicant will be asked to provide information considering future water needs over and above the amount being requested in the permit application.

vii. The impact of applicable industry standards on the efficient use of water, if adhered to by the applicant, will be considered. As part of the application for a new or expanding surface water permit for an industrial withdrawal, the applicant will be required to provide information on how applicable industry standards for the efficient use of water have been used in determining the amount of water being requested and the Department can take this information into account when determining the withdrawal for the proposed project.

viii. The Department shall notify the public of the Department's determination when the safe yield in a river or stream has been fully allocated.

b. An applicant for a new or expanding surface water withdrawal from an existing, licensed or otherwise flow controlled impoundment shall obtain a surface water withdrawal permit pursuant to the criteria below. Nothing in this regulation precludes the requirement for the owner and operator of a proposed new or expanding water withdrawal facility that will be constructed within the boundaries of a reservoir operated by a different entity from obtaining the reservoir operator's approval before construction of the proposed new or expanded surface water withdrawal facility.

i. Where the applicant is the owner of a licensed or otherwise flow controlled impoundment that utilizes water from the impoundment and the withdrawal is subject to review and approval of applicable state and federal laws and regulations, including its impoundment licensing authority, the Department shall issue a permit for the withdrawal upon submittal of a proper permit application to provide information needed for the Department to issue a permit consistent with the Act.

ii. Where the applicant is not the owner of the licensed impoundment that will be the source of the withdrawal, a permit will be issued upon proper application in accordance with the

criteria contained in E.3.a of this regulation. Where the owner or federally authorized agency managing the licensed impoundment or where the licensing agency requires review and approval subject to applicable state and federal laws and regulations, the Department will consider all information provided by the applicant as part of the process necessary to gain approval of the withdrawal. The Department reserves the right to require any additional information, over and above that required by the managing entity, deemed necessary to adequately review the proposed withdrawal, consistent with E.3.a above. Upon completion of the review process and determination of an acceptable withdrawal quantity that is within the safe yield and in compliance with the minimum water level of the impoundment, and submittal of a complete application, the Department will issue an appropriate permit for the withdrawal.

iii. Where the applicant is not the owner of the impoundment that is to be the source of the withdrawal and said impoundment is not licensed or the license does not include a flow prescription or minimum lake level, the Department will work with the impoundment owner and the applicant to determine the minimum water level and safe yield of the impoundment. The Department may require the applicant to supply information necessary to determine the safe yield of the impoundment. Upon completion of the review process and submittal of a complete application, the Department may issue an appropriate permit for the withdrawal, consistent with the provisions of this regulation.

iv. When a surface water withdrawal point is located on an impoundment that serves as a water supply for a federally licensed facility that is also an existing surface water withdrawer, a withdrawal permit may not authorize any new surface water withdrawer to withdraw surface water in an amount that would negatively impact the continued operation of the federally licensed facility. These requirements do not apply to an expansion or addition of units at a federally licensed facility.

4. Operations and Contingency Plan Requirements.

Anytime the flow at the point of the permitted withdrawal is less than or equal to the minimum instream flow and taking into consideration natural and artificial replenishment of the surface water and existing or planned consumptive and nonconsumptive uses affected by the withdrawal downstream, the permitted surface water withdrawer must implement applicable portions of its water contingency plan and, excepting public water systems addressed in Section 49-4-150(A)(6), will discontinue facility consumptive water uses from the surface water source such that continued withdrawals will result in no net decrease in flow below the facility's discharge.

a. Each permittee must prepare and maintain on site, available for inspection, an operational and contingency plan to promote an adequate water supply from the surface water during times when the actual flow of the surface water is less than the minimum instream flow, plus any flow necessary to protect downstream permitted and registered withdrawals, taking into account natural and artificial replenishment of the surface water, for that particular surface water segment. The existence of a plan is deemed to be an enforceable part of the permit under which the permittee is withdrawing surface water and shall be deemed to control a permitted surface water withdrawal in situations where the actual flow of the surface water is less than the minimum instream flow for that particular stream segment.

b. For applicable new or expanding surface water withdrawers, the plan must identify actions to be taken to address low flow conditions, including: water conservation, use of supplemental water supplies, use of off-stream water storage, operational changes, seasonal water flow fluctuation withdrawals, or hydroelectric operations in controlled surface waters. For expansion of permits initially issued under section D above, the requirements of this section only apply to the permitted amount over and above the permitted quantity of the initial permit.

c. Public water systems must develop operational and contingency plans consistent with E.4.b. above and implement their plan, applicable to their service territory, commensurate with the drought level declared by the State Drought Response Committee and in accordance with any drought response plan required by the owner of a licensed impoundment that they use as a water source.

d. Non-public water withdrawers must develop operational and contingency plans consistent with E.4.b. above and implement them consistent with the requirements of this section and act in

accordance with any drought response plan required by the owner of a licensed impoundment that they use as a water source.

e. For surface water withdrawers with an operational and contingency plan requiring one or more supplemental sources of water to be used for continued facility operations during minimum instream flow conditions, the supplemental water supply needed will be addressed as follows.

i. For a surface water withdrawer proposing to use surface water as all or a portion of the supplemental water supply:

(A) Where only surface water will be used as a supplemental supply, the volume of water required to be stored is set forth in Section 49-4-150(A)(2)(c), and the following used as an aid to such determinations.

(1) Using an appropriate USGS or Department approved gaging station, historical flow at the withdrawal point will be determined. Factors to be considered in determining an appropriate index station include but are not limited to drainage area, flow characteristics, physiographic province, period of record, and land use.

(2) Using the flow record at the appropriate index station, a daily flow record for the longest period of record feasible will be determined at the proposed withdrawal point. All years experiencing periods of flow below the minimum instream flow for the months July through November will be determined and evaluated, up to and including the drought of record. For the purposes of this section, the drought of record will be considered the July through November period, within the period of record, having the largest number of days with flows equal to or less than the minimum instream flow.

(3) Using the flow records of July through November periods experiencing flows equal to or less than the minimum instream flow, including but not limited to the drought of record, the Department will determine a supplemental water volume for inclusion in any permit to be issued for the withdrawal. The supplemental water volume is not required to be any larger than the quantity that allows for facility operations during twenty percent mean annual daily flow conditions, based upon a review of historical low flow data and projected facility consumptive water uses during low flow periods. Facility consumptive water uses means the amount of water that is lost and not returned to the source waterbody during normal operations.

(4) If an appropriate index station with an appropriate period of record is not available, the Department, in consultation with the applicant, will determine an appropriate storage volume using the best information available. The USGS and/or SCDNR may be consulted as needed.

(B) For a surface water withdrawer proposing to utilize surface water in conjunction with other supplemental sources to satisfy contingency plan requirements, the volume of supplemental supply needed will be determined as in item E.4.e.i(A) above with due consideration given to the volume of water to be supplied by sources other than surface water when determining drought contingency pond size.

(C) A permitted surface water withdrawer utilizing a drought contingency pond as all or some of its supplemental water source may withdraw the entire volume of water from the pond during low flow periods requiring supplemental water source usage. Water withdrawn from drought contingency ponds is not subject to environmental and permitting restrictions unless or until it is discharged to state waters. The Department will designate drought contingency ponds, a type of supplemental water source, as part of an approved operational and contingency plan.

(D) For withdrawals where the withdrawal point is not located on a licensed or otherwise flow controlled impoundment, a permitted surface water withdrawer may withdraw water from the permitted surface withdrawal point in order to refill its supplemental water source, or other drought contingency water supply vessels, anytime the river flow exceeds the minimum instream flow, provided the total amount withdrawn for daily operations and for refilling the supplemental water source or other drought contingency water supply vessel does not cause the flow downstream of the withdrawal point to go below the minimum instream flow plus any flow necessary to protect downstream permitted and registered withdrawals.

(E) For withdrawals where the withdrawal point is located on a licensed or otherwise flow controlled impoundment, the permitted withdrawer may withdraw water to refill his supplemental water source or other drought contingency water supply vessel anytime the total amount withdrawn for daily operations and for refilling the supplemental water source does not cause the reservoir water level to drop below its minimum water level or to be unable to release the lowest minimum flow specified in the license for the impoundment as issued by the appropriate government agency.

ii. For a surface water withdrawer proposing to utilize groundwater obtained on its site as a supplemental source, the applicant must document the availability of groundwater of sufficient quantity to provide for the withdrawer's daily needs for a period of time at least equal to the period of time the surface water will be unavailable as determined in item E.4.e.i(A) above. Any permits or approvals required to extract groundwater for use as a supplemental source must be obtained prior to issuance of a surface water withdrawal permit.

iii. For a surface water withdrawer proposing to utilize as their supplemental source water purchased from: another surface water withdrawer; a permitted discharger; a supplier using groundwater as its source; or other source approved by the Department, the withdrawer must demonstrate via contract or other legally binding commitment the availability of a sufficient quantity of water to provide for the withdrawer's daily needs for a period of time at least equal to the period of time the surface water will be unavailable as determined in item E.4.e.i(A) above.

iv. New surface water withdrawers are not required to engineer the supplemental water source identified in their contingency plan any larger than the quantity that allows for facility operations during twenty percent mean annual daily flow conditions, based upon a review of historical low flow data and projected facility consumptive water uses during low flow periods.

v. A new surface water withdrawer may not return to the withdrawal source when its supplemental water source is exhausted unless the supplemental water source has been engineered to meet the specifications of this section.

vi. If after all reasonable contingency plans have been implemented, and the surface water withdrawer is within fifteen (15) days of exhausting the usable water supply from its supplemental water source, a new surface water withdrawer may give notice to the Department that he is exhausting his supplemental water sources and that he intends to return to the withdrawal source in amounts up to his permitted amount. Notification must be made in writing as expeditiously as possible, to include electronic communication, to the address provided in the permit. Upon receiving notice, the Department must determine whether all or any portion of the withdrawal for facility consumptive water uses will result in a significant negative impact to an existing user or the environment if the permitted withdrawal is resumed. If the Department does not make its determination within ten (10) days of receipt of notice, the permittee may make withdrawals up to the permitted amount and do so until notified by the Department whether all or any portion of the withdrawal for facility consumptive water uses will result in a significant negative impact to an existing user or the environment during this low flow period. Upon notification by the Department, the permittee will cease withdrawals for facility consumptive water uses that will result in any significant negative impact.

f. The Department must consult with the SCDNR to determine which, if any, existing stream gaging station should be utilized to quantify the stream flow at the point of the proposed withdrawal. The Department may also seek the input of the applicant in determining a suitable means to measure or extrapolate the stream flow at the point of the proposed withdrawal. If no existing stream gage is suitable for measuring or extrapolating the flow at which the applicant's water withdrawal must be reduced due to inadequate stream flow, the SCDNR will recommend the location of a new stream gage.

g. The Department must consult with the SCDNR to quantify the stream flow measured at the specified measuring device that will require a reduction in the applicant's water withdrawal because of inadequate stream flow at the point of withdrawal.

5. Information to be Included in Permit.

Upon review of an application for a new surface water withdrawal permit, the Department will: issue the permit for the volume requested in the application; issue the permit for a lesser volume; or, deny the permit. If the Department intends to issue the permit for a lesser volume, or to deny the permit, the applicant will be notified prior to issuance of a final decision. A new surface water withdrawal permit issued by the Department shall include, at a minimum:

a. the location of the permittee's intake facility or facilities used or constructed to make withdrawals pursuant to the permit;

b. the amount of water that may be withdrawn;

c. the expiration date of the permit and the permit duration in years;

d. a copy of the final operational and contingency plan developed by the applicant, in conjunction with the Department, addressing operations during times when the actual flow of the surface water is less than or equal to the minimum instream flow plus any flow necessary to protect downstream permitted and registered withdrawals;

e. the amount of water to be discharged back into the surface water body and location of the discharge;

f. the volume of supplemental water supply, if needed;

g. the minimum instream flow at the point of withdrawal, if applicable;

h. the minimum instream flow triggers that will determine if the permittee's withdrawal must be reduced, if appropriate;

i. the stream flow that will be used to notify the applicant of starting the reduction of withdrawal as appropriate;

j. the minimum water level of an impoundment, if appropriate;

k. a clear statement that the terms and conditions of the permit are subject to the provisions of the S.C. Drought Response Act; and

l. the address to which a surface water withdrawer must mail notice of intent to return to withdrawing a consumptive amount of surface water.

F. PUBLIC NOTICE REQUIREMENTS FOR NEW OR EXPANDING SURFACE WATER WITHDRAWALS AFTER JANUARY 1, 2011.

Applications for new permits or to significantly increase the amount of water that may be withdrawn under an existing permit must be placed on public notice as required by this regulation to inform the public of the proposed activity and provide the public with the opportunity to comment on the proposed project and request that a public hearing be held. The applicant shall provide to the Department all appropriate information necessary to conduct public notice except that already on file with the Department.

1. Public Notice of New Permits Not Considered Interbasin Transfers or Expanding Surface Water Withdrawals After January 1, 2011.

Upon receipt of a complete application and filing fee for a new surface water withdrawal permit not considered an interbasin transfer under this regulation or a proposal to significantly increase the amount of water that may be withdrawn under an existing permit, the Department must, within thirty (30) days, provide the public with notice of the application.

a. The Department will publish notice of the proposed withdrawal or increased withdrawal:

i. in accordance with the Department's usual public notice procedures;

ii. in a newspaper of statewide circulation and in the local newspaper with the greatest general circulation in the affected area; and

iii. on the Department's website.

b. The public notice must contain:

i. the location of the proposed withdrawal or increased withdrawal;

ii. the amount of the proposed withdrawal;

iii. the use for which the water will be withdrawn;

iv. a description of the procedure that a person must follow to submit a comment concerning the proposed withdrawal or increase; and

v. the process for requesting a public hearing concerning the application.

c. If within thirty (30) days of the publication of the public notice the Department receives a request to hold a public hearing from at least twenty (20) citizens or residents of the affected area, the Department must conduct a hearing. A hearing may also be held whenever the Department staff determines that it may be useful in reaching a decision on an application. The hearing must be held within ninety (90) days of the close of the initial public notice period at an appropriate time and in an appropriate location near the specific site of the proposed surface water withdrawal. The hearing may not be held until after at least thirty (30) days' notice is given to the public. Notice shall be provided as in F.1.a above and shall include the provisions of F.1.b plus the date, time and location of the hearing.

d. If a public hearing is held, the public comment period on an application will automatically be extended to fifteen (15) days past the date of the hearing. Further extensions may be granted at the discretion of the Department.

e. The following fifteen (15) river basins are to be used when determining the affected area for a particular surface water withdrawal application. 'Affected area' is defined in section B as that portion of a county or counties within a river basin that, under the circumstances, are determined by the Department to likely be affected by a proposed surface water withdrawal.

i. The Upper Savannah River Basin drains the area from the headwaters of the Savannah River at the border with North Carolina and Georgia to Stevens Creek Dam and encompasses McCormick and Oconee Counties and portions of Abbeville, Aiken, Anderson, Edgefield, Greenwood, Pickens and Saluda Counties.

ii. The Lower Savannah River Basin drains the area from Stevens Creek Dam to the mouth of the Savannah River at the Atlantic Ocean and encompasses portions of Aiken, Allendale, Barnwell, Edgefield, Hampton and Jasper Counties.

iii. The Saluda River Basin drains the area from the headwaters of the North and South Saluda Rivers at the border with North Carolina to the confluence of the Saluda River with the Broad River and encompasses portions of Abbeville, Aiken, Anderson, Edgefield, Greenville, Greenwood, Laurens, Lexington, Newberry, Pickens, Richland and Saluda Counties.

iv. The Broad River Basin drains the area from the headwaters of the Tyger River in Greenville County, the Enoree and Pacolet Rivers in Spartanburg and Greenville Counties and the Broad River at the border with North Carolina to the confluence of the Broad River with the Saluda River and encompasses Cherokee, Spartanburg and Union Counties and portions of Chester, Fairfield, Greenville, Laurens, Lexington, Newberry, Richland and York Counties.

v. The Congaree River Basin drains the area from the confluence of the Broad and Saluda Rivers to the confluence of the Congaree River with the Wateree River and encompasses portions of Calhoun, Lexington and Richland Counties.

vi. The Catawba-Wateree River Basin drains the area from Lake Wylie at the North Carolina border to the confluence of the Wateree River with the Congaree River and encompasses portions of Chester, Fairfield, Kershaw, Lancaster, Lee, Richland, Sumter and York Counties.

vii. The Lynches River Basin drains the area from the Lynches River at the North Carolina border to the confluence of the Lynches River with the Pee Dee River and encompasses portions of Chesterfield, Darlington, Florence, Kershaw, Lancaster, Lee, Sumter and Williamsburg Counties.

viii. The Pee Dee River Basin drains the area from the Pee Dee River at the North Carolina border to the confluence of the Pee Dee River with the Waccamaw River at Winyah Bay and encompasses portions of Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Marion, Marlboro and Williamsburg Counties.

ix. The Little Pee Dee River Basin drains the area from the Little Pee Dee River and Lumber River at the North Carolina border to the confluence of the Little Pee Dee River with the Pee Dee River and encompasses portions of Dillon, Horry, Marion and Marlboro Counties.

x. The Black River Basin drains the area from the headwaters of the Black River in Kershaw County to the confluence of the Black River with the Pee Dee River and encompasses portions of Clarendon, Florence, Georgetown, Kershaw, Lee, Sumter and Williamsburg Counties.

xi. The Waccamaw River Basin drains the area from the Waccamaw River at the North Carolina border to the mouth of Winyah Bay at the Atlantic Ocean, the area drained by Bull Creek, the area drained by the Sampit River as well as the coastal areas north to Little River Inlet and the North Carolina border and south to South Island and encompasses portions of Georgetown, Horry and Williamsburg Counties.

xii. The Lower Santee River Basin drains the area from the confluence of the Congaree and Wateree Rivers to the mouth of the Santee River at the Atlantic Ocean and encompasses portions of Berkeley, Calhoun, Charleston, Clarendon, Georgetown, Orangeburg, Sumter and Williamsburg Counties.

xiii. The Edisto River Basin drains the area from the headwaters of the North Fork and South Fork Edisto Rivers in Edgefield, Lexington and Saluda Counties to the mouth of the South Edisto River at St. Helena Sound and the North Edisto River at the Atlantic Ocean and encompasses portions of Aiken, Bamberg, Barnwell, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Edgefield, Lexington, Orangeburg and Saluda Counties.

xiv. The Ashley-Cooper River Basin drains the area from the headwaters of Cypress Swamp and Wadboo Swamp in Berkeley County and the Diversion Canal between Lakes Moultrie and Marion to the mouths of the Ashley and Cooper Rivers at Charleston Harbor and the Atlantic Ocean as well as the coastal areas north to Murphy Island and south to Seabrook Island and encompasses portions of Berkeley, Charleston and Dorchester Counties.

xv. The Combahee-Coosawhatchie River Basin drains the area from the headwaters of the Salkehatchie River in Barnwell County to the confluence of the Combahee River with St. Helena Sound and the Atlantic Ocean and the headwaters of the Coosawhatchie River in Allendale County to the confluence of the Broad River with Port Royal Sound and the Atlantic Ocean as well as the coastal areas south to the Georgia border and encompasses Beaufort County and portions of Aiken, Allendale, Bamberg, Barnwell, Colleton, Hampton and Jasper Counties.

2. Public Notice of New Surface Water Withdrawals After January 1, 2011 Considered Interbasin Transfers.

Upon receipt of a complete application and filing fee for a new surface water withdrawal permit that will be considered an interbasin transfer under this regulation, the Department must, within thirty (30) days, provide notice of the proposed withdrawal and transfer, including notice of the mandatory public hearing for interbasin transfer projects.

a. Notice of the proposed new interbasin transfer permit will be made in the following manner:

i. in accordance with the Department's usual public notice procedures;

ii. by submittal for publication in the South Carolina State Register;

iii. by publication in a newspaper of statewide circulation and in a local newspaper of general circulation in the affected area of the river basin downstream from the point of withdrawal;

iv. by publication on the Department's website; and

v. through standard United States mail to:

(A) any person holding a permit issued by the Department authorizing surface water withdrawals, including interbasin transfers, from the river basin from which the water for the proposed transfer would be withdrawn;

(B) any person holding a National Pollutant Discharge Elimination System (NPDES) wastewater discharge permit authorizing wastewater discharge into the river basin where the proposed withdrawal point of the proposed interbasin transfer is located;

(C) any city or county governing body whose jurisdiction is located entirely or partially within the river basin that is the source of the proposed transfer;

(D) the governing body of a public water supply system that withdraws water from the same river basin where the proposed withdrawal point of the proposed transfer is located;

(E) any agency from another state where an interstate water basin is the source of the proposed transfer;

(F) the South Carolina Department of Natural Resources; and

(G) the owner of any licensed or otherwise flow controlled impoundment that would be impacted by the withdrawal.

b. The notice must include:

i. the location of the proposed withdrawal;

ii. the name of the losing basin and the gaining basin;

iii. the amount of the proposed withdrawal and the amount to be transferred from the losing basin;

iv. a non-technical description of the applicant's request;

v. the use for which the water will be withdrawn;

vi. a conspicuous statement in bold type describing the effects of the interbasin transfer on the river basin from which the water will be withdrawn and the river basin into which the withdrawn water will be transferred;

vii. a description of the procedure that a person must follow to submit a comment concerning the proposed interbasin transfer; and

viii. the location, date, and time of the mandatory hearing for the project which is to be held at an appropriate time and appropriate location near the withdrawal point of the interbasin transfer. The hearing may not be held until at least thirty (30) days after publication of the notice in the State Register.

c. The public comment period on an interbasin transfer application will automatically extend to fifteen (15) days past the date of the hearing. Further extensions may be granted at the discretion of the Department.

d. For the purposes of this regulation, an interbasin transfer is considered the transfer of three million (3,000,000) gallons or more of water in any one month from one of the following USGS defined basins to a different basin such that the water is permanently lost from the basin of origin. The transfer of water from one basin to another is not considered an interbasin transfer if transferred water is returned or discharged to the basin of origin such that the quantity of water permanently lost to the basin of origin is less than three million (3,000,000) gallons in any one month.

i. Savannah River Basin, Hydrologic Unit Codes: 03060101, 03060102, 03060103, 03060106, 03060107, 03060109, 03060110;

ii. Saluda River Basin, Hydrologic Unit Codes: 03050109, 03050110;

iii. Santee River Basin, Hydrologic Unit Codes: 03050111, 03050112, 03050201, 03050202, 03050209;

iv. Edisto River Basin, Hydrologic Unit Codes: 03050203, 03050204, 03050205, 03050206;

v. Salkehatchie River Basin, Hydrologic Unit Codes: 03050207, 03050208, 03050210;

vi. Pee Dee River Basin, Hydrologic Unit Codes, 03040104, 03040105, 03040201, 03040202, 03040203, 03040204, 03040205, 03040206, 03040207, 03040208;

vii. Catawba River Basin, Hydrologic Unit Codes: 03050101, 03050103, 03050104; or

viii. Broad River Basin, Hydrologic Unit Codes: 03050105, 03050106, 03050107, 03050108.

G. NONCONSUMPTIVE USE SURFACE WATER WITHDRAWAL PERMITS.

1. Requirements to be Considered a Nonconsumptive Use Withdrawer.

Upon proper application and submittal of appropriate fees, the Department shall issue permits for surface water withdrawals that are considered nonconsumptive uses. A nonconsumptive user is one that uses surface water in such a manner that more than ninety (90) percent of the water withdrawn is returned to its waters of origin within the boundaries of contiguous property owned by the surface water withdrawer; provided:

a. the amount of water not returned to the water source does not exceed three million (3,000,000) gallons during any one month; or

b. the amount of water not returned to the water source does not significantly reduce the safe yield at the point of withdrawal.

2. Additional Application Requirements for Nonconsumptive Use Permits.

For any person requesting a permit pursuant to Section 49–4–40 (non-consumptive use permit), the application must include, in addition to the other information required in subsection D.1 or E.2 of this regulation, as appropriate, the following:

a. a tax map showing intake and discharge points and property boundaries;

b. a discussion of the timing of the discharge of the water, e.g. is any form of hydrograph control release being considered;

c. for an existing surface water withdrawer as of January 1, 2011, who would like to be considered a nonconsumptive user, an analysis of withdrawal and discharge data for the previous twenty four (24) months showing that the provisions of subsection G.1 above will be met; and

d. for a proposed new or expanding surface water withdrawer who would like to be considered a nonconsumptive user, an engineering analysis demonstrating that the provisions of subsection G.1 above will be met.

3. Reconsideration of Nonconsumptive Use Status.

If, after twenty-four (24) months of operation, a nonconsumptive permittee is shown not to meet the criteria of a non-consumptive user, the original permit application will be reevaluated. For an existing surface water withdrawer, a permit will be issued under section D of this regulation. For a non-consumptive use permit issued under section E of this regulation, a full review under section E will be conducted and an appropriately conditioned permit issued if the project is found to be reasonable under the Act.

4. Information to be Included in Permit.

A permit for a nonconsumptive use must identify the surface water withdrawer, the point of withdrawal, the maximum withdrawal amount, and the point of return. Such permits are subject only to the reporting requirements of section N.

H. PERMIT DURATION.

Permits issued by the Department, unless revoked or suspended pursuant to statute or this regulation, shall be valid for a period to represent the economic life of any capital investments made by the permittee necessary to carry out the permittee's use of the withdrawn water.

1. Permit Duration for Existing Surface Water Withdrawers as of January 1, 2011.

Permits for existing surface water withdrawers as of January 1, 2011 must be issued for:

a. thirty (30) years for a permittee entitled to an initial permit pursuant to Section 49-4-70(B), or a greater period the Department considers reasonable based upon its review of all the facts and circumstances relevant to the proposed withdrawal not to exceed an additional ten (10) years; or

b. any additional period necessary, not to exceed a total of fifty (50) years, for a municipality or other governmental body to retire a bond it issued to finance the construction of waterworks.

2. Permit Duration for a New or Expanding Surface Water Withdrawer After January 1, 2011.

For applicants for new or expanding surface water withdrawers after January 1, 2011 whose use is found to be reasonable under the provisions of the Act and this regulation, permits must be issued for:

a. twenty (20) years, or a greater period the Department considers reasonable based upon its review of all the facts and circumstances relevant to a proposed withdrawal not to exceed an additional twenty (20) years; or

b. any additional period necessary, not to exceed a total of fifty (50) years, for a municipality or other governmental body to retire a bond it issued to finance the construction of waterworks.

I. RENEWAL PROCESS FOR SURFACE WATER WITHDRAWAL PERMITS.

1. Permits Issued to Existing Surface Water Withdrawers.

a. An existing surface water withdrawer as defined by this regulation may renew its surface water withdrawal permit by making application no more than six (6) months prior to the expiration date, on a form to be supplied by the Department, pursuant to the criteria of section D of this regulation. Renewals of permits held by existing surface water withdrawers are not subject to the permitting criteria in section E. of this regulation, minimum flow requirements, or additional supplemental water contingency planning requirements, and are not subject to the requirements of subsection I.2 of this regulation. A permit shall remain valid during the Department's consideration of a renewal application if the permittee files a complete renewal application prior to the expiration date of the permit. Renewal applications take priority over permit applications for new withdrawals. Renewal of a permit issued to an existing surface water withdrawer shall be for the quantity of water specified in the current permit unless the Department demonstrates that the quantity above the maximum withdrawals during the permit term are not necessary to meet the permittee's future needs.

b. An existing surface water withdrawer as defined by this regulation may, while renewing its surface water withdrawal permit, simultaneously apply for a modification to increase the amount of withdrawal. While the Department will review and approve the initially authorized amount consistent with section D. of this regulation, the proposed expansion will be evaluated based on the criteria of section E. of this regulation. If a modification is granted allowing additional withdrawal flow, subsequent permit renewals will evaluate the amount authorized in the initial permit under item I.1.a of this regulation while any additional amount authorized after issuance of the initial permit will be evaluated under item I.2.a. of this regulation. However, an application to modify an existing permit for a significant increase in the quantity of the withdrawal for surface water withdrawals authorized pursuant to Section 49–4–40 or Section 49–4–45 shall be subject only to the requirements set forth in that section.

2. Permits Issued to Surface Water Withdrawers Considered New or Expanding After January 1, 2011.

a. Any person considered a new surface water withdrawer permitted after January 1, 2011, or an existing surface water withdrawer issued a modification to their initial permit under section E may request renewal of its permit by making application no more than six (6) months prior to the expiration date, on a form to be supplied by the Department. A permit shall remain valid during the Department's consideration of a renewal application if the permittee files a complete renewal application prior to the expiration date of the permit. The renewal application for a new surface water withdrawer will be evaluated based on the criteria of section E of this regulation. The renewal application for an existing surface water withdrawer as defined by this regulation who has received an expanded surface water permit under section E will be evaluated under the appropriate criteria of sections D and E. Unless a modification is requested, permits must be renewed for a quantity equal to the expired permit unless the Department demonstrates that the quantity above maximum withdrawals during the permit term is not necessary to meet the permittee's future needs. Renewal applications take priority over permit applications for new withdrawals.

b. A surface water withdrawer may, while renewing its permit, simultaneously apply for a modification to increase the amount of withdrawal. Any proposed expansion quantity will be evaluated based on the criteria of section E. of this regulation; however, any significant increase in surface water withdrawals authorized pursuant to Section 49–4–40 or Section 49–4–45 shall be subject only to the requirements set forth in that section.

J. ACTIONS ON PERMIT APPLICATIONS MODIFICATIONS, REVOCATIONS AND DENIALS.

1. Authority to Take Action on Permits.

The Department may modify, suspend, or revoke a permit under the following conditions:

a. the permit holder withdraws water not authorized by its permit or fails to comply with the terms and conditions of its permit;

b. the permit holder obtains a permit by misrepresentation or fails to disclose a material fact in its application;

c. the permit holder ceases to withdraw water for a period of at least thirty-six (36) consecutive months;

d. a permanent change in natural conditions results in a permitted activity endangering human health or the environment; or

e. if a permit holder requests a significant increase in surface withdrawal quantity, a significant change in use, such as a new or increased interbasin transfer, or a change in consumptive use.

2. Transferability of Permits.

a. Surface water permits are transferable with the prior written consent of the Department provided:

i. the current permittee notifies the Department at least sixty (60) days in advance of the proposed transfer date; and

ii. the activities and uses of the new permittee are consistent with the activities of the original permittee.

b. In determining whether to allow the transferring of a permit, the Department will consider:

i. whether the use to be made of the water by the new permittee is consistent with the previous use;

ii. the quantity of water to be used by the new permittee as compared to permitted amount and previous use;

iii. if consumptive use under the new permittee is consistent with the previous permittee; and

iv. the location of water use under the new permittee.

c. Depending on the specifics of the proposed transfer, the Department may transfer the permit as originally issued, transfer the permit at a decreased flow or deny the transfer.

K. EXISTING INTERBASIN TRANSFER PERMITS AND REGISTRATIONS.

The expiration date of an interbasin transfer permit or interbasin registration, including any water withdrawal right or authority contained in the permit or registration, in existence on January 1, 2011, remains effective. For the purposes of this chapter, existing interbasin transfer permit or interbasin registration holders are deemed to be existing surface water withdrawers. A renewal of an interbasin transfer permit or registration must be made pursuant to the criteria established in Section 49–4–10 et seq. for existing surface water withdrawers, except that permits or registrations renewed within three (3) years after the effective date of this chapter must be renewed for a quantity at least equal to the permitted quantity in the expired permit. All other renewals must be issued in accordance with the criterion applicable to existing surface water withdrawers and for a quantity equal to the permitted quantity in the expired permit, unless the Department demonstrates by a preponderance of the evidence that the quantity above maximum withdrawals during the permit term are not necessary to meet the permittee's future need.

L. REGISTRATION OF AGRICULTURAL WITHDRAWALS.

1. Requirement to Register.

a. Persons withdrawing water in excess of three million (3,000,000) gallons during any one (1) month for agricultural purposes must register their use with the Department on forms provided by the Department.

b. Registered surface water withdrawers are subject to the reporting requirements but not the permitting requirements of this regulation.

c. A registered surface water withdrawer may, at any time, request an increase in its registered amount; however, withdrawals that are not substantially greater than the registered amount do not necessarily require a modification to the registration.

d. Nothing in this regulation prohibits a registered surface water withdrawer from applying for and receiving a surface water withdrawal permit, consistent with applicable provisions of this regulation. A registered surface water withdrawer that obtains a permit is entitled to all of the rights conferred upon by a permit.

2. Existing Agricultural Withdrawals.

a. An existing agricultural withdrawer already reporting its withdrawal to the Department as of January 1, 2011, may maintain its withdrawal(s) at its highest reported level or at the design capacity of the intake structure(s) existing as of January 1, 2011, and is deemed to be registered with the Department.

b. The Department will notify the withdrawer of the registration and the allowed level of withdrawal based on the highest reported level of withdrawal. The notification will stipulate that the withdrawer may, no later than sixty (60) days from the date of notification, provide to the Department appropriate documentation showing the permanent intake capacity as of January 1, 2011 to be greater than the highest reported level of withdrawal and be registered for the higher amount.

3. New or Expanding Agricultural Withdrawals After January 1, 2011.

a. A person proposing to withdraw water for agricultural purposes in a quantity anticipated to meet the criteria of a surface withdrawer or an existing registered withdrawer seeking to increase its registered amount must report, on a form to be supplied by the Department, its anticipated withdrawal quantity or increase to the Department for determination as to whether that quantity is within the safe yield for that water source at the time of the request. The safe yield will be determined consistent with item E.3.a.ii of this regulation.

b. Upon making a safe yield determination, the Department must send a description of its determination to the proposed registered surface water withdrawer by registered mail.

i. If the anticipated withdrawal quantity or increase is determined to be within the safe yield of the source waterbody, the withdrawal will be considered registered with the Department for the anticipated quantity and the notification will constitute authorization to proceed with construction and operation of the withdrawal at the specified amount.

ii. If the anticipated withdrawal quantity or increase is determined not to be within the safe yield of the source waterbody, then the proposed new registered surface water withdrawer may not proceed with the construction or installation of a new water intake pursuant to this regulation nor can an existing registrant increase withdrawals above their current registered amount. However, the registrant may modify its request to reflect a reduced withdrawal quantity or increase that is within the safe yield.

c. A person receiving authorization to construct and operate a withdrawal or expand an existing withdrawal under this section must notify the Department of completion of the intake or expansion within thirty (30) days after completing construction. If notification of completion of construction is not received by the Department within one (1) year of the date of authorization provided under item L.3.b.i above, authorization to construct or expand and operate a surface water withdrawal is revoked unless the Department extends the time period.

4. Application Requirements.

a. At a minimum, the form for reporting an anticipated withdrawal quantity, for registering a withdrawal, or for requesting an increase in the amount of surface water withdrawn must include the following information:

i. the name, address, phone number(s), principal place of business of the person applying for the registration or registration modification and, if applicable, the name and address of the agent for the applicant;

ii. the location of the proposed intake(s) or the existing intake(s) to be expanded, including:

(A) name of source waterbody;

(B) latitude and longitude of intake; and

(C) a map showing the withdrawal point(s) on a 1:24,000 scale USGS quadrangle or equivalent;

iii. the quantity of water for which the registration is being requested;

iv. the capacity of the intake; and

v. the type of intake, either permanent or mobile.

b. [Reserved]

5. Regulatory Authority.

The Department may modify the amount an existing registered surface water withdrawer may withdraw, or suspend or revoke a registered surface water withdrawer's authority to withdraw water, if the registered surface water withdrawer withdraws substantially more surface water than he is registered for and the withdrawals result in detrimental effects to the environment or human health.

M. TEMPORARY PERMITS AND EMERGENCY WITHDRAWALS.

1. Temporary Permits.

a. The Department may issue a temporary surface water withdrawal permit to a new applicant while its application is pending, if:

i. a complete application has been submitted pursuant to section E. of this regulation; and

ii. the temporary permit is necessary to address an imminent hazard to public health; or,

iii. the applicant demonstrates that without a temporary permit he will suffer physical or financial damage.

b. A temporary permit must contain an expiration date, which must not be more than one hundred eighty (180) days after it was issued.

c. A temporary permit for a new surface water withdrawal cannot be issued for a quantity of water greater than the quantity specified in the complete application.

d. A temporary permit must specify the minimum instream flow at the point of the proposed withdrawal and include a provision that the withdrawal cannot cause the instream flow below the withdrawal to fall below the minimum instream flow.

e. It shall be the responsibility of any new surface water withdrawer issued a temporary permit to document instream flow for the duration of the temporary permit.

f. A person may request a temporary permit through submittal of the initial permit application or at any time during the agency review of the initial permit application.

2. Emergency Withdrawals.

a. The following withdrawals are exempt from the permitting, registering, and reporting requirements:

i. firefighting;

ii. hazardous substance or waste-spill response; and

iii. other emergency withdrawal of water determined necessary by the Department to protect public health and safety.

b. An emergency withdrawal of water shall not exceed thirty (30) consecutive days.

c. It is the intent of this section to allow emergency withdrawals only in cases necessary to protect public health and safety. Economic duress is not considered an emergency under this regulation.

N. REPORTING.

1. Requirement to Report.

Each permitted or registered surface water withdrawer must file a report with the Department of the quantity of water withdrawn by that surface water withdrawer annually before February first, on forms furnished by the Department.

2. Methods of Measuring Withdrawal Quantity.

The quantity of surface water withdrawn must be determined by one of the following:

a. flow meters accurate to within ten percent of calibration;

b. the rated capacity of the pump in conjunction with the use of an hour meter, electric meter, or log;

c. the rated capacity of the cooling systems;

d. any standard or method employed by the USGS in determining these quantities; or

e. any other method found to provide reliable water withdrawal data approved by the Department.

3. Reporting Exemption.

Permitted and registered surface water withdrawers who are required to file a surface water withdrawal report pursuant to regulation are not required to submit the report if the monthly quantity withdrawn from each intake is being reported to the Department as a result of another environmental program reporting requirement, permit condition, or consent agreement.

O. ENFORCEMENT.

1. Violations.

A surface water withdrawer who commits a violation of this regulation:

a. is subject to a civil penalty of not more than ten thousand (10,000) dollars for each day that the violation occurred; or

b. is guilty of a misdemeanor and, upon conviction, must be fined not more than ten thousand (10,000) dollars for each day that the violation occurred, if the violation is willful.

2. Penalties.

All penalties and fines collected pursuant to this section must be deposited in the general fund of the State of South Carolina.

P. OTHER DEPARTMENT AUTHORITY.

1. Department Authority.

a. The Department may, in consultation with the SCDNR, negotiate agreements, accords, or compacts on behalf of and in the name of the State of South Carolina with other states or the United States, or both, with any agency, department, or commission of either, or both, relating to transfers of water that impact waters of this State, or are connected to or flowing into waters of this State. Any agreements, accords, or compacts made by the Board pursuant to this section must be approved by concurrent resolution of the General Assembly prior to being implemented.

b. The Department may represent the State in connection with water withdrawals, diversions, or transfers occurring in other states that may affect this State.

c. The Department must notify the Chairman of the Senate Agriculture and Natural Resources Committee and the Chairman of the House Agriculture, Natural Resources, and Environmental Affairs Committee when the Department enters into negotiations or otherwise represents the State as provided in this section. The Department must periodically report, as necessary or upon request, to the chairmen concerning the progress of the negotiations or representation.

d. Department representatives may enter upon any land or water for the purpose of conducting investigations, examinations, or surveys necessary to carry out its duties and responsibilities provided in this regulation. The Department will adhere to security and safety requirements that may apply at the site and/or facility.

e. The Department may receive financial and technical assistance from private entities, the federal government, or another state agency.

f. The Department may take any action reasonable and necessary to enforce the provisions of this regulation.

2. [Reserved]

Q. SURFACE WATER PERMITTING AND WITHDRAWAL FEES.

1. Fee Structure.

The Department is authorized to collect a fee for each permit application and an annual operating fee for each permitted intake. The fee collected must be returned to the Department for the purposes of implementing the Surface Water Permitting and Withdrawal regulatory program including permit application review, compliance inspections, and enforcement; and for providing technical assistance and monitoring. The fee(s) shall be as follows:

Existing surface water withdrawal permit application processing fee	$1,000
New surface water withdrawal permit application processing fee	$7,500
Modification of surface water withdrawal permit application processing fee	$2,000

Renewal of surface water withdrawal permit with modifications application processing fee	$1,000
Surface water withdrawal annual operating fee per permitted intake	$1,000

2. Application Processing Requirements.

a. Application fees shall be due when the application is submitted. The Department will not process an application until the application fee is received. If the applicant withdraws the permit application anytime before the application has been deemed administratively complete, the Department shall refund the entire application fee to the applicant.

b. Upon receipt of an application and appropriate fee, the Department must within ninety (90) days make a decision on the completeness of the application. If notice that the application is administratively complete or notice that the application is not Administratively Complete, together with notice of the specific items deemed to be lacking, is not mailed to an applicant within ninety (90) working days of receipt of an application, the application is deemed complete and the allowed processing time period will begin.

c. Once an applicant has been notified that the application is administratively complete or has been deemed complete according to item 2.b above, the Department shall issue or deny the permit within three hundred sixty five (365) days of that date. If no permit decision has been rendered by the end of the relevant time period, the application fee shall be refunded. If an application fee is refunded due to the Department exceeding the relevant time period, the application remains active.

d. The time period shall be tolled in the following instances.

i. The time period shall be tolled when the Department makes a written request for additional information and shall resume when the Department receives all requested information from the applicant. If an applicant fails to respond to or satisfy such a request within one-hundred eighty (180) days, the Department shall consider the application withdrawn and the application fee will be forfeited. The Department shall notify the applicant no later than ten (10) days prior to expiration of the 180-day period.

ii. The time period shall be tolled if the applicant requests that the permit review be suspended or if the applicant requests in writing that additional time be provided and the Department agrees to the request in writing and specifies an additional period.

iii. The time period shall be tolled if the Department, at least ten (10) days prior to the expiration date, requests a delay in the review process to which the applicant agrees.

iv. The time period shall be tolled if the Department holds a public hearing, in which case the time schedule will be tolled for no more than sixty (60) days.

v. The Department shall notify the applicant when the time period is being tolled and untolled.

e. All times given in days are given in calendar days unless otherwise noted. The last day of the period is to be included, unless it is a Saturday, Sunday, or legal holiday, in which case the period runs until the end of the next day which is not a Saturday, Sunday or legal holiday. The day notice is mailed to the applicant that the application is deemed administratively complete shall be counted.

f. The Department may determine that the applicant has filed a new application whenever additional information provided by the applicant during any Departmental review period, in response to any statement identifying deficiencies in the application or supporting materials, or during any period allowed for public comment, either:

i. results in a change in the category in which the permit application is classified; or

ii. significantly increases or changes the nature of the potential effects of the proposed project or activity on public health and safety or the environment.

iii. Upon making a determination that the applicant has filed a new application, the Department shall promptly notify the applicant in writing. The notice shall indicate the basis for the determination and summarize the provisions relative to such determinations.

(A) Immediately upon issuance of the notification, the schedule for timely action shall be suspended.

(B) If the determination resulted from a proposed change in design or operation of the proposed project or activity the applicant may, within thirty (30) days, withdraw the change and return to its previous proposal by so notifying the Department in writing. If the applicant so notifies the Department, the schedule for timely action shall resume at the point at which it was suspended.

(C) If the determination resulted from any other cause, or if the applicant does not elect to withdraw the change, the Department shall begin a review of the new application pursuant to the relevant schedule for timely action.

(D) Unless the applicant elects to proceed with the previous application, the original application shall be deemed withdrawn after the start of technical review, and the fee shall be forfeited. Appropriate fees as defined in this section shall be due for the modified application.

(E) The determination that a project has changed shall not be grounds for a request for adjudicatory hearing; however, an applicant aggrieved by such a determination may seek review of the determination as an issue in any appeal of the permit decision.

iv. This provision does not apply to initial permits issued pursuant to section D of this regulation.

g. The time periods for the Department to take any action shall be extended whenever:

i. action by another federal, state, or municipal governmental agency is required before the Department may act; or

ii. judicial proceedings then underway affect the ability of the Department or the applicant to proceed with the application; or

iii. when the Department has commenced enforcement proceedings that could result in revocation of an existing permit for that facility or activity and denial of the application; or

iv. a check or other form of payment of an application fee is returned for insufficient funds, or if payment in full is in any other manner prevented.

h. The applicant shall promptly notify the Department in writing whenever it believes that action by another governmental agency is required, or that judicial proceedings affect the ability of the Department or the applicant to proceed with the application.

i. The Department shall provide written notice to the permit applicant within fifteen (15) days of making a determination that an extension is necessary. Such notice shall contain a statement of the reasons for which the schedule must be extended.

j. When the Department determines that the reason for such extension is no longer applicable, the Department shall so notify the applicant in writing within fifteen (15) days of making such determination. The time period for the Department to complete a timely review shall begin on the day the notice is mailed.

3. Annual Operating Fees.

a. Annual operating fees per permitted intake are assessed on the State fiscal year of July 1 through June 30 of the following year. The holder of any valid permit on July 1 of each year will be assessed appropriate fees for the entire following fiscal period. Assessment of annual operating fees will begin July 1 following initial permit issuance.

b. Annual operating fees are due within thirty (30) days of billing. Unpaid fees, late fees, and returned checks are subject to the provisions of item Q.3.d below.

c. Unless the permittee seeks an extension of the time for making payment, the permittee shall make payment in full on or before the due date, and in the manner and form, specified in the invoice. Except to the extent authorized by the Department, late payment, nonpayment, partial payment, or failure to make payment in the specified manner and form shall constitute a failure by the permittee to pay the fee when due.

d. Annual operating fees remaining unpaid thirty (30) days after billing will be issued a late notice with no penalty due; however, it will contain advisement of penalty for non-payment after

sixty (60) days. Fees remaining unpaid after sixty (60) days will be assessed a ten (10) percent penalty. Persons delinquent will be issued a notice of the ten (10) percent penalty due the Department as well as advisement of further penalties should fees remain unpaid. Fees remaining unpaid at the end of ninety (90) days will be assessed a twenty-five (25) percent penalty in addition to the ten (10) percent sixty (60) day penalty. The sum of both penalties may not exceed five thousand (5,000) dollars. Persons delinquent at the end of ninety (90) days under this paragraph will be notified by the Department by certified mail at their last known address.

4. General Fee Provisions.

a. The Department will not issue new permits, modifications, revisions, or reissue a surface water withdrawal permit for a facility that is in default of fees due under this regulation.

b. All returned checks will be subject to a returned check fee as outlined in the DHEC Administrative Policy and Procedures Manual. This penalty will be in addition to those outlined in item Q.3.d above.

c. Failure to pay fees may result in the revocation of an existing permit.

d. All fees shall be payable to the Department of Health and Environmental Control and mailed to the Bureau of Finance, 2600 Bull Street, Columbia, S.C. 29201.

R. COMPLIANCE WITH OTHER STATUTES AND REGULATIONS.

Nothing in this regulation shall relieve any person regulated herein of the duty to comply with all other applicable statutes and regulations.

S. SEVERABILITY CLAUSE.

If any section, subsection, item, subitem, paragraph, subparagraph, sentence, clause, phrase, or word of this regulation is for any reason held to be unconstitutional or invalid, such holding shall not affect the constitutionality or validity of the remaining portions of this regulation.

HISTORY: Added by State Register Volume 36, Issue No. 6, eff June 22, 2012.

61–120. South Carolina Immunization Registry.

Statutory Authority: 1976 Code Section 44–29–40

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A. Purpose and Scope.

The purpose of this regulation is to provide rules, implementing Section 44–29–40 of the S.C. Code of Laws, 1976, as amended, regarding the South Carolina Immunization Registry requirements for reporting immunizations occurring in South Carolina, implementation and operation of the registry, data elements to be collected, content of electronic forms and reports, and the procedures for disclosure of confidential registry information. This regulation will apply to all healthcare providers who give immunizations in South Carolina. Nothing in this regulation shall be construed to affect statutory or common law principles governing the liabilities of health care providers for acts or omissions of their employees, agents, or contractors. Nothing in this regulation shall be construed to conflict with any state law or regulation governing immunizations or to alter, add to, or eliminate any requirement of state law or regulation regarding the administration of immunizations or to regulate the practice of any of the health care professions.

B. Definitions.

1. AUTHORIZED USER means an employee of an immunization provider who has been identified during the registration process as a user of the registry.

2. DEPARTMENT means the Department of Health and Environmental Control.

3. IMMUNIZATION PROVIDER means an individual health care provider licensed, certified, registered, or otherwise authorized by law to provide immunizations, and an organization, facility, or other entity that provides immunizations through such individual providers.

4. PATIENT means an individual who receives an immunization or other health care services.

5. REGISTRY means the data system for the collection, storage, and dissemination of information on immunizations administered in South Carolina established by the Department pursuant to Section 44–29–40.

C. Registration and Reporting Requirements.

1. Immunization providers shall register with the Department for access to the Registry.

a. All immunization providers shall register with the Department before administering any immunizations for which reporting is required under the implementation schedule in this regulation. This section governs only the registration requirement and is not intended to prohibit or restrict the administration of immunizations by any person authorized by law to do so.

b. Authorized users shall complete training under schedules established by the Department in a format determined by the Department. The Department will contact registered users to schedule and provide the training and other needed activities in order to use the registry. Immunization providers will not be responsible for completing the reporting requirements of this regulation until necessary training and set up have been completed by the Department.

c. An immunization provider that is a facility or business entity administering vaccines through employees, agents, or contractors may register in its own name, and the employees, agents, and contractors of such facilities or business entities need not register individually. An immunization provider that is a business entity with multiple locations may register once as a single provider for more than one location. Individual immunization providers who practice in a group or with a facility or business entity may register individually or in the name of the group or facility or business entity.

2. Each immunization provider shall identify one or more employees who will be authorized users of the registry on behalf of the immunization provider.

a. All authorized users shall maintain the confidentiality of their individual access codes and passwords for the immunization registry and shall not share or exchange such codes with any other person, regardless of whether or not that other person is an authorized user.

b. Each immunization provider and authorized user shall be individually responsible for complying with this regulation and the user agreement. The immunization provider shall be responsible, according to existing principles of agency law, for its authorized users' access to the registry and uses and disclosures of registry information, and compliance with this regulation and the user agreement.

c. Immunization providers and authorized users shall enter into and comply with user agreements specifying terms of use and confidentiality and other obligations. A breach of a user agreement is a violation of this regulation.

3. The immunization provider shall notify the Department within fifteen (15) business days after an authorized user is terminated or leaves employment for any reason. The immunization provider shall not be liable for applicable statutory penalties for its authorized users' post-employment violations of this regulation, if the immunization provider has notified the Department that the authorized user is no longer employed. This regulation shall not be construed to affect the immunization provider's liability to any third party for acts or omissions of its employee or other authorized user.

4. Immunization providers shall report all immunizations administered to the registry within ten (10) business days of administration. Immunizations shall be reported in a standard electronic format specified by the Department via the internet at a website specified by the Department, or via the South Carolina Health Information Exchange or other method specified by the Department. An immunization provider that is a facility or business entity administering vaccines through employees, agents, or contractors shall report immunizations administered by its employees, agents, and contractors.

5. For each immunization administered, immunization providers shall report, at a minimum, the date of immunization; specific type of vaccine given; first and last name, gender, and date of birth of the person receiving the vaccine; and name of the registered immunization provider. The Department may require reporting of other data as needed to comply with federal requirements.

6. In the event of a state or federal declared disaster, state of emergency, or public health emergency, at the Department's discretion, immunization providers shall report to the Department information regarding administration or dispensing of certain drugs, medications, chemicals, vaccines, or biological products used in response to the declared disaster, state of emergency, or public health emergency.

7. Immunization providers in other states who administer immunizations in South Carolina must comply with the requirements of this regulation. Immunization providers who administer immunizations in other states to South Carolina residents are not required to register with or report immunizations administered out of state to the registry, but may register and report voluntarily. Out-of-state immunization providers who register voluntarily are subject to and must comply with the provisions of this regulation governing permitted uses and disclosures of registry information and compliance and enforcement as fully as if located in and administering immunizations in South Carolina.

8. Immunization providers who do not administer vaccines may register with the Department for access to the registry. Immunization providers who register under this paragraph and their authorized users are subject to and will comply with all provisions of this regulation applicable to immunization providers and authorized users and may access and use registry information under Section D.

D. Permitted Uses and Disclosures of Immunization Registry Information.

1. Information in the immunization registry is confidential and shall be made available only to registered immunization providers through their authorized users. Immunizations providers who have registered for access to the registry may obtain information from the registry pertaining only to their own patients.

2. Immunization providers may use registry information for the following purposes:

a. To provide care and treatment to their patients;

b. To determine appropriate and needed immunizations for their patients;

c. To generate reports to review their practice's coverage;

d. To generate reminder and recall notices;

e. To review their practice's immunizations for quality improvement purposes;

f. To print a patient's immunization record;

g. To print a South Carolina Certificate of Immunization for a patient for school and daycare attendance; and for

h. Other uses specifically authorized by the Department.

3. Immunization providers and authorized users may not disclose identifying information obtained from the registry except as allowed or required by applicable law.

4. The Department may use registry information for public health purposes, including, but not limited to, the following:

a. To determine appropriate and needed immunizations for patients;

b. To print a patient's immunization record at the request or with permission of an immunization provider;

c. To print a copy of an immunization record or a South Carolina Certificate of Immunization for a patient and at the written request of the patient, or a parent or legal guardian of the patient if the patient is under eighteen (18) years of age;

d. To allow a patient, or a parent or legal guardian of the patient if the patient is under eighteen (18) years of age, to obtain a copy of the patient's immunization record through a Department authorized electronic Patient Portal;

e. To investigate vaccine fraud;

f. To prevent, investigate, and control outbreaks of vaccine preventable communicable diseases;

g. To conduct epidemiological studies;

h. To provide data that does not identify an individual either directly or indirectly for research and only if the researcher submits a research protocol describing, at a minimum: the intended use of

the data, the methodology of the research project; why access to the information is necessary, and approval by an official Institutional Review Board;

i. To assure the quality of the data entered into the registry;

j. To review the quality of the immunization practices of immunization providers;

k. To publish aggregate data that does not identify an individual either directly or indirectly;

l. When deemed necessary by the Director in the event of a disaster, state of emergency, or public health emergency;

m. To perform repairs, maintenance, and updates of the Immunization registry;

n. To provide information needed by law enforcement officers and agencies in the investigation or prosecution of a crime;

o. To implement this regulation, including compliance assistance and enforcement activities; and

p. To provide immunization records to the Revenue and Fiscal Affairs Office so that it may provide these records to health plans of members and enrollees of the health plan who received immunizations during the time in which they were enrolled in the health plan. Each immunization record may only be used by health plans for public health and Healthcare Effectiveness Data and Information Set (HEDIS) purposes. Health plans shall enter into a data sharing agreement with the Department and the Revenue and Fiscal Affairs Office prior to receiving immunization records.

5. Uses and disclosures by immunization providers or authorized users of registry information not authorized by this section are prohibited. Nothing in this regulation authorizes an immunization provider or authorized user to make any use or disclosure of registry information that is otherwise prohibited by law.

E. Compliance and Enforcement.

1. Immunization providers shall make immunization records available within a reasonable time to authorized representatives of the Department for inspection upon request.

2. For a violation of this regulation, the Department may:

a. Require an immunization provider or an authorized user to attend registry training;

b. Suspend or revoke access to the registry; or

c. Assess civil penalties as authorized by Section 44–1–150, S.C. Code of Laws, 1976, as amended.

3. A Department decision under Section E.2 may be appealed by an immunization provider or authorized user, pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.

F. Exceptions to Regulation.

1. The Department may grant a waiver to a requirement of this regulation, in its discretion when an immunization provider demonstrates to the Department's satisfaction that compliance would cause substantial hardship, that the waiver would protect and promote the health and safety of patients, and that the requirement is not specifically mandated by statute.

2. A delay in reporting caused by an act of God, war, strike, riot, or other catastrophe as to which negligence or willfulness on the part of the immunization provider was not the proximate cause will not be considered a violation of this regulation, as long as the immunization provider reports as required at the earliest practicable time after the event or catastrophe.

G. Severability.

If a court of competent jurisdiction rules any part of this regulation invalid or otherwise unenforceable, the remaining portions of this regulation shall remain in effect as if the invalid portions were not originally a part of this regulation.

HISTORY: Added by State Register Volume 37, Issue No. 5, eff May 24, 2013. Amended by SCSR 43–5 Doc. No. 4837, eff May 24, 2019.

61–122. Standards for Licensing In-Home Care Providers.

(Statutory Authority: 1976 Code Section 44–70–10 et seq.)

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SECTION 100. PURPOSE AND SCOPE, DEFINITIONS, AND REQUIREMENTS FOR LICENSURE.

101. Purpose and Scope.

This regulation implements the provisions of the South Carolina In-Home Care Providers Act codified at Section 44–70–10 et seq., S.C. Code of Laws, 1976, as amended. This regulation will apply to all in-home care providers in South Carolina.

102. Definitions.

For the purposes of these regulations the following definitions apply:

A. Administrator. The individual designated by the licensee to have the authority and responsibility to manage the in-home care provider and is in charge of all functions and activities of the provider.

B. Blood Assay for *Mycobacterium tuberculosis* (BAMT). A general term to refer to *in vitro* diagnostic tests that assess for the presence of tuberculosis (TB) infection with *M. tuberculosis*. This term includes, but is not limited to, interferon-gamma release assays (IGRA).

C. Caregiver. Individual employed by, contracted by, referred by, or agent of the in-home care provider who provides services to clients.

D. Client. A person that receives services or care from an in-home care provider licensed by the Department.

E. Department. The South Carolina Department of Health and Environmental Control.

F. Repeat Violation. The recurrence of a violation cited under the same section of the regulation or statute within a thirty-six (36) month period. The time-period determinant of repeat violation status is applicable in instances when there are ownership changes.

G. Responsible Party. A person who is authorized by law to make decisions on behalf of a client. This includes, but is not limited to, a court-appointed guardian, conservator, or any individual with health care or other durable power of attorney.

H. Revocation of License. An action by the Department to cancel or annul a provider's license by recalling, withdrawing, or rescinding the provider's authority to operate.

I. Suspension of License. An action by the Department requiring a provider to cease operations for a period of time or requiring a provider to cease admitting clients until such time as the Department rescinds the restriction.

103. Requirements for Licensure.

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise and/or market) as an in-home care provider in South Carolina without first obtaining a license from the Department. When it has been determined by the Department that services are being provided and the owner has not been issued a license from the Department to provide such care services, the owner shall cease operation immediately and ensure the safety, health, and well-being of its clients. Current and/or previous violations of the S.C. Code and/or Department regulations may jeopardize the issuance of a license for the provider or the licensing of any other provider or addition to an existing provider which is owned and/or operated by the licensee.

B. Issuance and Terms of License.

1. The license issued by the Department shall be posted in a conspicuous place in a public area of the provider's business office or readily available to the public.

2. The issuance of a license does not guarantee adequacy or quality of individual services, personal safety, fire safety, or the well-being of any client of the provider.

3. A license is not assignable or transferable and is subject to suspension or revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this State.

4. A license shall be effective for a specified provider at a specific location. A license shall be valid for a period of time specified by the Department.

5. The issuance of a license under this chapter does not guarantee provision of care by the licensee that meets or exceeds applicable standards of care. The Department is not liable to any party for acts or omissions of a licensee involving or relating to provision of care.

C. Provider Name. No proposed provider shall be named, nor shall any existing provider have its name changed to, the same or similar name as any other provider licensed in South Carolina. The Department shall determine if names are similar. If a provider is part of a franchise with multiple locations, the provider must include the geographic area in which it is located as part of its name.

D. Application. Applicants for a license shall submit to the Department a complete and accurate application on a form or by electronic means, as prescribed by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application includes both the applicant's oath assuring that the contents of the application are accurate and true and the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; in the case of a corporation, by two of its officers. The application shall set forth the full name and address of the provider for which the license is sought, the owner in the event the owner's name and address is different from that of the provider, and the names of the persons in control of the provider. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. When submitting an application for an initial or renewal license, the provider shall include evidence of:

1. Either liability insurance coverage or, in lieu of liability insurance coverage, a surety bond. The provider shall maintain such coverage for the duration of the license period. The minimum amount of coverage is one hundred thousand dollars ($100,000) per occurrence and three hundred thousand dollars ($300,000) aggregate;

2. Indemnity coverage to compensate clients for injuries and losses resulting from services provided; and

3. Workers compensation insurance in accordance with S.C. Code Section 42–5–10 et seq.;

4. Criminal record checks and drug test results for the prospective licensee; and

5. A random drug testing program pursuant to S.C. Code 44–70–70.

E. Licensing Fees. The initial license fee shall be one thousand dollars ($1,000). The fee for annual license renewal shall be eight hundred dollars ($800). Such fees shall be made payable by check or credit card to the Department and is not refundable. If the application is denied, a portion of the fee may be refunded based upon the remaining months of the licensure year.

F. Late Fee. The Department may order an entity to cease operations upon license expiration. Failure to submit a renewal application or fee within thirty (30) days of the expiration of a license may result in a late fee of twenty-five (25) percent of the licensing fee amount, in addition to the licensing

fee. Continual failure to submit completed and accurate renewal applications and/or fees by the time period specified by the Department may result in an enforcement action, including revocation.

G. License Renewal. For a license to be renewed, applicants shall file an application with the Department, pay a license fee of eight hundred dollars ($800), and must not be undergoing enforcement actions by the Department. If the license renewal is delayed due to enforcement actions, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department or when the adjudicatory process is completed, whichever is applicable.

1. Prior to reinstatement of a suspended license, the licensee shall submit a reinstatement fee of four hundred dollars ($400).

2. Prior to reinstatement of a revoked license, the licensee must apply for a license as provided for in Section 103 of this regulation along with the initial licensing fee. Any time remaining from the revoked license is forfeited.

H. Change of License.

1. A provider shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

a. Change of ownership; and/or

b. Change of provider location from one geographic site to another.

2. Changes in provider name or address (as notified by the post office) shall be accomplished by application or by letter from the licensee to the Department.

3. An amendment fee of fifty dollars ($50) is required for each amendment.

I. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where it is determined that the health, safety, and well-being of the clients are not compromised, and provided the standard is not specifically required by statute.

J. The in-home care provider shall ensure that it is accessible in person, by phone, or page during the hours of 9:00 A.M. to 5:00 P.M., Monday through Friday, except for those holidays recognized by the State of South Carolina. Those staff members shall have access to all records required for routine inspections and complaint investigations.

SECTION 200. ENFORCEMENT.

201. General.

The Department shall utilize inspections, investigations, applications, and other pertinent documentation regarding a proposed or licensed provider in order to enforce this regulation.

202. Violations.

When the Department determines that an in-home care provider is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such provider, the Department, upon proper notice to the licensee, may impose a monetary penalty, deny, suspend, or revoke licenses.

203. Monetary Penalties.

Monetary penalties assessed by the Department must be not less than one hundred dollars ($100) nor more than five thousand dollars ($5,000) for each violation of any of the provisions of this regulation. Each day a violation continues will be considered a subsequent offense.

SECTION 300. STAFF, CAREGIVERS, AND TRAINING REQUIREMENTS.

A. Before being employed as an in-home caregiver by a licensed in-home care provider, a person shall undergo a criminal background check as provided by S.C. Code Sections 44-70-60(B) and 44–7–2910 and submit to a drug test as provided by S.C. Code Section 44-70-60(B).

B. Licensed in-home care providers and individuals employed as in-home caregivers by licensed in-home care providers are subject to and must pass random drug testing as provided for in S.C. Code Section 44–70–70. The provider may choose the method of random testing that most suitably meets the provider's needs. The provider's policies and procedures must address random drug testing and describe the procedure chosen. At a minimum, a five (5) panel drug screen will be utilized that tests for cannabis, cocaine, amphetamines, opiates, and phencyclidine.

C. The provider shall maintain accurate information on all staff members including, but not limited to, current address, phone number, training, criminal background checks, and health assessments.

D. Caregivers shall receive or independently obtain necessary training to perform the duties for which they are responsible. Documentation of all in-service training shall be signed and dated by both the individual providing the training and the individual receiving the training. A signature for the individual providing the training may be omitted for computer-based training. The following training shall be provided by appropriate resources:

1. Basic first aid;

2. Medication assistance, if applicable;

3. Depending on the type of clients, care services for persons specific to the physical and/or mental condition of the individual, for example, Alzheimer's disease, related dementia, cognitive disabilities, or similar disabilities;

4. Confidentiality of client information and records and the protecting of client rights, including prevention of abuse and neglect;

5. Documentation and recordkeeping procedures;

6. Ethics and interpersonal relationships;

7. Proper lifting and transfer techniques, if applicable; and

8. Infection control techniques.

E. Minimum qualifications for caregivers.

A caregiver must:

1. Be able to read, write, and communicate effectively with client and supervisor;

2. Be capable of completing assigned job duties;

3. Be capable of following a care services plan with minimal supervision, if applicable;

4. Have a valid driver's license and proof of insurance if transportation is a part of the caregiver's duties. The provider must ensure the caregiver's license is valid while transporting any client of the provider by verifying the official highway department driving record of the employed individual. A copy of the driving record must be maintained in the caregiver's file;

5. Be at least eighteen (18) years of age;

6. Not have prior convictions or have pled no contest (nolo contendere) to crimes related to theft, abuse, neglect, or exploitation of a child or a vulnerable adult as defined in S.C. Code Section 43–35–10 et seq., for child or adult abuse, neglect or mistreatment, or a criminal offense similar in nature to the crimes listed in this subsection. The provider shall coordinate with appropriate abuse-related registries prior to the employment of staff or the contracting with or referral of caregivers to ensure compliance with this provision; and

7. Not have prior convictions or have pled no contest (nolo contendere) to crimes related to drugs within ten (10) years of providing in-home care to clients. The provider shall coordinate with appropriate abuse-related registries prior to the employment of staff or the contracting with or referral of caregivers to ensure compliance with this provision.

SECTION 400. HEALTH STATUS.

A. All staff members and caregivers who have contact with clients shall have a health assessment within twelve (12) months prior to initial client contact. The health assessment shall include tuberculosis screening in a manner prescribed in the Center for Disease Control and Prevention's and the Department's most current tuberculosis guidelines.

B. All in-home care providers shall conduct an annual tuberculosis risk assessment in the Appendix to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

SECTION 500. REPORTING.

501. Incidents

A. Serious incidents and/or any sudden or unexpected illness or staff member error resulting in death or inpatient hospitalization shall be reported immediately via telephone to the client's next-of-kin or responsible party.

B. A serious incident is one that results in death or a significant loss of function or damage to a body structure not related to the natural course of a client's illness or underlying condition and resulting from an incident that occurs during staff contact with clients. A serious incident shall be considered as, but is not limited to:

1. Falls or trauma resulting in fractures of major limbs or joints;
2. Client suicide;
3. Criminal events or assaults against clients which are reported and filed with the police; and/or
4. Allegations of client abuse, neglect, or exploitation, as defined in S.C. Code Section 43–35–5 et seq., by an employee.

C. The Department's Bureau of Health Facilities Licensing shall be notified in writing within three (3) days of the occurrence of a serious incident.

D. Reports submitted to the Department shall contain at a minimum: provider name, client age and sex, date of incident, location, witness name(s), extent and type of injury and how treated, for example, hospitalization, cause of incident, internal investigation results if applicable, identity of other agencies notified of incident and the date of any such report(s).

E. The provider shall report any allegation of abuse, neglect, or exploitation of clients to the Adult Protective Services Program in the Department of Social Services in accordance with S.C. Code Section 43–35–25, or Child Protective Services, as appropriate.

502. Provider Closure.

A. Prior to the temporary closure of a provider, the Department's Bureau of Health Facilities Licensing shall be notified, in writing, of the intent to close and the effective closure date. Within ten (10) business days prior to the closure, the provider shall notify the Department's Bureau of Health Facilities Licensing of provisions for the maintenance of records, identification of clients that will require transfer to another provider, and date of anticipated reopening. If the provider closes for a period longer than one year and there is a desire to reopen, the provider shall re-apply to the Department for licensure and shall be subject to all licensing requirements at the time of application as if for a new provider. In the event that the license expires during the period of temporary closure, the licensee shall submit a license renewal application and licensing fee on schedule as if the provider is operating.

B. Prior to permanent closure of a provider, the Bureau of Health Facilities Licensing shall be notified, in writing, of the intent to close and effective closure date. Within ten (10) business days prior to the closure, the provider shall notify the Bureau of Health Facilities Licensing of provisions for maintenance of the records, identification of clients that will require transfer to another provider, and dates and amounts of client refunds. On the date of closure, the provider shall return the license to the Department's Bureau of Health Facilities Licensing.

SECTION 600. SEVERABILITY.

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 700. GENERAL.

Conditions arising which have not been addressed in these regulations shall be managed in accordance with the best practices as determined by the Department. These regulations do not create a duty on the part of the State of South Carolina or the South Carolina Department of Health and Environmental Control independent or in addition to any other duty otherwise prescribed by law.

APPENDIX

Annual Tuberculosis Risk Assessment In-Home Care Providers

The Tuberculosis (TB) risk assessment worksheet of this appendix applies to Section 400.B of this regulation and shall be used in performing TB risk assessments for in-home care providers. Providers with more than one type of setting shall apply this worksheet to each setting.

Contact the Department of Health and Environmental Control's TB control program to obtain epidemiologic data necessary to conduct the TB risk assessment.

Provider: _____

Number of Clients: _____

Address: _____

Phone: _____ County: _____

Completed by: _____ Title: _____

Date completed: _____

Part A. Incidence of TB in the provider organization

1. Number of TB cases identified in provider staff, caregivers under contract or otherwise eligible for referral, and clients combined in the past year? (Check only one box)

☐ No cases within the last 12 months.

☐ Less than 3 cases identified in the past year.

☐ 3 or more cases identified in the past year.

☐ Evidence of ongoing *M. tuberculosis* transmission.

2. Number of TB cases identified in your County in the last year? _____

Information may be obtained from the TB Control section of the South Carolina Department of Health and Environmental Control's web site.

3. Number of TB cases identified in the State of South Carolina the last year? _____

Information may be obtained from the TB Control section of the South Carolina Department of Health and Environmental Control's web site.

Part B. TB Infection Control Procedure

☐ Yes ☐ No Are all new hires and caregivers newly contracted or newly eligible for referral screened for TB before initial client contact?

☐ Yes ☐ No Does the provider have a written procedure for managing confirmed or suspected TB cases? (See Section 400.A for the requirement of a written procedure.)

☐ Yes ☐ No Does the provider's procedure assure prompt detection and appropriate management of infectious persons, including prevention of further transmission of TB?

Part C. Assigning a Risk Classification (*check only one box*)

☐ If there have been no cases of TB identified in the provider in the past 12 months, this provider may be classified as LOW RISK.

☐ If there have been less than 3 cases of TB identified in the provider in the past 12 months, this provider may be classified as LOW RISK.

☐ If there have been 3 or more cases of TB identified in the provider in the past 12 months, this provider may be classified as MEDIUM RISK.

☐ There is evidence of ongoing *M. tuberculosis* transmission and the provider has reported the events to the County Health Department and appropriate measures have been implemented. *(This is a temporary classification only warranting immediate investigation. After the ongoing transmission has ceased, the setting will be reassessed for classification).*

This TB risk assessment is performed annually to assess and assign an appropriate risk classification.

Date of next TB Risk Assessment Review (annually) _____

Provider TB Risk Classification

Low Risk Setting	Low Risk TB Screening
Less than 3 TB cases/year (see Part A) **AND** No risk factors are present (See Part B)	• Baseline two step TST or single BAMT upon hire or contract/eligible for referral and prior to client contact. • If TST is positive or employee or caregiver is symptomatic, obtain chest X-

	ray and refer to Health Department for a symptom assessment and medical evaluation. • NO ANNUAL TST or BAMT required. • Perform/obtain annual symptom assessment if documented prior positive TST or has documentation of prior active TB disease. • Persons identified as a contact to an infectious case and having unprotected exposure will be evaluated in accordance with the Health Department's contact investigation policies and procedures.
Medium Risk Setting 3 or more TB cases/year (see Part A) **OR** Other risk factors apply (see Part B)	Medium Risk TB Screening • Baseline two step TST or single BAMT upon hire contract/eligible for referral and prior to client contact. • If TST is positive or employee or caregiver is symptomatic, obtain chest X-ray and refer to Health Department for a symptom assessment and medical evaluation. • Perform/obtain ANNUAL TB screening test (TST, BAMT or symptom assessment) for each employee and caregiver. • Perform/obtain annual symptom assessment if documented prior positive TST or has documentation of prior active TB disease treatment. • Persons identified as contact to an infectious case and having unprotected exposure will be evaluated in accordance with the Health Department's investigation policies and procedures.
Potential Ongoing Transmission Setting Evidence of ongoing *M. tuberculosis* transmission *This is a temporary classification only, warranting immediate investigation. After the ongoing transmission has*	Potential Ongoing Transmission TB Screening • Report to local health department immediately. • Persons identified as a contact to an infectious case and having unprotected exposure will be evaluated in accordance with the Health Department's contact investigation policies and procedures. • Baseline two-step TST for TB or single BAMT for any new hire or any caregiver newly contracted or newly eligible for referral and prior to client contact while in this category. • Consult and coordinate with the Health Department for guidance as to when transmission has ceased and

ceased, the setting will be reassessed for classification.	a new risk assessment can be completed.

Sample Indications for Two-Step Tuberculin Skin Testing - TST

Employee & Client TST Situation	Recommended TST Testing
1. No previous TST or BAMT result.	1. Two-step baseline TST or single BAMT completed upon hire or contract/eligible for referral and prior to client contact.
2. Previous negative TST or BAMT result > 12 months before new employment or contract/eligible for referral.	2. Two-step baseline TST or single BAMT completed upon hire or contract/eligible for referral and prior to client contact.
3. a. Previous documented negative TST result within 12 months before employment or contract/eligible for referral. b. Previous documented negative BAMT.	3. a. Single TST needed for baseline testing; this will be the second step. b. Single BAMT needed.
4. Previous documented positive TST result in millimeters.	4. No TST or BAMT; need TB symptom assessment.
5. Undocumented history of prior positive TST result.	5. Two-step baseline or single BAMT upon hire or contract/eligible for referral and prior to client contact.

HISTORY: Amended by State Register Volume 38, Issue No. 6, Doc. No. 4433, eff June 27, 2014; State Register Volume 38, Issue No. 7, Doc. No. 4433, eff July 25, 2014 (errata).

61–123. Critical Congenital Heart Defects Screening on Newborns.

(Statutory Authority: 1976 Code Section 44–37–70 et seq.)

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SECTION 200. Screening Criteria and Procedures.

SECTION 300. Religious Objection.

SECTION 100. Purpose and Scope; Definitions.

101. Purpose and Scope.

The purpose of this regulation is to provide requirements regarding screening of newborns for critical congenital heart defects. Congenital heart defects are the leading cause of infant death due to birth defects. Some critical congenital heart defects can cause severe and life-threatening symptoms that require intervention within the first days of life. Newborns with abnormal pulse oximetry screening results require immediate confirmatory testing and intervention. Many newborn lives potentially could be saved by earlier detection and treatment of congenital heart defects. The South Carolina Birth Outcomes Initiative, established by the Department of Health and Human Services to improve care and outcomes for mothers and newborns, has acknowledged the value of pulse oximetry screening of newborns, and under this initiative all South Carolina birthing hospitals have committed to implementing this screening for newborns. The American Academy of Pediatrics, the American College of Cardiology Foundation, and the American Heart Association recommend pulse oximetry screening for newborns.

102. Definitions.

A. Birthing facility. An inpatient or ambulatory health care facility licensed by the Department of Health and Environmental Control that provides birthing and newborn care services.

B. Department. The South Carolina Department of Health and Environmental Control.

C. Department Approved Screening. A critical congenital heart defects screening approved by the Department of Health and Environmental Control as an alternative to pulse oximetry screening based on standards set forth by the United States Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children, the American Heart Association, and the American Academy of Pediatrics.

D. Pulse Oximetry. Pulse oximetry is a noninvasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen.

SECTION 200. Screening Criteria and Procedures.

201. Screening Criteria.

Each birthing facility licensed by the Department shall perform on every newborn in its care a pulse oximetry or other Department approved screening to detect critical congenital heart defects when the baby is twenty-four (24) to forty-eight (48) hours of age, or as late as possible if the baby is discharged from the hospital before reaching twenty-four (24) hours of age.

202. Procedures.

A. When performing pulse oximetry screenings, licensed facilities shall use motion-tolerant pulse oximeters that report functional oxygen saturation, have been validated in low-perfusion conditions, have been cleared by the Food and Drug Administration (FDA) for use in newborns, and have a two percent root-mean-square accuracy. Any pulse oximeter used for screening shall meet FDA recommendations.

B. If reusable probes are utilized, licensed facilities shall appropriately clean the probes between uses to minimize the risk of infection. Pulse oximeters are validated only with the specific probes recommended by the manufacturer; therefore, to optimize valid screening, licensed facilities shall use only manufacturer-recommended pulse oximeter probe combinations.

C. Performing a pulse oximetry or Department approved screening does not replace a complete history and physical examination.

SECTION 300. Religious Objection.

If a parent or guardian of a newborn objects, in writing, to the screening, for reasons pertaining to religious beliefs only, the newborn is exempt from the screening required by Section 44–37–70 of the South Carolina Code of Laws of 1976, as amended.

HISTORY: Added by State Register Volume 38, Issue No. 6, Doc. No. 4429, eff June 27, 2014.

61–124. Consumer Electronic Equipment Collection and Recovery.

(Statutory Authority: 1976 Code Section 48–60–5 et seq.)

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A. Purpose and Scope; Applicability.

1. The South Carolina Manufacturer Responsibility and Consumer Convenience Information Technology Equipment Collection and Recovery Act (hereafter referred to as the Act), S.C. Code Section 48–60–5 et seq., establishes requirements for the sale, management and recovery of covered electronic devices, specifically for household computers, printers, monitors and televisions. The purpose of this regulation is to execute the provisions of the Act.

2. This regulation applies to the proper management of consumer computers, printers, monitors and televisions by the manufacturers, retailers, and recoverers of these devices.

3. A manufacturer of a covered device that sells five hundred or fewer such devices in the State per year is exempt from registration, penalty, or shortfall fees proposed in this chapter. However, should a manufacturer that is exempt from registration choose to be included on the Department's webpage list of manufacturers with compliant consumer electronic device stewardship programs, then the manufacturer shall provide details of their program for the previous year.

B. Definitions.

1. "Act" means the South Carolina Manufacturer Responsibility and Consumer Convenience Information Technology Equipment Collection and Recovery Act of 2010.

2. "Collect" or "collection" means to facilitate the delivery of a covered device to a collection site included in a manufacturer's consumer electronic device stewardship program and to transport the covered device for recovery.

3. "A computer manufacturer" means a person who:

a. Manufactures a covered computer device under its own brand for sale or without affixing a brand;

b. Sells in this State a covered computer device produced by another supplier under its own brand or label;

c. Imports covered computer devices; provided that if a company from which an importer purchases a covered computer device has a presence or assets in the United States, that company must be considered the manufacturer; or

d. Manufactures a covered computer device, supplies a covered computer device to a person within a distribution network that includes wholesalers or retailers in this State, and benefits from the sale of a covered device through that distribution network.

4. "A computer monitor manufacturer" means a person who:

a. Manufactures a covered computer monitor device under its own brand for sale or without affixing a brand;

b. Sells in this State a covered computer monitor device produced by another supplier under its own brand or label;

c. Imports covered computer monitor devices; provided that if a company from which an importer purchases a covered computer monitor device has a presence or assets in the United States, that company must be considered the manufacturer; or

d. Manufactures a covered computer monitor device, supplies a covered computer monitor device to a person within a distribution network that includes wholesalers or retailers in this State, and benefits from the sale of a covered device through that distribution network.

5. "Consumer" means an occupant of a single detached dwelling unit or a single unit of a multiple dwelling unit who has used a covered device primarily for personal or home business use.

6. "Consolidate" means to gather for transport or storage covered devices prior to delivery to a recovery or recycling facility. Consolidation programs may include, but are not limited to, local government programs, private collection networks, and other forms of collection associated with consumer electronic device stewardship programs.

7. "Covered computer device" means a desktop, laptop or notebook computer or a printing device marketed and intended for use by a consumer, but does not include a covered television device. An integrated all-in-one unit, containing both a display greater than thirteen inches, and a computer, is considered a covered computer device for the purposes of this regulation.

8. "Covered computer monitor device" means a display device typically manufactured without an internal tuner that can display pictures and sound and is designed for use with a desktop computer.

9. "Covered devices" means a covered computer device, a covered computer monitor device and a covered television device marketed and intended for use by a consumer. "Covered device," "covered computer device," "covered computer monitor device" and "covered television device" do not include any of the following:

a. A covered device that is a part of a motor vehicle or a component part of a motor vehicle assembled by, or for, a vehicle manufacturer or franchised dealer, including replacement parts for use in a motor vehicle;

b. A covered device that is functionally or physically a part of, or connected to, or integrated within equipment or a system designed and intended for use in an industrial, governmental, commercial, research and development, or medical setting, including, but not limited to, diagnostic, monitoring, control or medical products as defined under the federal Food, Drug, and Cosmetic Act, or equipment used for security, sensing, monitoring, antiterrorism, or emergency services purposes or equipment designed and intended primarily for use by professional users;

c. A covered device that is contained within a clothes washer, clothes dryer, refrigerator, refrigerator and freezer, microwave oven, conventional oven or range, dishwasher, room air conditioner, dehumidifier, air purifier, water heater, or exercise equipment;

d. Telephones of any type, including but not limited to mobile telephones, a personal digital assistant (PDA), a global positioning system (GPS), or a hand-held gaming device; or

e. A plastic, wood or composite case that once held a covered device or was a subassembly of a covered device but is void of any electronics, leaded glass or metal electronic components.

10. "Covered television device" means any electronic device that contains a tuner that locks on to a selected carrier frequency and is capable of receiving and displaying television or video programming via broadcast, cable, or satellite, including, but not limited to, a direct view or projection television with a viewable screen of nine inches or larger whose display technology is based on cathode ray tube, plasma, liquid crystal display, digital light processing, liquid crystal on silicon, silicon crystal reflective display, light emitting diode, or similar technology marketed and intended for use by a consumer primarily for personal purposes. The term does not include a covered computer device.

11. "Department" means the South Carolina Department of Health and Environmental Control (DHEC).

12. "Individual Recycling Obligation" means:

a. The total weight in pounds of covered television and computer monitor devices that a television or computer monitor manufacturer participating in Section I is required to recycle, recover, or pay the cost for recovery, during a program year; or

b. The coverage obligation as determined by the representative organization for a member manufacturer pursuant to Section J to recycle, recover, or pay the cost for recovery during a program year.

13. "Manufacturer's brands" means a manufacturer's name, brand name either owned or licensed by the manufacturer, or brand logo for which the manufacturer has legal responsibility.

14. "Market share" means the total weight of a manufacturer's televisions or computer monitors that were sold at retail in the United States to individuals during the previous program year, multiplied by the population fraction of South Carolina to the United States population, based on the most recent United States Census data, divided by the weight of all of the televisions or computer monitors that were sold at retail to individuals in the State during the previous year.

15. "Printing device" means a desktop printer that prints on paper and is designed for use with a desktop or portable computer. The term includes, but is not limited to, a daisy wheel, dot matrix, inkjet or laser printer. The term includes devices that perform other functions in addition to printing such as copying, scanning or transmitting a facsimile, but does not include free-standing devices that

are primarily copiers or facsimile machines used independently of desktop or portable computers. The term does not include floor-standing printers, small household printers such as a calculator with printing capabilities or label makers, or printing devices that are embedded into products that are not covered computer devices.

16. "Program year" means the calendar year.

17. "Person" means an individual, business entity, partnership, limited liability company, corporation, not-for-profit corporation, association, government entity, public benefit corporation, or public authority.

18. "Recover" means to reuse or recycle.

19. "Recoverer" means a person that reuses or recycles a covered device.

20. "Repairer" means a person or entity that primarily replaces broken or malfunctioning parts or refurbishes and upgrades covered devices primarily for resale or reuse but does not disassemble covered devices beyond their subassembly components for the purpose of recovering metals, glass or plastics.

21. "Representative organization" means an organization created to develop and oversee implementation of a statewide plan consisting of one or more consumer electronic device stewardship programs, both in the State and in other jurisdictions that authorize such a representative organization.

22. "Retail sale" means the sale of a new product through a sales outlet, the Internet, mail order or otherwise, whether or not the seller has a physical presence in this State. A retail sale includes the sale of new products.

23. "Retailer" means a person engaged in retail sales.

24. "Sale" or "sell" means a transfer for consideration of title including, but not limited to, transactions conducted through sales outlets, catalogs, or the Internet, or any other similar electronic means, but does not mean leases.

25. "Shortfall fee" means a fee due to the Department from the manufacturer of a covered television device or computer monitor device that fails to achieve its individual recycling obligation for a given program year.

26. "Subassemblies" means pieces of a covered device that have been disconnected by breakage or removed during disassembly of the device. It does not refer to a keyboard, mouse, speaker or other peripheral device or to parts of covered devices that are void of any electronics, leaded glass, or metal electronic components.

27. "Television" means any electronic device that contains a tuner that locks on to a selected carrier frequency and is capable of receiving and displaying television or video programming via broadcast, cable, or satellite, including, but not limited to, a direct view or projection television with a viewable screen of nine inches or larger whose display technology is based on cathode ray tube, plasma, liquid crystal display, digital light processing, liquid crystal on silicon, silicon crystal reflective display, light emitting diode, or similar technology marketed and intended for use by a consumer primarily for personal purposes. The term does not include a covered computer device.

28. "Television manufacturer" means a person who:

a. Manufactures covered television devices under a brand that it licenses or owns, for sale in this State;

b. Manufactures covered television devices without affixing a brand for sale in this State;

c. Resells into this State a covered television device under a brand it owns or licenses produced by other suppliers, including retail establishments that sell covered television devices under a brand the retailer owns or licenses;

d. Imports covered television devices; provided that if a company from which an importer purchases a covered device has a presence or assets in the United States, that company must be considered the manufacturer;

e. Manufactures covered television devices, supplies them to a person or persons within a distribution network that includes wholesalers or retailers in this State, and benefits from the sale in this State of those covered television devices through the distribution network; or

f. Assumes the responsibilities and obligations of a television manufacturer under this chapter. If the television manufacturer is one who manufactures, sells, or resells under a brand it licenses, the licensor or brand owner of the brand must not be included in the definition of television manufacturer under items 28 a. or c.

C. Audits, Inspection and Recordkeeping.

1. The Department or its representatives may conduct audits and inspection of covered device manufacturers, retailers and recoverers to determine compliance with State law and this regulation.

2. Records necessary to determine compliance with this regulation must be maintained for a period of not less than three years and made available for inspection by Department personnel upon request.

3. No manufacturer shall report or claim the weight of covered devices collected from consumers outside of the borders of the State for the purposes of meeting recycling obligations within the State.

D. Manufacturer's Labels and Retailer Sale Requirements.

1. A computer, computer monitor, or television manufacturer may not sell or offer to sell a covered device unless a label indicating the computer, computer monitor, or television manufacturer's brand is permanently affixed to the covered device in a readily visible location.

2. A retailer only may sell or offer to sell a covered device that:

a. Bears a manufacturer label as provided in Section D. 1; and

b. Is manufactured by a manufacturer that offers a consumer electronic device stewardship program as provided in Sections G, I or K of this regulation.

3. The requirements of this section do not apply to a television sold by a retailer for less than one hundred dollars.

4. A retailer is not responsible for an unlawful sale if the manufacturer's compliance status expired or was revoked and the retailer took possession of the covered device prior to the expiration or revocation of the manufacturer's compliance status and the unlawful sale occurred within six months after the expiration or revocation.

E. Disposal Prohibition for Covered Devices.

1. A consumer must not knowingly place or discard a covered device or subassemblies of a covered device containing any electronics, leaded glass or metal electronic components in a waste stream that is to be disposed of in a solid waste landfill.

2. An owner or operator of a solid waste landfill must not, at the gate, knowingly accept, for disposal, loads containing more than an incidental amount of covered devices.

3. The owner or operator of a solid waste transfer station or landfill must post, in a conspicuous location, a sign informing the public that covered devices or any components of covered devices containing any electronics, leaded glass or metal electronic components are not accepted for disposal at the landfill.

F. Standards for Management of Covered Devices.

1. Covered devices must be recovered in a manner that complies with all applicable federal, state, and local requirements.

2. Recovery of covered devices should be performed in a manner that utilizes consolidation and management practices of the industry, to include but not limited to:

a. Unattended or unsecured drop-off of covered devices shall be allowed when instruction is provided to the public to prevent mishandling and breakage of covered devices;

b. Storage areas or containers utilized for the recovery of covered devices are reasonably protected from weather with tarps or other suitable means to prevent accumulation of water within storage containers during periods of rain;

c. Covered devices shall be handled and stored in such a way as to minimize breakage;

d. Debris from broken covered devices shall be cleaned up immediately and managed appropriately;

e. Covered devices shall be transported in manner that minimizes breakage and prevents contents from being ejected onto roads and highways; and

f. Shipping containers shall be labeled clearly to identify the type of material enclosed.

3. Covered devices shall not be disassembled, dismantled, shredded, transformed, or demanufactured, unless the practice provides a safer working environment for employees such as the removal of power cords and cables to prevent trips and falls, and the practice is communicated to the recoverer in advance, prior to the delivery of all the parts to a certified recoverer.

4. Residential recovery programs of local governments and manufacturer stewardship programs shall assure that all covered devices are transported to recycling or recovery facilities that are currently certified by an acceptable program such as Responsible Recycling (R)(2) Practices, e-Stewards, or other certification program recognized by the Department or the United States Environmental Protection Agency.

5. Covered television and computer monitor devices, or subassemblies containing any electronics, leaded glass or metal electronic components of such covered devices, collected from residential recovery programs must not knowingly be placed or discarded in a waste stream that is to be disposed of in a solid waste landfill.

6. Repairers and refurbishers of covered devices are exempt from registration, reporting, and recordkeeping requirements so long as all non-reusable parts containing any electronics, leaded glass or metal electronic components are transported to recycling or recovery facilities that are currently certified by an acceptable program such as Responsible Recycling (R)(2) Practices, e-Stewards, or other certification program recognized by the Department or the United States Environmental Protection Agency.

7. Local governments that receive recycling services from a consumer electronic device stewardship program participating in a representative organization must not charge the representative organization for collection costs and shall offer the representative organization all covered devices consolidated by a participating local government at no cost.

G. Requirements for Manufacturers of Computers, Printers, and other Computer Devices.

1. A manufacturer may not sell or offer to sell in this State a covered computer device unless the manufacturer provides a consumer electronic device stewardship program at no charge or provides a financial incentive of equal or greater value, such as a coupon. A consumer electronic device stewardship program must:

a. Require a computer device manufacturer to offer to collect from a consumer a covered computer device bearing a label as provided in Section D; and

b. Make the collection service as convenient to a consumer as the purchase of a covered computer device from a computer manufacturer as follows:

(1) A computer device manufacturer may utilize a mail-back system in which a consumer can return an end-of-life covered device by mail, including a system in which a consumer can go online, print a prepaid shipping label, package the product, and affix the prepaid label to the package for deposit with the United States Postal Service or other carrier selected by the manufacturer.

(2) If the computer device manufacturer does not provide a mail-back system, the manufacturer must provide collection sites or collection events, or both, that are centrally located in a county, region, or other locations based on population. Manufacturers of computer devices shall work in coordination with the Department to determine an appropriate number of collection sites or collection events, or both.

2. At the beginning of each program year and no later than February 15 of a program year, a manufacturer of a computer device that sells more than five hundred devices in the State per year, must register with the Department and pay a registration fee in the amount as prescribed by the Act.

3. A consumer electronic device stewardship program may use existing consolidation infrastructure for recovering covered devices, including retailers, recyclers, reuse organizations, private networks and local governments.

4. Manufacturers of computer devices may work collectively and cooperatively with other manufacturers to offer collection services to consumers.

5. A consumer electronic device stewardship program must be described on a computer device manufacturer's Internet website if a manufacturer maintains an Internet website.

6. Collection events under this section must accept any covered computer device regardless of brand.

H. Requirements for Manufacturers of Covered Televisions or Computer Monitors.

1. No television manufacturer or computer monitor manufacturer shall sell or offer for sale a covered television device or covered computer monitor device in this State unless the television manufacturer or computer monitor manufacturer provides a consumer electronic device stewardship program at no charge or provides a financial incentive of equal or greater value, such as a coupon.

2. A television manufacturer or computer monitor manufacturer may fulfill the requirements of this regulation either individually or in participation with other manufacturers, or through a representative organization. A consumer electronic device stewardship program may use existing consolidation infrastructure for recovering covered television or covered computer monitor devices, including retailers, recyclers, reuse organizations, private networks and local governments.

3. By January 1, 2015, and by February 15, annually thereafter, a television manufacturer or computer monitor manufacturer that sold more than five hundred covered devices in South Carolina during the prior calendar year shall register with the Department. The manufacturer shall:

a. Notify the Department that they intend to participate in a representative organization and identify the representative organization they will join for the program year, or notify the Department of its intent to fulfill its obligations under this chapter by implementing their own consumer electronic device stewardship program that meets the requirements of Section I of this regulation.

b. Provide the Department with contact information for the manufacturer's designated agent or employee whom the Department may contact for information related to the manufacturer's compliance with the requirements of this regulation.

I. Consumer Electronic Device Stewardship Programs for Manufacturers Not Participating in a Representative Organization.

1. If a television or computer monitor manufacturer does not participate in a representative organization, the manufacturer annually shall recycle or arrange for the recycling of covered television devices and covered computer monitor devices in the amount of eighty percent of the weight of the covered devices sold by the manufacturer in the State during the previous program year.

2. A manufacturer shall pay an annual registration fee in the amount as prescribed by the Act. A manufacturer that produces computer monitors, computers, or televisions is required to pay only one annual registration fee, unless exempt from fees as described in Section A.4 of this regulation. Upon registration the manufacturer shall provide the Department with a statement that all recycling or recovery facilities used by their recoverers as part of their South Carolina consumer electronic device stewardship program are currently certified by an acceptable program such as Responsible Recycling (R)(2) Practices, e-Stewards or other certification program recognized by the Department or the United States Environmental Protection Agency.

3. By February 15 of each program year, a television or computer monitor manufacturer shall submit an annual report to the Department. The annual report shall include:

a. The estimated total weight of the manufacturer's covered television devices or covered computer monitor devices sold at retail in the United States or in this State, if the information is available, for the previous program year;

b. The total weight of covered devices collected and recycled and listed by county of the State during the previous program year;

c. Any recovered weight exceedance credits earned, redeemed, sold or purchased from other manufacturers in the previous year along with the names of those manufacturers, the county of origin for the material, and dates of transactions.

4. Recovery exceedance credits may be earned by exceeding the individual recycling obligation for the program year. A manufacturer may also notify the Department of their intent to sell or transfer exceedance credits of recovery to another manufacturer along with the weight and county of origin from which the covered devices were consolidated. Exceedance credits earned for a program year shall be valid for three years.

5. The year-to-date recovery amounts for material recovered state-wide shall be readily available for Department review during the program year and at most quarterly and within thirty days of request by the Department.

6. A manufacturer of a covered television device or covered computer monitor device with a consumer electronic device stewardship program pursuant to Section I that fails to meet its individual recycling obligation for the previous program year as outlined in this regulation may elect to:

a. Pay a shortfall fee as determined by the Department; or

b. Account for the amount of the shortfall in the following year. A manufacturer electing to account for the amount of a shortfall in the following year only may elect this option once every three years.

7. The shortfall fee for manufacturers not participating in a representative organization is calculated as follows:

a. If the manufacturer of a covered television or computer monitor device recycles at least ninety percent, but less than one hundred percent of its individual recycling obligation, the shortfall fee is thirty cents multiplied by the number of additional pounds that should have been recycled in order for the manufacturer to have met its individual recycling obligation.

b. If the manufacturer of a covered television or computer monitor device recycles at least fifty percent, but less than ninety percent of its individual recycling obligation, the shortfall fee is forty cents multiplied by the number of additional pounds that should have been recycled in order for the manufacturer to have met its individual recycling obligation.

c. If the manufacturer of a covered television or computer monitor device recycles less than fifty percent of its individual recycling obligation, the shortfall fee is fifty cents multiplied by the number of additional pounds that should have been recycled in order for the manufacturer to have met its individual recycling obligation.

J. Responsibilities of Manufacturers Participating in a Representative Organization.

1. No later than February 15 each program year, a television or computer monitor manufacturer participating in a representative organization shall submit to the Department an annual report unless a representative organization will report on behalf of the manufacturer. The report shall include, but not be limited to, the following:

a. The best available market share data for participating manufacturers available on September 1 of the previous year;

b. The estimated total weight of the manufacturer's covered television devices or covered computer monitor devices sold at retail in the United States or in this State, if the information is available, for the previous program year;

c. The total weight of covered devices collected and recycled, listed by county of origin during the previous program year;

d. A statement of assurance that all recycling or recovery facilities used by the manufacturer as part of their consumer electronic device stewardship program are currently certified by an acceptable program such as Responsible Recycling (R)(2) Practices, e-Stewards or other certification program recognized by the Department or the United States Environmental Protection Agency; and

e. A description of any individual recycling obligation for which the participating manufacturer was deficient in the previous year.

2. A manufacturer that participates in an approved representative organization is not required to pay an annual registration fee to the Department for the program year of participation with the representative organization.

3. A manufacturer that fails to meet an individual recycling obligation as assigned by a representative organization shall either submit a plan for increasing the recycling obligation in the coming year by the amount of the deficiency or pay a shortfall fee based on the shortfall as calculated by the representative organization for the previous program year. A manufacturer may elect to account for the shortfall in the next program year but only may elect this option once every three years.

4. The shortfall fee for manufacturers participating in a representative organization is calculated as follows:

a. If the manufacturer of a covered television or computer monitor device fulfills at least ninety percent, but less than one hundred percent of its individual recycling obligation, the shortfall fee is thirty cents multiplied by the number of additional pounds that should have been recycled in order for the manufacturer to have met its individual recycling obligation.

b. If the manufacturer of a covered television or computer monitor device fulfills at least fifty percent, but less than ninety percent of its individual recycling obligation, the shortfall fee is forty cents multiplied by the number of additional pounds that should have been recycled in order for the manufacturer to have met its individual recycling obligation.

c. If the manufacturer of a covered television or computer monitor device fulfills less than fifty percent of its individual recycling obligation, the shortfall fee is fifty cents multiplied by the number of additional pounds that should have been recycled in order for the manufacturer to have met its individual recycling obligation.

5. A television manufacturer or computer monitor manufacturer participating in a representative organization with an approved consumer electronic device stewardship program that falls below seventy-five percent of its obligation, as determined by a representative organization at the end of the program year, is ineligible to participate in the consumer electronic device stewardship program the following year and shall implement a consumer electronic device stewardship program as described in Section I.

6. Any manufacturer that is denied participation in a representative organization shall implement a consumer electronic device stewardship program as described in Section I.

K. Requirements for Representative Organizations.

1. By February 15 of each year, the representative organization shall submit the final roster of manufacturers, local governments, private networks and participating companies for the program year with any deletions, additions, and updates from previously approved plans summarized for Department review.

2. By February 15 of each year, the representative organization shall submit a final report summarizing the activities of the previous program year for all of the manufacturers and private collection networks participating in the representative organization unless the members of the representative organization opt to provide annual reports individually. The report shall include:

a. A description of the methods used to collect, transport, and process covered devices from residential consumers in the State;

b. The results of a survey of county and municipal recycling representatives concerning the availability of opportunities for consumers to recycle covered electronic devices;

c. An accounting of the weight of covered devices collected, reported by county of origin for consolidation, including the weight of covered television and computer monitor devices contributed through all sources, including private collection networks;

d. A description of services provided to each of the local government participants including, but not limited to, collection event services and the number and location of collection locations used during the prior year, and logistical support for preparing the consolidated devices for transportation offsite;

e. A list of manufacturers, as determined by the representative organization, failing to meet their recycling obligation as assigned by the representative organization and any shortfall penalties, pursuant to Section 48–60–160 of the Act. The report shall summarize the contributions of each manufacturer participating in the plan. Any participants that failed to meet their obligations shall be listed in the final report along with any shortfall as calculated by the representative organization, or any expulsions from the plan for manufacturers that contributed less than seventy-five percent of their obligation; and

f. A description of services in counties with three percent or less of the total population of the State. If the services provided within these jurisdictions is disproportionate to the other services provided for counties with populations above three percent of the State's total population, the representative organization must provide the Department an explanation of these differences.

3. Not later than October 1 of each year, a representative organization shall submit an annual plan for a consumer electronic device stewardship program. The plan shall:

a. List the local governments for which ongoing collection services will be provided. In determining the number and composition of local governments to include in the plan, the representative organization shall target a percentage of the State population that is approximately equal to the combined market share percentage of all of the manufacturers participating in the representative organization. The Department may consider a local government's election to either participate or not participate in a consumer electronic device stewardship program, and any other circumstances or factors the representative organization provides regarding their determination of the appropriate State population percentage and counties to be serviced for the program year;

b. Provide a description of incentives to ensure convenient mechanisms to collect used consumer electronic devices throughout the State. These incentives may include private collection networks and a description of how they lessen the burden and expense for local government collection and increase recycling opportunities by providing additional convenience to consumers across the State. The Department may consider the regional coverage, volume of historical collection from private networks, and the projected success of new private collection networks during plan evaluation;

c. Describe projected collection events, if any, that will be used to augment collection in a. or b. above, to increase recycling opportunities and provide additional convenience to consumers in less populated counties;

d. Describe specifically the elements of the plan that provide service to counties with less than three percent of the State's population and to counties with less than one percent of the State's population;

e. Calculate the sum total of weight from all sources of consumer covered television and computer monitor devices encompassed in the plan for the previous program year and the projected weight from new sources in the plan to illustrate the scale of projected recycling activities anticipated by participating manufacturers in the new program year;

f. Address how its members will ensure continuous service to local governments and other sources specified in the annual plan, throughout the program year, to recover all covered television and computer monitor devices of the participants in the plan; and

g. Establish fair and reasonable policies for administration of the plan.

4. The plan shall include:

a. A point of contact for the organization, including email and phone number;

b. An identification of each manufacturer participating in the consumer electronic device stewardship program included in the representative organization plan and the brands of consumer electronic devices sold in the State that are covered by the program;

c. An identification of each local government participating in the consumer electronic device stewardship program included in the representative organization plan, including a list of projected consolidation locations and projected collection events to be made available to consumers and the phone number and email address for the principal person to contact for the local government;

d. An identification of each private collection network participating in the consumer electronic device stewardship program along with the historic data of television devices and monitor devices consolidated by each private network in the previous program year, and a list of projected consolidation locations and projected collection events to be made available to consumers, along with the phone number and email address for the principal person to contact for the private collection network;

e. A description of how collection service to be provided to local residents by any private consolidator or private network included in the plan supplement and relieve collection and recycling burden of local governments through a level of service that may approach or be equivalent to service provided by local governments;

f. A description of how the organization will provide consumers with information and educational materials regarding the consumer electronic device stewardship program to promote the recycling and reuse of covered television devices and covered computer monitor devices;

g. A description of how the organization will achieve environmentally sound management for covered television devices and covered computer monitor devices that are collected for reuse and recycling;

h. A description of the participation requirements for manufacturers, and penalties for failure to comply with the plan, including the process for excluding manufacturers from participating in the organization;

i. Documentation of how the collection component of the plan was developed with input from local government recycling representatives and other stakeholders;

j. A description of incentives and directives to ensure convenient mechanisms to collect covered devices from consumers throughout the state and throughout the program year;

k. Provide a statement that all recycling or recovery facilities used by their member manufacturers' recoverers as part of their South Carolina consumer electronic device stewardship program are currently certified by an acceptable program such as Responsible Recycling (R)(2) Practices, e-Stewards or other certification program recognized by the Department or the United States Environmental Protection Agency;

l. An explanation of why a disruption of commercial activity that may arise from implementation of the plan is consistent with fulfilling the intent of this regulation and provide sufficient information to allow the Department to confirm the consistency of the plan with this regulation by review of the plan's financial and operational elements; and, if applicable,

m. A summary of any corrections or additions made to the final report for the previous program year.

5. A representative organization shall be prepared to confer with the Department and local government stakeholders involved in the representative organization plan at least quarterly to address compliance, efficiency, and management practices for implementing the representative organization's plan, and to report year-to-date recovery amounts, at most quarterly, to the Department within thirty days of such request.

L. Representative Organization Plan Approvals and Implementation.

1. Not later than thirty calendar days after submission of the plan pursuant to Section K, the Department shall approve the plan for the establishment of a consumer electronic device stewardship program by the submitting representative organization if it meets the requirements of Section K.

2. If the Department finds activities included in the plan that do not fulfill those requirements, it shall specify in writing what the Department believes to be the plan's deficiencies, promptly meet with the representative organization to discuss the Department's concerns, and allow the representative organization at least thirty days after the denial notice to submit a revised plan. If a revised plan is submitted, the Department shall review and approve or disapprove the plan within thirty calendar days of submission.

3. Upon approval of a representative organization plan by the Department, a representative organization shall pay a registration fee in the amount as prescribed by the Act.

M. Recoverer Requirements.

1. Covered devices must be managed in a manner that complies with all federal, state, and local requirements, and shall not be stored for more than one year at a facility.

2. No recoverer shall accept covered devices unless the recoverer can document they are currently certified by an acceptable program such as Responsible Recycling (R)(2) Practices, e-Stewards, or other certification program recognized by the Department or the United States Environmental Protection Agency.

3. All recoverers must maintain records of the weight and county of origin of the covered devices they accept for recycling. This information must be provided to the Department in a report no later than February 15 of each program year.

4. All recoverers that store, consolidate or process covered devices in the State, must register with the Department the locations of all storage and processing activities.

5. Recoverers shall comply with the following registration requirements:

a. The registrant must provide the Department with the address of the processing or storage location(s) along with a contact name, phone number, and e-mail address.

b. A recoverer must provide, for each storage, consolidation, or processing location, adequate financial assurance to cover third party removal of all covered devices or waste material from the facility.

c. The financial assurance shall be issued in favor of the Department and shall consist of one or more of the following mechanisms: surety bond, irrevocable letter of credit, insurance, trust fund, corporate financial test, or other evidence of financial responsibility assurance approved by the Department.

d. The financial mechanism(s) and amount must be approved by the Department and the approved financial assurance mechanism submitted prior to beginning storage or processing operations.

e. The registrant shall provide continuous coverage for closure until released from financial assurance requirements by the Department.

f. Upon closing the storage, consolidation, or processing facility, the registrant shall request that the Department inspect the facility to ensure removal of all covered devices and waste. Upon Department approval, the registrant shall be released from financial assurance requirements.

N. Violations and Penalties. Any person who fails to comply with a requirement of S.C. Code Section 48–60–05 et seq. is subject to a civil penalty not to exceed one thousand dollars per violation.

O. Severability. Should any section, paragraph, sentence, word, clause or phrase of this regulation be declared unconstitutional or invalid for any reason, the remainder of this regulation shall not be affected thereby.

P. Repeal of Regulation. This regulation, except for the provisions of Section E, shall be repealed effective December 31, 2021.

State Register Volume 40, Issue No. 2, Doc. No. 4539, eff February 26, 2016.

61–125. Standards for Licensing Crisis Stabilization Unit Facilities.

(Statutory Authority: 1976 Code Section 44–7–260)

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SECTION 100 - DEFINITIONS AND LICENSURE

101. Definitions.

For the purpose of this regulation, the following definitions shall apply:

A. Abuse. Physical abuse or psychological abuse.

1. Physical Abuse. The act of intentionally inflicting or allowing infliction of physical injury on a patient by an act or failure to act. Physical abuse includes, but is not limited to, slapping, hitting, kicking, biting, choking, pinching, burning, actual or attempted sexual battery, use of medication outside the standards of reasonable medical practice for the purpose of controlling behavior, and unreasonable confinement. Physical abuse also includes the use of a restrictive or physically intrusive procedure to control behavior for the purpose of punishment except that of a therapeutic procedure prescribed by a licensed physician or other legally authorized healthcare professional. Physical abuse does not include altercations or acts of assault between patients.

2. Psychological Abuse. The deliberate use of any oral, written, or gestured language or depiction that includes disparaging or derogatory terms to a patient or within the patient's hearing distance, regardless of the patient's age, ability to comprehend, or disability, including threats or harassment or other forms of intimidating behavior causing fear, humiliation, degradation, agitation, confusion, or other forms of serious emotional distress.

B. Administrator. The staff member designated by the licensee to have the authority and responsibility to manage the facility, and is in charge of all functions and activities of the facility.

C. Adult. A person eighteen (18) years of age or older.

D. Annual. A time period that requires an activity to be performed at least every twelve to thirteen (12 to 13) months.

E. Assessment. A procedure for determining the nature and extent of the problems and needs of a patient or potential patient to ascertain if the facility can adequately address those problems, meet those needs, and to secure information for use in the development of the individual plan of care ("IPC").

F. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina as a physician, advanced practice registered nurse, or physician assistant to provide specific treatments, care, or services to patients.

G. Blood Assay for *Mycobacterium tuberculosis* ("BAMT"). A general term to refer to *in vitro* diagnostic tests that assess for the presence of tuberculosis ("TB") infection with *M. tuberculosis*. This term includes, but is not limited to, IFN-γ release assays ("IGRA").

H. Contact Investigation. Procedures that occur when a case of infectious TB is identified, including finding persons (contacts) exposed to the case, testing and evaluation of contacts to identify Latent TB Infection ("LTBI") or TB disease, and treatment of these persons, as indicated.

I. Controlled Substance. A medication or other substance included in Schedule I, II, III, IV, and V of the Federal Controlled Substances Act or the South Carolina Controlled Substances Act.

J. Consultation. A visit by Department representatives who will provide information to the licensee with the goal of facilitating compliance with these regulations.

K. Crisis Stabilization Unit Facility ("CSU"). A facility, other than a health care facility, operated by the Department of Mental Health, or operated in partnership with the Department of Mental Health that provides a short-term residential program, offering psychiatric stabilization services and brief, intensive crisis services to individuals eighteen (18) years of age or older, twenty-four (24) hours a day, seven (7) days a week.

L. Department. The S.C. Department of Health and Environmental Control ("DHEC").

M. Designee. A staff member designated by the administrator to act on his or her behalf.

N. Direct Care Staff. Those individuals who are employees (full- and part-time) of the facility who provide direct treatment, care, and services to patients, and those individuals contracted to provide treatment, care, and services to patients.

O. Discharge. The point at which treatment, care, and services in a facility are terminated and the facility no longer maintains active responsibility for the treatment, care, and services of the patient.

P. Dispensing Medication. The transfer of possession of one (1) or more doses of a medication or device by a licensed pharmacist or individual as permitted by law, to the ultimate user or his or her agent pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by a patient.

Q. Elopement. An instance when a patient who is physically, mentally, or chemically impaired wanders, walks, runs away, escapes, or otherwise leaves the CSU unsupervised or unnoticed.

R. Exploitation. 1) Causing or requiring a patient to engage in an activity or labor that is improper, unlawful, or against the reasonable and rational wishes of a patient. Exploitation does not include requiring a patient to participate in an activity or labor that is a part of a written individual plan of care or prescribed or authorized by the patient's attending physician; 2) an improper, unlawful, or unauthorized use of the funds, assets, property, power of attorney, guardianship, or conservatorship of a patient by an individual for the profit or advantage of that individual or another individual; or 3) causing a patient to purchase goods or services for the profit or advantage of the seller or another individual through undue influence, harassment, duress, force, coercion, or swindling by overreaching, cheating, or defrauding the patient through cunning arts or devices that delude the patient and cause him or her to lose money or other property.

S. Facility. A Crisis Stabilization Unit Facility licensed by the Department.

T. Health Assessment. An evaluation of the health status of a staff member or volunteer by a physician, other authorized healthcare provider, or registered nurse, pursuant to written standing orders and protocol approved by a physician's signature. The standing orders and protocol shall be reviewed annually by the physician, with a copy maintained at the facility.

U. Incident. An unusual unexpected adverse event in the facility or on facility grounds, including any accidents, that could potentially cause harm, injury, or death to patients or staff members.

V. Individual Plan of Care ("IPC"). A documented regimen of appropriate care and services or written action plan prepared by the facility for each patient based on the patient's needs and preferences to be implemented for the benefit of the patient.

W. Inspection. A visit by Department representatives for the purpose of determining compliance with this regulation.

X. Investigation. A visit by Department representatives to a licensed or unlicensed entity for the purpose of determining the validity of allegations received by the Department relating to statutory and regulatory compliance.

Y. Latent TB Infection ("LTBI"). Infection with *M. tuberculosis*. Persons with Latent TB Infection carry the organism that causes TB but do not have TB disease, are asymptomatic, and are noninfectious. Such persons usually have a positive reaction to the tuberculin skin test and/or positive BAMT.

Z. Legend Drug.

1. A drug when, under federal law, is required, prior to being dispensed or delivered, to be labeled with any of the following statements:

a. "Caution: Federal law prohibits dispensing without prescription";

b. "Rx only" or;

2. A drug which is required by any applicable federal or state law to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only;

3. Any drug products considered to be a public health threat, after notice and public hearing as designated by the S.C. Board of Pharmacy; or

4. Any prescribed compounded prescription drug within the meaning of the S.C. Pharmacy Practice Act.

AA. License. The authorization to operate a facility as defined in this regulation and as evidenced by a current certificate issued by the Department to a facility.

BB. Licensed Nurse. A person to whom the S.C. Board of Nursing has issued a license as a registered nurse or licensed practical nurse or an individual licensed as a registered nurse or licensed practical nurse who resides in another state that has been granted multi-state licensing privileges by the S.C. Board of Nursing may practice nursing in any facility or activity licensed by the Department subject to the provisions and conditions as indicated in the Nurse Licensure Compact Act.

CC. Licensee. The individual, corporation, organization, or public entity that has received a license to provide care and services at a facility and with whom rests the ultimate responsibility for compliance with this regulation.

DD. Medication. A substance that has therapeutic effects, including, but not limited to, legend, non-legend, herbal products, over-the counter, nonprescription, vitamins, and nutritional supplements.

EE. Neglect. The failure or omission of a direct care staff member to provide the care, goods, or services necessary to maintain the health or safety of a patient including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Failure to provide adequate supervision resulting in harm to patients, including altercations or acts of assault between patients, may constitute neglect. Neglect may be repeated conduct or a single incident that has produced or could result in physical or psychological harm or substantial risk of death. Noncompliance with regulatory standards alone does not constitute neglect.

FF. Non-legend Drug. A drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with state and federal law.

GG. Patient. Any individual, other than staff members, volunteers or owners and their family members, who resides in a facility.

HH. Physical Examination. An examination of a patient by a physician or other authorized healthcare provider that meets the requirements set forth in Section 1100 of this regulation.

II. Physician. An individual currently licensed to practice medicine by the S.C. Board of Medical Examiners.

JJ. Physician Assistant. An individual currently licensed as such by the S.C. Board of Medical Examiners.

KK. Quality Improvement Program. The process used by a facility to examine its methods and practices of providing care and services, identify the ways to improve its performance, and take actions that result in higher quality of care and services for the facility's patients.

LL. Quarterly. A time period that requires an activity to be performed at least four (4) times a year within intervals ranging from eighty-one to ninety-nine (81 to 99) days.

MM. Restraint. Any means by which movement of a patient is inhibited, whether physical, mechanical, or chemical. In addition, devices shall be considered a restraint if a patient is unable to easily release from the device.

NN. Revocation of License. An action by the Department to cancel or annul a facility license by recalling, withdrawing, or rescinding the facility's authority to operate.

OO. Screening. The process by which the facility, prior to admission, determines a prospective patient requires the level of services and active treatment provided by the CSU.

PP. Self-Administration. A procedure by which any medication is taken orally, injected, inserted, or topically or otherwise administered by a patient to himself or herself without prompting. The procedure is performed without assistance and includes removing an individual dose from a previously dispensed and labeled container (including a unit dose container), verifying it with the directions on the label, taking it orally, injecting, inserting, or applying topically or otherwise administering the medication.

QQ. Staff Member. An adult, to include the administrator, who is a compensated employee of the facility on either a full- or part-time basis, including those in partnership or contracted with the S.C. Department of Mental Health ("SCDMH").

RR. Suspension of License. An action by the Department requiring a facility to cease operations for a period of time or to require a facility to cease admitting patients, until such time as the Department rescinds that restriction.

SS. Tuberculosis Risk Assessment. An initial and ongoing evaluation of the risk for transmission of *M. tuberculosis* ("TB") in a particular healthcare setting. To perform a risk assessment, the following factors shall be considered: the community rate of TB, number of TB patients encountered in the setting, and the speed with which patients with TB disease are suspected, isolated, and evaluated. The TB risk assessment determines the types of administrative and environmental controls and respiratory protection needed for a setting.

TT. Volunteer. An individual who performs a task at the facility at the direction of the administrator or his or her designee without compensation.

102. Licensure. (II)

A. License. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent itself (advertise or market) as a crisis stabilization unit facility in South Carolina without first obtaining a license from the Department. The facility shall not admit patients prior to the effective date of the license. When it has been determined by the Department that treatment, care, or services are being provided at a location, and the owner has not been issued a license from the Department to provide such treatment, care, and services the owner shall cease operation immediately and ensure the safety, health, and well-being of the patients. Current or previous violations of the S.C. Code or Department regulations may jeopardize the issuance of a license for the facility or the licensing of any other facility, or addition to an existing facility which is owned and/or operated by the licensee. The facility shall provide only the treatment, care, and services it is licensed to provide pursuant to the definition in Section 101.L of this regulation. (I)

B. Compliance. An initial license shall not be issued to a proposed facility until the licensee has demonstrated to the Department that the proposed facility is in substantial compliance with the licensing standards. In the event a licensee who already has a facility or activity licensed by the

Department makes application for another facility or increase in licensed bed capacity, the currently licensed facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a license to the proposed facility or amended license to the existing facility. A copy of the licensing standards shall be maintained at the facility and accessible to all staff members and volunteers. Facilities shall comply with applicable local, State, and Federal laws, codes, and regulations.

C. Licensed Bed Capacity. No facility that has been authorized to provide a set number of licensed beds, as identified on the face of the license, shall exceed the bed capacity. No facility shall establish new care or services or occupy additional beds or renovated space without first obtaining authorization from the Department. Licensed beds shall not be utilized by any individuals other than facility patients.

D. Issuance and Terms of License.

1. The license issued by the Department shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a license does not guarantee adequacy of individual care, services, personal safety, fire safety, or the well-being of any patient or occupant of a facility.

3. A license is not assignable or transferable and is subject to revocation at any time by the Department for the licensee's failure to comply with the laws and regulations of this state.

4. A license shall be effective for a specified facility, at a specific location, for a specified period following the date of issue as determined by the Department. A license shall remain in effect until the Department notifies the licensee of a change in that status.

5. Facilities owned by the same entity but which are not located on the same adjoining or contiguous property shall be separately licensed. Roads or local streets, except limited access, shall not be considered as dividing otherwise adjoining or contiguous property. For facilities owned by the same entity, separate licenses are not required for separate buildings on the same or adjoining grounds where a single level or type of care is provided.

6. Multiple types of facilities on the same premises shall be licensed separately even though owned by the same entity.

E. Facility Name. No proposed facility shall be named nor shall any existing facility have its name changed to the same or similar name as any other facility licensed in South Carolina.

F. Application. Applicants for a license shall submit to the Department a complete and accurate application on a form prescribed and furnished by the Department prior to initial licensing and periodically thereafter at intervals determined by the Department. The application shall include both the applicant's oath assuring that the contents of the application are accurate and true, and that the applicant will comply with this regulation. The application shall be signed by the owner(s) if an individual or partnership; by two (2) officers if a corporation; or by the head of the governmental department having jurisdiction if a governmental unit. The application shall set forth the full name and address of the facility for which the license is sought and of the owner in the event his or her address is different from that of the facility, and the names of the persons in control of the facility. The Department may require additional information, including affirmative evidence of the applicant's ability to comply with these regulations. Corporations or limited partnerships, limited liability companies or any other organized business entity shall be registered with the S.C. Secretary of State's Office if required to do so by state law. (II)

G. Required Documentation. The application for initial licensure shall include:

1. Completed application;

2. Proof of ownership of real property in which the facility is located, or a rental or lease agreement allowing the licensee to occupy the real property in which the facility is located;

3. Proof the facility is operated by the SCDMH or operated in partnership with the SCDMH;

4. Business license (where applicable);

5. Zoning letter (where applicable);

6. Verification of emergency evacuation plan (see Section 1400); and

7. Verification of administrator's qualifications.

H. Licensing Fees. Each applicant shall pay a license fee prior to the issuance of a license. The annual license fee shall be ten dollars ($10.00) per licensed bed or seventy-five dollars ($75.00),

whichever is greater. Annual licensing fees shall also include any outstanding inspection fees. All fees are non-refundable, shall be made payable by check or credit card to the Department or online, and shall be submitted with the application. (II)

I. Licensing Late Fee. Failure to submit a renewal application and fee to the Department by the license expiration date shall result in a late fee of seventy-five dollars ($75.00) or twenty-five percent (25%) of the licensing fee amount, whichever is greater, in addition to the licensing fee. Failure to submit the licensing fee and licensing late fee to the Department within thirty (30) days of the license expiration date shall render the facility unlicensed. (II)

J. License Renewal. For a license to be renewed, applicants shall file an application with the Department, shall pay the license fee, and shall not have pending enforcement actions by the Department. If the license renewal is delayed due to enforcement actions, the renewal license shall be issued only when the matter has been resolved satisfactorily by the Department, or when the adjudicatory process is completed, whichever is applicable. Annual license fees shall also include any outstanding inspection fees.

K. Amended License. A facility shall request issuance of an amended license by application to the Department prior to any of the following circumstances:

1. Change of licensed bed capacity;
2. Change of facility location from one geographic site to another; or
3. Changes in facility name or address (as notified by the post office).

L. Change of Licensee. A facility shall request issuance of a new license by application to the Department prior to any of the following circumstances:

1. A change in the controlling interest even if, in the case of a corporation or partnership, the legal entity retains its identity and name; or
2. A change of the legal entity, for example, sole proprietorship to or from a corporation, partnership to or from a corporation, even if the controlling interest does not change.

M. Exceptions to Licensing Standards. The Department has the authority to make exceptions to these standards where the Department determines the health, safety, and well-being of the patients are not compromised, and provided the standard is not specifically required by statute.

SECTION 200 - ENFORCEMENT OF REGULATIONS

201. General.

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or licensed facility in order to enforce this regulation.

202. Inspections and Investigations.

A. Inspections by the Department shall be conducted prior to initial licensing of a facility and subsequent inspections conducted as deemed appropriate by the Department. (I)

B. All facilities are subject to inspection and investigation at any time without prior notice by individuals authorized by South Carolina Code of Laws. When staff members and patients are absent, the facility shall post information at the entrance of the facility to those seeking legitimate access to the facility, including visitors. The posted information shall include contact information and the expected time of return of the staff members and patients. The contact information shall include the name of a designated contact and his or her telephone number. The telephone number for the designated contact shall not be the facility's telephone number. (I)

C. Individuals authorized by South Carolina law shall be allowed to enter the facility for the purpose of inspection and/or investigation and granted access to all properties and areas, objects, requested records, and documentation at the time of the inspection or investigation. The Department shall have the authority to require the facility to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used only for purposes of enforcement of regulations and confidentiality shall be maintained except to verify the identity of individuals in enforcement action proceedings. Physical area of Department inspections and investigations shall be determined by the Department based on the potential impact or effect upon patients. (I)

D. When there is noncompliance with the licensing standards, the facility shall submit an acceptable plan of correction in a format determined by the Department. The plan of correction shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar); and
3. The actual or expected completion dates of those actions.

E. In accordance with S.C. Code Section 44–7–270, the Department may charge a fee for inspections. The fee for initial and routine inspections shall be seventy-five dollars ($75.00) plus five dollars ($5,00) per licensed bed. The fee for a bed increase is ten dollars ($10.00) per licensed bed. The fee for follow-up inspections shall be sixty dollars ($60.00) plus five dollars ($5.00) per licensed bed.

F. The licensee shall pay the following inspection fees during the construction phase of the project. The plan inspection fee is based on the total estimated cost of the project whether new construction, an addition, or a renovation. The fees are detailed in the table below.

Construction Inspection Fees	
Plan Inspection	
Total Project Cost	**Fee**
< $10,001	$750
$10,001 - $100,000	$1,500
$100,001 - $500,000	$2,000
> $500,000	$2,500 plus $100 for each additional $100,000 in project cost
Site Inspection	
50% Inspection	$500
80% Inspection	$500
100% Inspection	$500

203. Consultations.

Consultations may be provided by the Department as requested by the facility or as deemed appropriate by the Department.

SECTION 300 - ENFORCEMENT ACTIONS

301. General.

When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice to the licensee, may deny, suspend, or revoke licenses, or assess a monetary penalty, or both.

302. Violation Classifications.

Violations of standards in this regulation are classified as follows:

A. Class I violations are those that present an imminent danger to the health, safety, or well-being of the persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of the time established by the Department shall be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that have a negative impact on the health, safety or well-being of persons in the facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices. The citation of a Class III violation shall specify the time within

which the violation is required to be corrected. Each day such violation exists after expiration of this time shall be considered a subsequent violation.

D. The notations "(I)" or "(II)", placed within sections of this regulation, indicate those standards are considered Class I or II violations if they are not met, respectively. Failure to meet standards not so annotated are considered Class III violations.

E. In determining an enforcement action the Department shall consider the following factors:

1. Specific conditions and their impact or potential impact on health, safety or well-being of the patients including, but not limited to: deficiencies in medication management; critical waste water problems; housekeeping, maintenance, or fire and life safety-related problems that pose a health threat to the patients; power, water, gas, or other utility and/or service outages; patients exposed to air temperature extremes that jeopardize their health; unsafe condition of the building or structure; indictment of an administrator for malfeasance or a felony, which by its nature indicates a threat to the patients; direct evidence of abuse, neglect, or exploitation; lack of food or evidence that the patients are not being fed properly; no staff available at the facility with patients present; unsafe procedures and/or treatment being practiced by staff; (I)

2. Repeated failure of the licensee or facility to pay assessed charges for utilities and/or services resulting in repeated or ongoing threats to terminate the contracted utilities and/or services; (II)

3. Efforts by the facility to correct cited violations;

4. Overall conditions of the facility;

5. History of compliance; and

6. Any other pertinent conditions that may be applicable to current statutes and regulations.

F. When imposing a monetary penalty, the Department may invoke S.C. Code Section 44–7–320(C) to determine the dollar amount or may utilize the following schedule:

FREQUENCY OF VIOLATION	CLASS I	CLASS II	CLASS III
1st	$500–1,500	$300–800	$100–300
2nd	1000–3000	500–1500	300–800
3rd	2000–5000	1000–3000	500–1500
4th	5000	2000–5000	1000–3000
5th	5000	5000	2000–5000
6th	5000	5000	5000

SECTION 400 - POLICIES AND PROCEDURES

A. The facility shall maintain written policies and procedures addressing the manner in which the requirements of this regulation shall be met. The written policies and procedures shall be implemented and reflect current facility practice regarding care, treatment, procedures, services, record keeping and reporting, admission and transfer, physician services, nursing services, social services, patient rights and assurances, medication management, pharmaceutical services, meal service operations, emergency procedures, fire prevention, maintenance, housekeeping and infection control, operation of the facility, and other special care and procedures as identified in this section. The policies and procedures shall address the provision of any special care offered by the facility that would include how the facility shall meet the specialized needs of the affected patients. The facility shall have written policies and procedures to address patient exit-seeking and elopement, including prevention and actions to be taken in the event of occurrence, and to control the use and application of physical restraints and all facility practices that meet the definition of a restraint. (II)

B. All policies and procedures shall be accessible to facility staff, printed or electronically, at all times.

C. The facility shall establish a time period for review, not to exceed two (2) years, of all policies and procedures, and such reviews shall be documented and signed by the administrator.

SECTION 500 - STAFF AND TRAINING

501. General. (II)

A. Before being employed or contracted as a staff member or volunteer, a direct caregiver shall undergo a criminal background check pursuant to S.C. Code Section 44–7–2910. Staff members and volunteers of the facility shall not have a prior conviction or pled no contest (nolo contendere) to unlawful conduct toward a child, as defined by S.C. Code Section 63–45–70; abuse, neglect, or exploitation of a vulnerable adult, as defined by S.C. Code Sections 43–35–10, et seq.; or any similar criminal offense. (I)

B. The facility shall define in writing the responsibilities, qualifications, and competencies of staff for all positions. The facility shall ensure that the type and number of staff are:

1. Properly licensed or credentialed in the professional field as required for assigned job duties;
2. Present in numbers to provide services, support, care, and treatment to individuals as required; and
3. Trained as necessary to perform the duties for which they are responsible in an effective manner.

C. Staff members shall have at least the following qualifications: (I)

1. Capable of rendering care and services to patients; and
2. Capable of following applicable regulations.

D. The facility shall maintain current information regarding all staff members, to include:

1. Name, address, and telephone number;
2. Date of hire and date of initial patient contact;
3. Past employment, experience, and education;
4. Professional licensure or credentials; and
5. Job description signed by the staff member.

E. When a facility engages a source other than the facility to provide services normally provided by the facility, there shall be a written agreement with the source describing how and when the services are to be provided, the exact services to be provided, and that these services are to be provided by qualified individuals. The source shall comply with this regulation in regard to patient treatment, care, and services.

502. Administrator. (II)

A. Each facility shall have a full-time administrator who is responsible for the overall management and operation of the facility and has at least a bachelor's degree in the human services field or nursing.

B. A staff member shall be designated in writing to act in the absence of the administrator, such as, a listing of the lines of authority by position title, including the names of the persons filling these positions.

C. The facility shall notify the Department in writing within seventy-two (72) hours of any change in administrator status and shall provide the Department the name of the newly-appointed administrator, the effective date of the appointment, and the hours each day the individual will be working as the administrator of the facility.

503. Staff. (I)

A. There shall be at least one (1) registered nurse immediately accessible by phone and available to be in the facility within thirty (30) minutes at all times patients are present in the facility.

B. There shall be at least one (1) staff member on duty for each eight (8) patients or a fraction thereof. All staff members on duty shall be awake and dressed at all times. Staff members shall be able to appropriately respond to patient needs.

C. In a facility with multiple floors or buildings, there shall be a staff member available on each floor and/or building at all times patients are present on that floor or in that building.

504. Inservice Training. (I)

A. All staff and volunteers in the facility shall complete the required SCDMH training in accordance with specific duties and responsibilities outlined in their job description. Training shall be documented in a staff or volunteer record and maintained at the facility.

B. The documentation of all inservice training shall include topic, training source, duration, and shall be signed and dated by the trainer and trainee. A signature by the trainee and the individual providing the training may be omitted for computer-based training. Training shall be provided by qualified persons and electronic media to all staff members and volunteers in the context of their job duties. All required training shall be completed prior to patient contact and at a frequency determined by the SCDMH, but at least annually unless otherwise specified by certificate, for example, cardiopulmonary resuscitation. Training for each staff and volunteer of the facility whose responsibilities include direct patient care shall include:

1. Basic first-aid to include emergency procedures as well as procedures to manage and care for minor accidents and injuries (non-nursing staff only);

2. Management and care of persons with contagious and/or communicable disease (non-nursing staff only);

3. OSHA standards regarding bloodborne pathogens;

4. Medication management including storage, interactions, and adverse reactions (as applicable to job duties);

5. Assessment and prevention of suicide;

6. Crisis interventions and treatment;

7. Patient rights and grievance procedures;

8. Confidentiality of patient information and records;

9. Abuse, neglect, and exploitation;

10. Elopement;

11. Use of restraint techniques that promote patient safety, including alternatives to physical restraints, in accordance with the provisions of Section 903;

12. Fire response training within twenty-four (24) hours of their first day on the job in the facility (see Section 1503); and

13. Emergency procedures and disaster preparedness to address various types of potential disasters within twenty-four (24) hours of initial patient contact (see Section 1400).

505. Job Orientation.

All staff members and volunteers shall have documented orientation to the purpose and environment of the facility within twenty-four (24) hours of their first day on the job in the facility. (I)

506. Health Status. (I)

A. All staff members and volunteers who have contact with patients, including food service staff and volunteers, shall have a documented health assessment within twelve (12) months prior to initial patient contact. The health assessment shall include tuberculin skin testing as described in Section 1702.

B. If a staff member or volunteer is working at multiple facilities operated by the same licensee, copies of the documented health assessment shall be accessible at each facility. For any other staff member or volunteer, a copy of the tuberculin skin testing shall be acceptable provided the test had been completed within three (3) months prior to patient contact.

SECTION 600 - REPORTING

601. Incidents.

A. The facility shall document every incident, and include an incident review, investigation or evaluation, as well as corrective action taken, if any. The facility shall retain all documented incidents reported pursuant to this section for six (6) years after the patient involved is last discharged.

B. The facility shall report the following types of incidents to the Department within twenty-four (24) hours of the incident on the Department's electronic reporting system or as otherwise determined by the Department. In addition to reporting to the Department, the facility shall immediately, within twenty-four (24) hours, notify the attending physician and emergency contact of patients or staff injured or affected by one of the following incidents, and shall immediately, within twenty-four (24) hours, notify local law enforcement of a patient elopement. Incidents requiring immediate, within twenty-four (24) hours, reporting to the Department, other specified individuals, and to appropriate authorities, include, but are not limited to, the following:

1. Crimes against patients;
2. Confirmed or suspected abuse, neglect, or exploitation;
3. Medication errors with adverse reaction;
4. Hospitalization or death resulting from the incident;
5. Severe hematoma, laceration or burn requiring medical attention or hospitalization;
6. Bone or joint fracture;
7. Severe injury;
8. Attempted suicide;
9. Fire; (II)
10. Natural disaster; (II)
11. Displacement or relocation of patients; and
12. Elopement.

C. The facility shall submit a separate written investigation report within five (5) days of every incident required to be immediately reported to the Department pursuant to Section 601.B via the Department's electronic reporting system or as otherwise determined by the Department. The facility's investigation report to the Department shall at least include, but is not limited to, the following information about the incident: incident type, description, date, location, number of patients, staff, and visitors injured or affected, patients' age, gender, record numbers or last four (4) digits of Social Security number, names of any witnesses, and identified cause of incident or internal investigation results.

D. The facility shall immediately notify a patient's attending physician and emergency contact within twenty-four (24) hours of significant changes in a patient's condition and shall document the significant changes and notification in the patient's record. (I)

E. The facility shall maintain documentation that all reporting of abuse, neglect, and exploitation of adults is conducted in accordance with S.C. Code Section 43–35–25.

602. Closure and Zero Census.

A. The facility shall notify the Department in writing prior to permanent closure of the facility and shall provide the effective closure date. The facility shall return its license to the Department on the date of closure. The facility shall notify the Department in writing within ten (10) days of closure on provisions for records maintenance and identification of displaced patients and their relocation.

B. The facility shall notify the Department in writing within fifteen (15) days prior to a temporary closure or within twenty-four (24) hours if the temporary closure is due to an emergency and provide the reason for the temporary closure, patient relocations, records maintenance plan, and anticipated reopening date. Facilities that are temporarily closed longer than one (1) year shall reapply for licensure with the Department and be subject to all applicable licensing and construction requirements for new facilities.

C. The facility shall notify the Department in writing if there have been no patients in the facility for any reason for ninety (90) days or more no later than one hundred (100) days after the last patient is discharged. Facilities that are zero census longer than one (1) year shall reapply for licensure with the Department and be subject to all applicable licensing and construction requirements for new facilities.

SECTION 700 - PATIENT RECORDS

701. Content. (II)

A. The facility shall initiate and maintain on site an organized record for each patient. The record shall contain sufficient documented information to identify the patient and the agency and/or person responsible for each patient; support the diagnosis and secure the appropriate care and services (as needed); justify the care and services provided to include the course of action taken and results; the symptoms or other indications of sickness or injury; changes in physical and/or mental condition; the response and/or reaction to care, medication, and diet provided; and promote continuity of care among providers, consistent with acceptable standards of practice. All entries shall be written legibly in ink, typed or electronic media, and signed, and dated.

B. If the facility permits any portion of a patient's record to be generated by electronic or optical means, there shall be policies and procedures to prohibit the use or authentication by unauthorized users.

C. Specific entries and documentation shall include at a minimum:

1. Consultations by physicians or other authorized healthcare providers;

2. Signed and dated orders and recommendations for all medication, care, services, procedures, and diet from physicians or other authorized healthcare providers, which shall be completed prior to, or at the time of admission, and subsequently, as warranted; (I)

3. Intake screening and initial physical assessment completed by a nurse;

4. Signed and dated original consent for treatment; (I)

5. The report of the mental status examination and other mental health assessments, as appropriate;

6. Daily progress notes by the direct care staff involved in the treatment of the patient, as applicable, to include documentation of significant behavioral events and actions taken by staff; and

7. Medication management and administration, and treatment records.

702. Screening. (I)

A. The facility shall have written protocols for screening individuals presenting for evaluation. The facility shall maintain documentation of the rationale for the denial of admission and referral of the individual as applicable.

B. Each facility shall provide screening services on a twenty-four (24) hours per day, seven (7) days per week basis. No person shall remain in the facility for more than eight (8) hours without being admitted or denied admission.

C. Initial screening for risk of suicide or harm to self or others shall be conducted and documented for each individual presenting to the facility.

703. Assessments. (II)

A. A nursing assessment shall be documented for all patients admitted within twenty-four (24) hours.

B. An emotional and behavioral assessment shall be documented for all patients admitted within twenty-four (24) hours. This assessment shall be completed by a mental health professional or other unit staff under the supervision of a mental health professional.

C. A direct psychiatric evaluation, including diagnosis, shall be documented by a physician, psychiatrist, physician assistant, or advanced practice registered nurse for all patients admitted within twenty-four (24) hours.

704. Individual Plan of Care. (II)

A. An individual plan of care ("IPC") shall be developed for each admitted patient. The plan shall be based on initial and ongoing needs, and completed within twenty-four (24) hours of admission. The IPC shall be documented in the patient's record and shall include the following:

1. Patient's name;

2. Diagnosis;

3. Date of IPC development;

4. Problems and strengths of the patient;

5. Individual objectives that relate to the specific problems identified;

6. Interventions that address each specific objective;

7. Signatures of direct care staff involved in the treatment of the patient and the development of the ICP;

8. Signature of the patient. Reasons for refusal to sign and/or inability to participate in IPC development shall be documented; and

9. Projected discharge date and anticipated post-discharge needs, including documentation of resources needed in the community.

B. A documented review of the IPC shall occur at least daily or upon completion of the stated goal(s) and objective(s).

705. Record Maintenance.

A. The licensee shall provide accommodations, space, supplies, and equipment for the protection, storage, and maintenance of patient records. Patient records shall be stored in an organized manner.

B. The patient record is confidential and shall be made available only to individuals authorized by the facility and/or the South Carolina Code of Laws. (II)

C. Records generated by organizations or individuals contracted by the facility for care or services shall be maintained by the facility that has admitted the patient.

D. Upon discharge of a patient, the record shall be completed within thirty (30) days, and filed in an inactive or closed file maintained by the licensee. Prior to the closing of a facility for any reason, the licensee shall arrange for preservation of records to ensure compliance with these regulations. The licensee shall notify the Department, in writing, describing these arrangements and the location of the records.

E. Records of patients shall be maintained for at least six (6) years following the discharge of the patient. Unless otherwise indicated, other regulation-required documents shall be retained at least twelve (12) months or since the last Department general inspection, whichever is the longer period.

F. Records of current patients are the property of the facility. The records of current patients shall be maintained at the facility and shall not be removed without court order.

SECTION 800 - ADMISSION AND RETENTION (I)

A. Individuals seeking admission shall be appropriate for the services, treatment, and care offered. The facility shall establish admission criteria that are consistently applied and comply with the facility's policies and procedures.

B. No supervision, care, or services shall be provided to individuals who have not been admitted as patients of the facility.

C. Patient stays shall not exceed fourteen (14) consecutive calendar days.

D. A facility shall not retain any patients who primarily need detoxification services.

E. A facility shall not retain any of the following persons:

1. A patient with a psychiatric condition of such severity that it can only be safely treated in an inpatient setting;

2. A patient with an unstable medical condition of such severity that it can only be safely managed in an inpatient setting;

3. A patient that does not voluntarily consent to admission or treatment; or

4. A patient that is violent or combative, and/or posing an imminent risk to themselves or others.

SECTION 900 - PATIENT CARE AND SERVICES

901. General. (II)

A. The written informed consent between the patient and the facility shall include at least the following:

1. An explanation of the specific care, services, and/or equipment provided by the facility;

2. An explanation of the conditions under which the patient may be discharged and the agreement terminated; and

3. Documentation of the explanation of the patient's rights (see Section 1000) and the grievance procedure.

B. The facility shall provide necessary items and assistance, if needed, for patients to maintain their personal cleanliness.

C. The provision of care and services to patients shall be guided by the recognition of and respect for cultural differences to ensure reasonable accommodations for patients with regard to differences, such as, but not limited to, religious practice and dietary preferences.

D. The facility shall make opportunities for participation in religious services available. Reasonable assistance in obtaining pastoral counseling shall be provided by the facility upon request by the patient.

902. Transportation. (II)

The facility shall secure or provide transportation for patients when a physician's services are needed. If a physician's services are not immediately available and the patient's condition requires immediate medical attention, the facility shall provide or secure transportation for the patient to appropriate health care providers.

903. Safety Precautions and Restraints. (I)

A. Periodic or continuous mechanical, physical or chemical restraints during routine care of a patient shall not be used, nor shall patients be restrained for staff convenience or as a substitute for care or services. However, in cases of extreme emergencies when a patient is posing an immediate danger to him or herself or others, mechanical and/or physical restraints may be initiated by staff of the facility to prevent harm to the patient, to other patients, or to staff, provided that use of mechanical and/or physical restraints must be ended as soon as the immediate threat of harm has ended, and in no case shall the use of restraints continue beyond one (1) hour unless ordered by a physician or other authorized healthcare provider. An order for use of restraints must provide that their use shall be discontinued as soon as the immediate threat of harm posed by the patient has ended or until appropriate medical care can be secured, but in no case shall an order be valid for more than eight (8) hours. Only those devices specifically designed as restraints may be used.

B. Emergency restraint orders shall specify the reason for the use of the restraint, the type of restraint to be used, the maximum time the restraint may be used, and instructions for observing the patient while restrained, if different from the facility's written procedures. Patients certified by a physician or other authorized healthcare provider as requiring restraint for more than eight (8) hours shall be transferred to an appropriate facility.

C. During emergency restraint, patients shall be monitored at least every fifteen (15) minutes, and provided with an opportunity for motion and exercise at least every thirty (30) minutes. Prescribed medications and treatments shall be administered as ordered, and patients shall be offered nourishment and fluids and given bathroom privileges.

D. The use of mechanical restraints shall be documented in the patient's record, and shall include the date and time implemented, the length of time restrained, observations while patient is restrained, and the requirements of Section 903.C above.

904. Discharge and Transfer.

A. A discharge summary, based upon the particular needs of the patient, shall be documented and provided to the patient at the time of discharge that includes:

1. Reason(s) for discharge;

2. Specific instructions for post-discharge care; and

3. Contact information for how to access community services, if applicable.

B. Any of the following criteria is sufficient for transfer or discharge from the facility:

1. The patient manifests behavioral, substance-related, and/or psychiatric symptoms that require a less intensive level of care;

2. The patient is at imminent risk of causing serious physical harm to self or others;

3. The symptoms are a result of or complicated by a medical condition that warrants admission to a medical setting for treatment;

4. Any other medical condition or behavior which the facility staff deems unsafe for continued retention in the facility; or

5. The patient requires treatment, care, or services for longer than fourteen (14) days.

SECTION 1000 - RIGHTS AND ASSURANCES

A. The facility shall comply with all current federal, state, and local laws and regulations concerning patient care, patient rights and protections, and privacy and disclosure requirements, such as the Omnibus Adult Protection Act notice and Title VII, Section 601 of the Civil Rights Act of 1964. (I)

B. Patient rights shall be guaranteed and, at a minimum, the facility shall inform the patient of: (II)

1. The care to be provided and the opportunity to participate in care and treatment planning;
2. Grievance and complaint procedures;
3. Confidentiality of patient records;
4. Respect for the patient's property;
5. Specific coverage and non-coverage of services and of his or her liability for payment;
6. Freedom from abuse and exploitation; and (I)
7. Respect and dignity in receiving treatment, care, and services. (I)

C. A copy of the facility's patient rights shall be provided to the patient. (II)

D. Patients shall not be locked in or out of their rooms or any common usage areas in the facility, or in or out of the facility building. Exit doors may be equipped with delayed egress locks as permitted by the codes referenced in Section 1902. (I)

EXCEPTION: Exit doors may be locked with written approval by the Department and as permitted by the codes referenced in Section 1902.

E. The facility shall develop a grievance and complaint procedure to be exercised on behalf of the patients which includes the address and phone number of the Department, and a provision prohibiting retaliation should the grievance right be exercised. (II)

SECTION 1100 - PATIENT PHYSICAL EXAMINATION (I)

A. All patients admitted to a facility shall have a signed and dated physical examination conducted by a physician or other authorized healthcare provider within twenty-four (24) hours of admission. The physical examination shall include a medical history and diagnosis supporting admission.

B. If a patient or potential patient has a communicable disease, the administrator shall seek advice from a physician or other authorized healthcare provider in order to:

1. Ensure the facility has the capability to provide adequate care and prevent the spread of that condition, and that the staff members and volunteers are adequately trained; and
2. Transfer the patient to an appropriate facility, if necessary.

SECTION 1200 - MEDICATION MANAGEMENT

1201. General. (I)

Medications, including controlled substances, medical supplies, and those items necessary for the rendering of first aid, shall be properly managed in accordance with federal, state, and local laws and regulations. Such management shall address the securing, storing, and administering of medications, medical supplies, first aid supplies, and biologicals, their disposal when discontinued or expired, and their disposition at discharge, death, or transfer of a patient.

1202. Medication and Treatment Orders. (I)

A. Medications and treatments, including oxygen, shall be administered to patients only upon orders of a physician or other authorized healthcare provider. Medications accompanying patients at admission may be administered to patients provided the medication is in the original labeled container and the order is subsequently obtained as a part of the admission physical examination.

B. All verbal orders shall be received by a nurse and shall be signed and dated by a physician or other authorized healthcare provider no later than three (3) business days after the order is given.

C. Medications and medical supplies ordered for a specific patient shall not be provided or administered to any other patient.

1203. Administering Medication and/or Treatments. (I)

A. Doses of medication shall be administered by the same nurse who prepared them for administration. Preparation shall occur no earlier than one (1) hour prior to administering. Preparation of doses for more than one (1) scheduled administration shall not be permitted. Each treatment or medication dose administered shall be recorded on the patient's medication administration record ("MAR") as it is administered, or treatment administration record ("TAR") after it is rendered. Should an ordered dose of medication or treatment not be administered or rendered, an explanation as to the reason shall be recorded on the MAR or TAR. The MAR shall be documented to include the medication name, dosage, mode of administration, date and time of administration, and the signature of the nurse administering the medication. If the ordered dosage is to be given on a varying schedule, for example, "take two tablets the first day and one tablet every other day by mouth with noon meal," the number of tablets shall also be recorded. The TAR shall be documented to include the type of treatment, date and time of treatment, and the signature of the nurse rendering the treatment.

B. A facility nurse may monitor patient blood sugar levels provided the facility has received a "Certificate of Waiver" from the Clinical Laboratories Improvement Amendments ("CLIA").

C. Self-administering of medications by a patient is permitted only:

1. Upon the specific written orders of the physician or other authorized healthcare provider; and

2. The facility shall ascertain by patient demonstration to the staff and document that she or he remains capable of self-administering medications.

D. A facility may prohibit self-administration of medications and treatments.

E. At each shift change, there shall be a documented review of the MARs by the incoming and outgoing nurses to verify that medications were administered in accordance with orders, and the administrations were documented. All errors and/or omissions indicated on the MARs shall be addressed and corrective action taken at that time.

1204. Medication Containers (I)

A. Medications for patients shall be obtained from a permitted pharmacy or authorized healthcare provider as allowed by law on an individual prescription basis. These medications shall bear a label affixed to the container which reflects at least the following: name of pharmacy, name of patient, name of the prescribing physician or other authorized healthcare provider, date and prescription number, directions for use, and the name and dosage unit of the medication. The label shall be brought into accord with the directions of the physician or other authorized healthcare provider each time the prescription is refilled. Medication containers having soiled, damaged, incomplete, illegible, or makeshift labels shall be returned to the pharmacy for re-labeling or disposal.

B. Medications for each patient shall be kept in the original containers including unit dose systems. There shall be no transferring between containers, or opening blister packs to remove medications for destruction or adding new medications for administration.

1205. Medication Storage (I)

A. Medications shall be stored and safeguarded in a locked medicine preparation room, cabinet or cart. Medications shall be monitored and attended at all times to prevent access by unauthorized individuals. Expired or discontinued medications shall not be stored with current medications. Storage areas shall not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf life.

B. Medications requiring refrigeration or freezing shall be stored in a locked refrigerator or freezer as appropriate at the temperature range established by the manufacturer used exclusively for that purpose. Food and drinks shall not be stored in the same refrigerator or freezer in which medications and biologicals are stored. Refrigerators and freezers shall be provided with a thermometer accurate to plus or minus two (2) degrees Fahrenheit.

C. Medications shall be stored:

1. In accordance with manufacturer's directions and in accordance with all applicable federal, state, and local laws and regulations;

2. Separately from poisonous substances, such as cleaning and germicidal agents, or body fluids;

3. In a manner that provides for separation between topical and oral medications, and which provides for separation of each patient's medication; and

4. In medicine preparation rooms or cabinets that are well-lighted and of sufficient size to permit orderly storage and preparation of medications. Keys to the medicine preparation room, cabinet, refrigerator or medication cart at the staff work area shall be under the control of a designated licensed nurse.

D. Unless the facility has a permitted pharmacy, legend drugs shall not be stored in the facility except those specifically prescribed for individual patients. Non-legend drugs that can be obtained without a prescription may be retained and labeled as stock in the facility for administration as ordered by a physician or other authorized healthcare provider.

E. Prescribed and over-the-counter medications may be maintained at patient's bedside upon physician orders if kept in an individual cabinet or compartment that is locked, such as the drawer of the patient's night stand, in the room of each patient who has been authorized in writing to self-administer by a physician or other authorized healthcare provider, in accordance with facility policies and procedures.

F. Medications scheduled as Schedule II controlled substances pursuant to the federal or state Controlled Substances Act shall be stored in separately locked, permanently affixed, compartments within a locked medicine preparation room, cabinet, or medication cart, unless otherwise authorized by a change in the state or federal law pertaining to the unit dose or multidose system.

G. A facility shall maintain records of receipt, administration and disposition of all controlled substances in sufficient detail to enable an accurate reconciliation including:

1. Separate records for controlled substances shall be maintained and include the following information: date, time administered, name of patient, dose, signature of individual administering, name of physician or other authorized healthcare provider ordering the medication, and all scheduled controlled substances balances; and

2. At each shift change, there shall be a documented review of the controlled substance records by the incoming and outgoing nurses to verify an accurate reconciliation of the controlled substances.

H. The medications prescribed for a patient shall be protected from use by any other individuals. For those patients who have been authorized by a physician or other authorized healthcare provider to self-administer medications, such medications may be kept on the patient's person, such as, a pocketbook, pocket, or any other method that would enable the patient to control the items.

1206. Disposition of Medications (I)

A. Upon discharge or death of a patient, a facility in possession of unused medications belonging to the patient that do not constitute a controlled substance under 21 U.S.C. Section 802(32) shall release the unused medications to the patient, family member, or responsible party, as appropriate, and shall document the release with the signature of the person receiving the unused medications unless specifically prohibited by the attending physician or other authorized healthcare provider.

B. Upon death of a patient, a facility in possession of unused medications belonging to the patient that constitute a controlled substance under 21 U.S.C. Section 802 shall release the unused medication to an applicable person under 21 C.F.R. Section 1317.30 for disposal in accordance with requirements of the federal Drug Enforcement Administration. The facility shall document the release for disposal in the patient's record.

C. Upon discharge of a patient, a facility in possession of unused medications belonging to the patient that constitute a controlled substance under 21 U.S.C. Section 802 shall release the unused medication to the "ultimate user" under 21 U.S.C. Section 802. The facility shall document the release in the patient's record.

SECTION 1300 - MEAL SERVICE

1301. General. (II)

A. All facilities that prepare food on-site shall be approved by the Department, and regulated, inspected, and permitted pursuant to Regulation 61–25, Retail Food Establishments.

B. When meals are catered to a facility, such meals shall be obtained from a food service establishment graded by the Department pursuant to R.61–25, and there shall be a written executed contract with the food service establishment.

C. All food served to the patients shall meet the requirements of R.61–25 for temperature, storage, display, and general protection against contamination. The use of home canned foods is prohibited.

D. There shall be at least one (1) hand sink equipped with hot and cold water, liquid soap, and an individualized method of drying hands. A handwashing sink shall be equipped to provide water at a temperature of at least one hundred (100) degrees Fahrenheit through a mixing valve or combination faucet.

E. Washing and sanitation of all food contact and non-food contact surfaces, equipment, and utensils shall meet the standards required by R.61–25.

1302. Meals and Special Diets.

A. All facilities shall provide dietary services to meet the daily nutritional needs of the patients. (I)

B. A minimum of three (3) nutritionally-adequate meals in each twenty-four (24) hour period shall be provided for each patient unless otherwise directed by the patient's physician or other authorized healthcare provider. Not more than fourteen (14) hours shall elapse between the serving of the evening meal and breakfast the following day. (II)

C. Specific times for serving meals shall be established.

D. Suitable food and snacks shall be available and offered between meals at no additional cost to the patients. (II)

E. Special diets shall be prescribed, dated and signed by the physician. (I)

1303. Diets. (I)

If the facility accepts patients in need of medically-prescribed special diets, the menus for such diets shall be planned by a professionally-qualified dietitian or shall be reviewed and approved by a physician or other authorized healthcare provider. The facility shall maintain documentation that each of these menus has been planned by a dietitian, a physician or other authorized healthcare provider. At a minimum, documentation for each patient's special diet menu shall include the signature of the dietitian, the physician or other authorized healthcare provider, his or her title, and the date he or she signed the menu. Facility staff preparing a patient's special diet shall be knowledgeable of the procedure to prepare each special diet. The preparation of any patient's special diet shall follow the written guidance provided by a registered dietitian, physician, or other authorized healthcare provider authorizing the patient's special diet. For each patient receiving a special diet, this written guidance shall be documented in the patient's record.

1304. Menus.

One (1) week's menus, including routine and special diets and any substitutions or changes made, shall be readily available and posted in one (1) or more conspicuous places in a public area.

1305. Ice and Drinking Water. (II)

A. Ice from a water system in accordance with Regulation 61–58, State Primary Drinking Water Regulations, shall be available and precautions shall be taken to prevent contamination. The ice scoop shall be stored in a sanitary manner outside of the ice container.

B. Potable drinking water shall be available and accessible to patients at all times.

C. The usage of common cups shall be prohibited.

D. Ice delivered to patient areas in bulk shall be in nonporous, covered containers that shall be cleaned after each use.

SECTION 1400 - EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

1401. Disaster Preparedness. (II)

A. All facilities shall develop, by contact and consultation with their county emergency preparedness agency, a written plan for actions to be taken in the event of a disaster and/or emergency

evacuation. The plan shall be implemented as necessary and at the time of need. Prior to initial licensing and at the time of each license renewal, a completed form prescribed and furnished by the Department addressing specific components of the plan shall be included with each application submitted to the Department for license renewal. Additionally, in instances where applications include an increase in the licensed bed capacity, the plan shall be updated to address the proposed new total licensed bed capacity and an updated form shall be provided to the Department with the application. All staff members and volunteers shall be made familiar with this plan and instructed as to any required actions of the plan. A copy of the plan shall be available for inspection by the patient and/or responsible party and the Department upon request. The plan shall be reviewed and updated annually, and as appropriate. The facility shall conduct and document a rehearsal of the emergency and disaster evacuation plan at least annually and shall not require patient participation.

B. Evacuation is a temporary measure in order to evacuate patients from potentially hazardous and/or harmful circumstances and shall not exceed seven (7) calendar days. In the event evacuated patients are unable to return to the facility within seven (7) days due to damage to the facility or its components, the lack of electricity and/or water, or other similar reasons, the facility shall endeavor to assess each patient's current condition and identify each patient's current needs and preferences. Based on the resources available, the facility shall implement each patient's discharge plan. For patients needing assistance or support following discharge, the facility shall coordinate the transfer of the patients to their responsible parties or to appropriately licensed facilities capable of meeting the patients' needs.

C. The disaster and/or emergency evacuation plan shall include, but not be limited to:

1. A sheltering plan to include:

a. The licensed bed capacity and average occupancy rate;

b. Name, address and phone number of the sheltering facility(ies) to which the patients will be relocated during a disaster; and

c. A letter of agreement signed by an authorized representative of each sheltering facility which shall include: the number of relocated patients that can be accommodated; sleeping, feeding, and medication plans for the relocated patients; and provisions for accommodating relocated staff members and volunteers. The letter shall be updated with the sheltering facility at least every three (3) years and whenever significant changes occur. For those facilities located in Beaufort, Charleston, Colleton, Georgetown, Horry, and Jasper counties, at least one (1) sheltering facility shall be located in a county other than these counties.

2. A transportation plan, to include agreements with entities for relocating patients, which addresses:

a. Number and type of vehicles required;

b. How and when the vehicles are to be obtained;

c. Who (by name or organization) will provide drivers;

d. Procedures for providing appropriate medical support, food, water, and medications during transportation and relocation based on the needs and number of the patients;

e. Estimated time to accomplish the relocation; and

f. Primary and secondary routes to be taken to the sheltering facility.

3. A staffing plan for the relocated patients, to include:

a. How care will be provided to the relocated patients, including the number and type of staff members that will accompany patients who are relocated;

b. Prearranged transportation arrangements to ensure staff members are relocated to the sheltering facility; and

c. Co-signed statement by an authorized representative of the sheltering facility if staffing is to be provided by the sheltering facility.

1402. Emergency Call Numbers. (II)

Emergency call data shall be posted in a conspicuous place and shall include at least the telephone numbers of fire and police departments, ambulance service, and the poison control center. Other

emergency call information shall be available, to include the names, addresses, and telephone numbers of staff members and volunteers to be notified in case of emergency.

1403. Continuity of Essential Services. (II)

There shall be a written plan to be implemented to ensure the continuation of essential patient support services for such reasons as power outage, water shortage, or in the event of the absence from work of any portion of the workforce resulting from inclement weather or other causes.

SECTION 1500 - FIRE PREVENTION

1501. Arrangements for Fire Department Response and Protection. (I)

A. Each facility shall develop, in coordination with its supporting fire department and/or disaster preparedness agency, suitable written plans for actions to be taken in the event of fire, such as, fire plan and evacuation plan.

B. Facilities located outside of a service area or range of a public fire department shall arrange for the nearest fire department to respond in case of fire by written agreement with that fire department. A copy of the agreement shall be kept on file in the facility and a copy shall be forwarded to the Department. If the agreement is changed, a copy shall be forwarded to the Department.

1502. Tests and Inspections. (I)

Fire protection and suppression systems shall be maintained and tested in accordance with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the facility.

1503. Fire Response Training. (I)

A. Fire response training shall address at a minimum, the following:

1. Fire plan, including the training of staff members and volunteers;
2. Reporting a fire;
3. Use of the fire alarm system, if applicable;
4. Location and use of fire-fighting equipment;
5. Methods of fire containment; and
6. Specific responsibilities, tasks, or duties of each individual.

B. A plan for the evacuation of patients, staff members, and visitors, to include evacuation routes and procedures, in case of fire or other emergencies, shall be established and posted in conspicuous public areas throughout the facility.

C. All patients capable of assisting in their evacuation shall be trained in the proper actions to take in the event of a fire, for example, actions to take if the primary escape route is blocked.

D. Patients shall be made familiar with the fire plan and evacuation plan upon admission and a copy of the evacuation floor diagram shall be provided to each patient and/or the patient's responsible party.

1504. Fire Drills. (I)

A. An unannounced fire drill shall be conducted at least quarterly for all shifts. Each staff member and volunteer shall participate in a fire drill at least once each year. Records of drills shall be maintained at the facility, indicating the date, time, shift, description, and evaluation of the drill, and the names of staff members and volunteers and patients directly involved in responding to the drill. If fire drill requirements are mandated by statute or regulation, then provisions of the statute or regulation shall be complied with and shall supersede the provisions of Section 1504.

B. Drills shall be designed and conducted in consideration of and reflecting the content of the fire response training described in Section 1503 above.

C. All patients shall participate in fire drills. In instances when a patient refuses to participate in a drill, efforts shall be made to encourage participation, for example, counseling, implementation of incentives rewarding patients for participation, specific staff or volunteer to patient assignments to promote patient participation. Continued refusal may necessitate implementation of the discharge planning process to place the patient in a setting more appropriate to their needs and abilities.

D. In conducting fire drills, all patients shall evacuate to the outside of the building to a selected assembly point. Drills shall be designed to ensure that patients attain the experience of exiting through all exits.

SECTION 1600 - MAINTENANCE

The facility shall keep all equipment and building components (for example, doors, windows, lighting fixtures, plumbing fixtures) in good repair and operating condition. The facility shall document preventive maintenance. The facility shall comply with the provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the facility. (II)

SECTION 1700 - INFECTION CONTROL

1701. Staff Practices. (I)

Staff and volunteer practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures and practices shall be in compliance with applicable guidelines of the *Bloodborne Pathogens Standard of the Occupational Safety and Health Act (OSHA) of 1970*, as amended; the Centers for Disease Control and Prevention ("CDC"); and Regulation 61–105, Infectious Waste Management Regulations; and other applicable federal, state, and local laws and regulations.

1702. Tuberculosis Risk Assessment and Screening. (I)

A. All facilities shall conduct an annual tuberculosis risk assessment (see Section 101.SS) in accordance with CDC guidelines to determine the appropriateness and frequency of tuberculosis screening and other tuberculosis related measures to be taken.

B. The risk classification, for example, low risk, medium risk, shall be used as part of the risk assessment to determine the need for an ongoing TB screening program for staff and volunteers and patients and the frequency of screening. A risk classification shall be determined for the entire facility. In certain settings, for example, healthcare organizations that encompass multiple sites or types of services, specific areas defined by geography, functional units, patient population, job type, or location within the setting may have separate risk classifications.

C. Staff and Volunteers Tuberculosis Screening.

1. Tuberculosis Status. Prior to date of hire or initial patient contact, the tuberculosis status of staff and volunteers shall be determined in the following manner in accordance with the applicable risk classification:

2. Low Risk:

a. Baseline two-step Tuberculin Skin Test ("TST") or a single Blood Assay for *Mycobacterium tuberculosis* ("BAMT"): All staff and volunteers (within three (3) months prior to contact with patients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff or volunteer has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered and read to serve as the baseline prior to patient contact.

b. Periodic TST or BAMT is not required.

c. Post-exposure TST or a BAMT for staff and volunteers upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or a BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

d. Baseline positive with or without documentation of treatment for latent TB infection ("LTBI") (see Section 101.Z) or TB disease shall have a symptoms screen prior to employment and annually thereafter.

e. Upon hire, staff and volunteers with a newly positive test result for *M. tuberculosis* infection (for example, TST or BAMT) or signs or symptoms of tuberculosis, for example, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). Repeat

radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a physician. These staff members and volunteers will be evaluated for the need for treatment of TB disease or LTBI and will be encouraged to follow the recommendations made by a physician with TB expertise (for example, the Department's TB Control program).

3. Medium Risk:

a. Baseline two-step TST or a single BAMT: All staff and volunteers (within three (3) months prior to contact with patients) unless there is a documented TST or a BAMT result during the previous twelve (12) months. If a newly employed staff member or volunteer has had a documented negative TST or a BAMT result within the previous twelve (12) months, a single TST (or the single BAMT) can be administered to serve as the baseline prior to patient contact.

b. Periodic testing (with TST or BAMT): Annually, of all staff and volunteers who have risk of TB exposure and who have previous documented negative results. Instead of participating in periodic testing, staff and volunteers with documented TB infection (positive TST or BAMT) shall receive a symptom screen annually. This screen shall be accomplished by educating the staff or volunteer who have documented TB infection about symptoms of TB disease (including the staff's and/or volunteers' responses concerning symptoms of TB disease), documenting the questioning of the staff or volunteers about the presence of symptoms of TB disease, and instructing the staff or volunteers to report any such symptoms immediately to the administrator. Treatment for LTBI shall be considered in accordance with CDC and Department guidelines and, if recommended, treatment completion shall be encouraged.

c. Post-exposure TST or a BAMT for staff or volunteers upon unprotected exposure to *M. tuberculosis*: Perform a contact investigation (see Section 101.I) when unprotected exposure is identified. Administer one (1) TST or a BAMT as soon as possible to all staff and volunteers who have had unprotected exposure to an infectious TB case or suspect. If the TST or the BAMT result is negative, administer another TST or BAMT eight to ten (8 to 10) weeks after that exposure to *M. tuberculosis* ended.

4. Baseline Positive or Newly Positive Test Result:

a. Baseline positive with or without documentation of treatment for LTBI or TB disease shall have a symptoms screen prior to employment and annually thereafter.

b. Upon hire, staff and volunteers with a newly positive test result for *M.tuberculosis* infection (for example, TST or BAMT) or signs or symptoms of tuberculosis, for example, cough, weight loss, night sweats, fever, shall have a chest radiograph performed immediately to exclude TB disease (or evaluate an interpretable copy taken within the previous three (3) months). Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician. These staff members and volunteers will be evaluated for the need for treatment of TB disease or LTBI and will be encouraged to follow the recommendations made by a physician with TB expertise (for example, the Department's TB Control program).

c. Staff and volunteers who are known or suspected to have TB disease shall be excluded from work, required to undergo evaluation by a physician, and permitted to return to work only with written approval by the Department's TB Control program. Repeat chest radiographs are not required unless symptoms or signs of TB disease develop or unless recommended by a physician.

D. Patients who are known or suspected to have TB disease shall be transferred from the facility if the facility does not have an Airborne Infection Isolation room, required to undergo evaluation by a physician, and permitted to return to the facility only with written approval by the Department's TB Control program.

E. Individuals who have been declared in writing to be in an emergency crisis stabilization status may be admitted to the facility without the initial step of the two-step tuberculin skin test and/or while awaiting the result of a BAMT. If an individual has any symptoms of active tuberculosis, he or she shall be placed in an area separate from the general population. This admission to the facility may be made provided that:

1. There is documentation at the facility of the declaration by the SCDMH that the admission is, in fact, an emergency (NOTE: Only this agency may declare these crisis stabilization admissions to be an emergency); and

2. The patient will receive the initial step of the two-step tuberculin test within seventy-two (72) hours of admission to the facility. The second step of the two-step tuberculin skin test must be administered within the next seven to fourteen (7 to 14) days; or

3. There is written evidence of a chest x-ray within one (1) month prior to admission and a written assessment by a physician or other authorized healthcare provider that there is no active TB present and a negative assessment for signs and/or symptoms of tuberculosis.

1703. Housekeeping. (II)

The facility and its grounds shall be clean, and free of vermin and offensive odors.

A. Interior housekeeping shall, at a minimum, include:

1. Cleaning each specific area of the facility;

2. Cleaning and disinfection, as needed, of equipment used and/or maintained in each area appropriate to the area and the equipment's purpose or use;

3. Chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be in locked storage areas and inaccessible to patients; and

4. During use of chemicals indicated as harmful on the product label, cleaning materials, and supplies shall be in direct possession of the staff member and monitored at all times.

B. Exterior housekeeping shall, at a minimum, include:

1. Cleaning of all exterior areas, such as, porches and ramps, and removal of safety impediments such as snow and ice;

2. Keeping facility grounds free of weeds, rubbish, overgrown landscaping, and other potential breeding sources for vermin; and

3. Safe storage of chemicals indicated as harmful on the product label, equipment and supplies inaccessible to patients.

1704. Infectious Waste. (I)

Accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, shall be disposed of in a manner compliant with *OSHA Bloodborne Pathogens Standard*, and R.61–105.

1705. Clean and Soiled Linen and Clothing. (II)

A. Clean Linen and Clothing.

1. A supply of clean, sanitary linen and clothing shall be available at all times.

2. In order to prevent the contamination of clean linen and clothing by dust or other airborne particles or organisms, clean linen and clothing shall be stored and transported in a sanitary manner, for example, enclosed and covered.

3. Clean linen and clothing shall be separated from storage for other purposes.

B. Soiled Linen and Clothing.

1. Soiled linen and clothing shall neither be sorted, rinsed, nor washed outside of the laundry service area;

2. Provisions shall be made for collecting, transporting, and storing soiled linen and clothing;

3. Soiled linen and clothing shall be kept in solid enclosed, covered, and leak proof containers; and

4. Laundry operations shall not be conducted in patient rooms, dining rooms, or in locations where food is prepared, served, or stored.

SECTION 1800 - QUALITY IMPROVEMENT PROGRAM (II)

A. There shall be a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care and services provided by the facility.

B. The quality improvement program, at a minimum, shall:

1. Establish desired outcomes and the criteria by which policy and procedure effectiveness is regularly, systematically, and objectively accomplished;

2. Identify, evaluate, and determine the causes of any deviation from the desired outcomes;

3. Identify the action taken to correct deviations and prevent future deviation, and the person(s) responsible for implementation of these actions;

4. Analyze the appropriateness of IPCs and the necessity of care and services rendered;

5. Analyze all incidents and accidents, to include all medication errors and patient deaths;

6. Analyze any infection, epidemic outbreaks, or other unusual occurrences which threaten the health, safety, or well-being of the patients; and

7. Establish a systematic method of obtaining feedback from patients and other interested persons, for example, family members and peer organizations, as expressed by the level of satisfaction with care and services received.

SECTION 1900 - DESIGN AND CONSTRUCTION

1901. General. (II)

A facility shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient. Facility design shall be such that all patients have access to required services. There shall be at least two hundred (200) gross square feet per licensed bed in facilities with ten (10) beds or less, and in facilities licensed for more than ten (10) beds, at least an additional one hundred (100) gross square feet per licensed bed.

1902. Codes and Standards. (II)

A. Facility design and construction shall comply with provisions of the codes officially adopted by the South Carolina Building Codes Council and the South Carolina State Fire Marshal applicable to the facility.

B. Unless specifically required otherwise by the Department, all facilities shall comply with the adopted construction codes and construction provisions of this regulation applicable at the time its initial license was issued.

1903. Submission of Plans. (II)

A. Plans and specifications shall be submitted to the Department for review and approval for new construction, additions or alterations to existing buildings, replacement of major equipment, buildings being licensed for the first time, buildings changing license type, and for facilities increasing occupant load or licensed capacity. Final plans and specifications shall be prepared by an architect and/or engineer registered in South Carolina and shall bear their seals and signatures. Architectural plans shall also bear the seal of a South Carolina registered architectural corporation. Unless directed otherwise by the Department, submit plans at the schematic, design development, and final stages. All plans shall be drawn to scale with the title, stage of submission and date shown thereon. Any construction changes from the approved documents shall be approved by the Department. Construction work shall not commence until a plan approval has been received from the Department. During construction, the owner shall employ a registered architect and/or engineer for observation and inspections. The Department shall conduct periodic inspections throughout each project.

B. Plans and specifications shall be submitted to the Department for review and approval for projects that have an effect on:

1. The function of a space;

2. The accessibility to or of an area;

3. The structural integrity of the facility;

4. The active and/or passive fire safety systems (including kitchen equipment such as exhaust hoods or equipment required to be under an exhaust hood);

5. Doors;

6. Walls;

7. Ceiling system assemblies;

8. Exit corridors;

9. Life safety systems; or

10. That increase the occupant load or licensed capacity of the facility.

C. All subsequent addenda, change orders, field orders, and documents altering the Department review must be submitted. Any substantial deviation from the accepted documents shall require written notification, review and re-approval from the Department.

D. Cosmetic changes utilizing paint, wall covering, floor covering, etc. that are required to have a flame-spread rating or to satisfy other safety criteria shall be documented with copies kept on file at the facility and made available to the Department.

1904. Inspections.

Construction work which violates codes or standards will be required to be brought into compliance. All projects shall obtain all required permits from the locality having jurisdiction. Construction without proper permitting shall not be inspected by the Department.

SECTION 2000 - FIRE PROTECTION, PREVENTION, AND LIFE SAFETY (I)

A. Facilities with six (6) or more licensed beds shall have a partial, manual, automatic, supervised fire alarm system. The facility shall arrange the system to transmit an alarm automatically to a third party. The alarm system shall notify by audible and visual alarm all areas and floors of the building. The alarm system shall shut down central recirculation systems and outside air units that serve the area(s) of alarm origination as a minimum.

B. All fire, smoke, heat, sprinkler flow, and manual fire alarming devices must be connected to and activate the main fire alarm system when activated.

SECTION 2100 - GENERAL CONSTRUCTION

2101. Floor Finishes. (II)

A. Floor coverings and finishes shall meet the requirements of the building codes.

B. All floor coverings and finishes shall be appropriate for use in each area of the facility and free of hazards, such as slippery surfaces. Floor finishes shall be composed of materials that permit frequent cleaning, and when appropriate, disinfection.

2102. Wall Finishes. (I)

A. Wall finishes shall meet the requirements of the building codes.

B. Manufacturers' certifications or documentation of treatment for flame spread and other safety criteria shall be furnished and maintained.

2103. Curtains and Draperies. (II)

In bathrooms and patient rooms, window treatments shall be arranged in a manner to provide privacy.

2104. Gases. (I)

A. Safety precautions shall be taken against fire and other hazards when oxygen is dispensed, administered, or stored. "No Smoking" signs shall be posted conspicuously, and cylinders shall be properly secured in place.

B. Smoking shall be allowed only in designated areas in accordance with the facility smoking policy. No smoking is permitted in patient rooms or staff bedrooms or restrooms.

2105. Furnishings and Equipment. (I)

A. The facility shall maintain the physical plant to be free of fire hazards or impediments to fire prevention.

B. No portable electric or unvented fuel heaters shall be permitted in the facility.

C. Fireplaces and fossil-fuel stoves, for example, wood-burning, shall have partitions or screens or other means to prevent burns. Fireplaces shall be vented to the outside. "Unvented" type gas logs are not allowed. Gas fireplaces shall have a remote gas shutoff within the room and not inside the fireplace.

D. Wastebaskets, window dressings, cubicle curtains, mattresses, and pillows shall be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant.

SECTION 2200 - EXITS (I)

A. The facility shall maintain halls, corridors and all other means of egress from the building to be free of obstructions.

B. Each patient room shall open directly to an approved exit access corridor without passage through another occupied space or shall have an approved exit directly to the outside at grade level and accessible to a public space free of encumbrances.

EXCEPTION: When two (2) patient rooms share a common "sitting" area that opens onto the exit access corridor.

SECTION 2300 - WATER SUPPLY AND HYGIENE

2301. Design and Construction. (II)

A. Patient and staff hand washing lavatories and patient showers and tubs shall be supplied with hot and cold water at all times.

B. Plumbing fixtures that require hot water and are accessible to patients shall be supplied with water that is thermostatically controlled to a temperature of at least one hundred (100) degrees Fahrenheit and not to exceed one hundred twenty (120) degrees Fahrenheit at the fixture.

C. The water heater or combination of heaters shall be sized to provide at least six (6) gallons per hour per bed at the above temperature range.

D. Hot water supplied to the kitchen equipment and utensil washing sink shall be supplied at one hundred twenty (120) degrees Fahrenheit provided all kitchen equipment and utensils are chemically sanitized. For those facilities sanitizing with hot water, the sanitizing compartment of the kitchen equipment and utensil washing sink shall be capable of maintaining the water at a temperature of at least one hundred eighty (180) degrees Fahrenheit.

E. Hot water provided for washing linen and clothing shall not be less than one hundred sixty (160) degrees Fahrenheit. Should chlorine additives or other chemicals which contribute to the margin of safety in disinfecting linen and clothing be a part of the washing cycle, the minimum hot water temperature shall not be less than one hundred ten (110) degrees Fahrenheit, provided hot air drying is used.

2302. Cross-connections. (I)

There shall be no cross-connections in plumbing between safe and potentially unsafe water supplies. Water shall be delivered at least two (2) delivery pipe diameters above the rim or points of overflow to each fixture, equipment, or service unless protected against back-siphonage by approved vacuum breakers or other approved back-flow preventers. A faucet or fixture to which a hose may be attached shall have an approved vacuum breaker or other approved back-flow preventer.

SECTION 2400 - ELECTRICAL

2401. Receptacles. (II)

A. Patient Room. Each patient room shall have duplex grounding type receptacles located to include one (1) at the head of each bed.

B. Corridors. Duplex receptacles for general use shall be installed approximately fifty (50) feet apart in all corridors and within twenty-five (25) feet of the ends of corridors.

2402. Ground Fault Protection. (I)

A. Ground fault circuit-interrupter protection shall be provided for all outside receptacles and bathrooms.

B. The facility shall provide ground fault circuit-interrupter protection for any receptacles within six (6) feet of a sink or any other wet location. If the sink is an integral part of the metal splashboard grounded by the sink, the entire metal area is considered part of the wet location.

2403. Exit Signs. (I)

A. In facilities licensed for six (6) or more beds, required exits and ways to access thereto shall be identified by electrically-illuminated exit signs.

B. Changes in egress direction shall be marked with exit signs with directional arrows.

C. Exit signs in corridors shall be provided to indicate two (2) directions of exit.

2404. Emergency Electric Service. (I)

Emergency electric services shall be provided as follows:

A. Exit lights, if required;

B. Exit access corridor lighting;

C. Illumination of means of egress; and

D. Fire detection and alarm systems, if required.

SECTION 2500 - HEATING, VENTILATION, AND AIR CONDITIONING (HVAC) (II)

A. The HVAC system shall be inspected at least once a year by a certified or licensed technician.

B. The facility shall maintain a temperature of between seventy-two (72) and seventy-eight (78) degrees Fahrenheit in patient areas.

C. No HVAC supply or return grille shall be installed within three (3) feet of a smoke detector. (I)

D. HVAC grilles shall not be installed in floors.

E. Intake air ducts shall be filtered and maintained to prevent the entrance of dust, dirt, and other contaminating materials. The system shall not discharge in such a manner that would be an irritant to the patients, staff, or volunteers.

F. All kitchen areas shall be adequately ventilated in order for all areas to be kept free from excessive heat, steam, condensation, vapors, smoke, and fumes.

G. Each bathroom and/or restroom shall have either operable windows or have approved mechanical ventilation.

SECTION 2600 - PHYSICAL PLANT

2601. Facility Accommodations and Floor Area. (II)

A. There shall be sufficient living arrangements providing for patients' quiet reading, study, relaxation, entertainment, or recreation, to include living, dining, and recreational areas available for patients' use.

B. Methods for ensuring visual and auditory privacy between patient and staff, volunteers, and visitors shall be provided as necessary.

2602. Patient Rooms.

A. Each patient room shall be equipped with the following as a minimum for each patient:

1. A comfortable single bed having a mattress with moisture-proof cover, sheets, blankets, bedspread, pillow, and pillowcases; roll-away type beds, cots, bunkbeds, and folding beds shall not be used; and (II)

2. A closet, wardrobe, or bureau to accommodate each patient's personal clothing, belongings, and toilet articles.

B. Beds shall not be placed in corridors, solaria, or other locations not designated as patient room areas. (I)

C. No patient room shall contain more than three (3) beds. (II)

D. No patient room shall be located in a basement.

E. Access to a patient room shall not be by way of another patient room, toilet, bathroom, or kitchen.

2603. Patient Room Floor Area.

A. Each patient room shall be an outside room with an outside window or door. (I)

B. In non-apartment units, the patient sleeping room floor area is a usable or net area and does not include wardrobes (built-in or freestanding), closets, or the entry alcove to the room. The following is the minimum floor space allowed: (II)

1. Rooms for only one (1) patient: one hundred (100) square feet; and

2. Rooms for more than one (1) patient: eighty (80) square feet per patient.

C. Patient sleeping rooms shall be of sufficient size to allow three (3) feet between two (2) beds. (II)

2604. Bathrooms and Restrooms. (II)

A. Separate bathroom facilities shall be provided for staff members, volunteers, public, and/or family.

B. Toilets shall be provided in ample number to serve the needs of staff members, volunteers, and the public. The minimum number for patients shall be one (1) toilet for each six (6) licensed beds or fraction thereof.

C. There shall be at least one (1) handwash lavatory adjacent to each toilet. Liquid soap shall be provided in public restrooms and bathrooms used by more than one (1) patient. Communal use of bar soap is prohibited. A sanitary individualized method of drying hands shall be available at each lavatory.

D. There shall be one (1) bathtub or shower for each eight (8) licensed beds or fraction thereof.

E. All bathtubs, toilets, and showers used by patients shall have approved grab bars securely fastened in a usable fashion.

F. Privacy shall be provided at toilets, urinals, bathtubs, and showers.

G. Toilet facilities shall be at or adjacent to the kitchen for kitchen employees.

H. Facilities for handicapped persons shall be provided whether or not any of the patients are classified as handicapped.

I. All bathroom floors shall be entirely covered with an approved nonabsorbent covering. Walls shall be nonabsorbent, washable surfaces to the highest level of splash.

J. There shall be a mirror above each bathroom lavatory for patients' grooming.

K. An adequate supply of toilet tissue shall be maintained in each bathroom.

L. Easily cleanable receptacles shall be provided for waste materials. Such receptacles in toilet rooms for women shall be covered.

M. Bar soap, bath towels, and washcloths shall be provided to each patient as needed. Bath linens assigned to specific patients may not be stored in centrally located bathrooms. Provisions shall be made for each patient to properly keep their bath linens in their room, such as, on a towel hook or bar designated for each patient occupying that room, or bath linens to meet patient needs shall be distributed as needed, and collected after use and stored properly, see Section 1705.

2605. Doors. (II)

A. All patient rooms and bathrooms and restrooms shall have opaque doors for the purpose of privacy.

B. All glass doors, including sliding or patio type doors shall have a contrasting or other indicator that causes the glass to be observable, for example, a decal located at eye level.

C. Bathroom and restroom door widths shall be at least thirty-six (36) inches wide.

D. Doors to patient occupied rooms shall be at least thirty-six (36) inches wide.

E. Doors that have locks shall be unlockable and openable with one (1) action.

F. If patient room doors are lockable, there shall be provisions for emergency entry. There shall not be locks that cannot be unlocked and operated from inside the room.

G. All patient room doors shall be solid-core. Patient room doors shall be rated and provided with closers and latches as required by the codes referenced in Section 1902.

2606. Ramps. (II)

A. At least one (1) exterior ramp, accessible by all patient, staff members, volunteers, and visitors shall be installed from the first floor to grade.

B. The ramp shall serve all portions of the facility where patients are located.

C. The surface of a ramp shall be of nonskid materials.

D. Ramps in facilities with eleven (11) or more licensed beds shall be of noncombustible construction. (I)

E. Ramps shall discharge onto a surface that is firm and negotiable by a wheelchair in all weather conditions and to a location accessible for loading into a vehicle.

2607. Screens. (II)

Windows, doors, and openings intended for ventilation shall be provided with insect screens.

2608. Windows and Mirrors.

A. The window dimensions and maximum height from floor to sill shall be in accordance with the building codes, as applicable.

B. Where patient safety awareness is impaired, safety (non-breakable) mirrors shall be used.

2609. Janitor's Closet. (II)

There shall be a lockable janitor's closet in all facilities. Each closet shall be equipped with a mop sink or receptor and space for the storage of supplies and equipment.

2610. Storage Areas.

A. General storage areas shall be provided for patient, staff, and volunteer belongings, equipment, and supplies as well as clean linen, soiled linen, wheel chairs, and general supplies and equipment.

B. Storage buildings on the premises shall meet the building codes requirements regarding distance from the licensed building. Storage in buildings other than on the facility premises shall be secure and accessible. An appropriate controlled environment shall be provided if necessary for storage of items requiring such an environment.

C. In mechanical rooms used for storage, the stored items shall be located away from mechanical equipment and shall not be a type of storage that might create a fire or other hazard. (I)

D. Supplies and equipment shall not be stored directly on the floor. Supplies and equipment susceptible to water damage and/or contamination shall not be stored under sinks or other areas with a propensity for water leakage.

E. There shall be a soiled linen storage room which shall be designed, enclosed, and used solely for that purpose, and provided with mechanical exhaust directly to the outside.

2611. Telephone Service.

A. At least one (1) telephone shall be available on each floor of the facility with at least one (1) active main or fixed-line telephone service available.

B. At least one (1) telephone shall be provided by the facility on each floor for staff members and volunteers to conduct routine business of the facility and to summon assistance in the event of an emergency. Patients shall have telephone privacy.

2612. Location.

A. The facility shall be served by roads that are passable at all times and are adequate for the volume of expected traffic.

B. The facility shall have a parking area to reasonably satisfy the needs of patients, staff members, volunteers, and visitors.

C. Facilities shall maintain adequate access to and around the building(s) for firefighting equipment. (I)

2613. Outdoor Area.

A. Outdoor areas where unsafe, unprotected physical hazards exist shall be enclosed by a fence or a natural barrier of a size, shape, and density that effectively impedes travel to the hazardous area. (I)

B. Mechanical or equipment rooms that open to the outside of the facility shall be kept protected from unauthorized individuals. (II)

SECTION 2700 - SEVERABILITY

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect as if such invalid portions were not originally a part of these regulations.

SECTION 2800 - GENERAL

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

HISTORY: Added by SCSR 43–5 Doc. No. 4809, eff May 24, 2019.