

SOUTH CAROLINA STATE REGISTER DISCLAIMER

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SOUTH CAROLINA STATE REGISTER

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of the
GENERAL ASSEMBLY

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This issue contains notices, proposed regulations, emergency regulations, final form regulations, and other documents filed in the Office of the Legislative Council, pursuant to Article 1, Chapter 23, Title 1, Code of Laws of South Carolina, 1976.

SOUTH CAROLINA STATE REGISTER

An official state publication, the *South Carolina State Register* is a temporary update to South Carolina's official compilation of agency regulations--the *South Carolina Code of Regulations*. Changes in regulations, whether by adoption, amendment, repeal or emergency action must be published in the *State Register* pursuant to the provisions of the Administrative Procedures Act. The *State Register* also publishes the Governor's Executive Orders, notices or public hearings and meetings, and other documents issued by state agencies considered to be in the public interest. All documents published in the *State Register* are drafted by state agencies and are published as submitted. Publication of any material in the *State Register* is the official notice of such information.

STYLE AND FORMAT

Documents are arranged within each issue of the *State Register* according to the type of document filed:

Notices are documents considered by the agency to have general public interest.

Notices of Drafting Regulations give interested persons the opportunity to comment during the initial drafting period before regulations are submitted as proposed.

Proposed Regulations are those regulations pending permanent adoption by an agency.

Pending Regulations Submitted to the General Assembly are regulations adopted by the agency pending approval by the General Assembly.

Final Regulations have been permanently adopted by the agency and approved by the General Assembly.

Emergency Regulations have been adopted on an emergency basis by the agency.

Executive Orders are actions issued and taken by the Governor.

2016 PUBLICATION SCHEDULE

Documents will be accepted for filing on any normal business day from 8:30 A.M. until 5:00 P.M. All documents must be submitted in the format prescribed in the *Standards Manual for Drafting and Filing Regulations*.

To be included for publication in the next issue of the *State Register*, documents will be accepted no later than 5:00 P.M. on any closing date. The modification or withdrawal of documents filed for publication must be made **by 5:00 P.M.** on the closing date for that issue.

	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.
Submission Deadline	1/8	2/12	3/11	4/8	5/13	6/10	7/8	8/12	9/9	10/14	11/11	12/9
Publishing Date	1/22	2/26	3/25	4/22	5/27	6/24	7/22	8/26	9/23	10/28	11/25	12/23

REPRODUCING OFFICIAL DOCUMENTS

Documents appearing in the *State Register* are prepared and printed at public expense. Media services are encouraged to give wide publicity to documents printed in the *State Register*.

PUBLIC INSPECTION OF DOCUMENTS

Documents filed with the Office of the State Register are available for public inspection during normal office hours, 8:30 A.M. to 5:00 P.M., Monday through Friday. The Office of the State Register is in the Legislative Council, Fourth Floor, Rembert C. Dennis Building, 1000 Assembly Street, in Columbia. Telephone inquiries concerning material in the *State Register* or the *South Carolina Code of Regulations* may be made by calling (803) 212-4500.

ADOPTION, AMENDMENT AND REPEAL OF REGULATIONS

To adopt, amend or repeal a regulation, an agency must publish in the *State Register* a Notice of Drafting; a Notice of the Proposed Regulation that contains an estimate of the proposed action's economic impact; and, a notice that gives the public an opportunity to comment on the proposal. If requested by twenty-five persons, a public hearing must be held at least thirty days after the date of publication of the notice in the *State Register*.

After the date of hearing, the regulation must be submitted to the General Assembly for approval. The General Assembly has one hundred twenty days to consider the regulation. If no legislation is introduced to disapprove or enacted to approve before the expiration of the one-hundred-twenty-day review period, the regulation is approved on the one hundred twentieth day and is effective upon publication in the *State Register*.

EMERGENCY REGULATIONS

An emergency regulation may be promulgated by an agency if the agency finds imminent peril to public health, safety or welfare. Emergency regulations are effective upon filing for a ninety-day period. If the original filing began and expired during the legislative interim, the regulation can be renewed once.

REGULATIONS PROMULGATED TO COMPLY WITH FEDERAL LAW

Regulations promulgated to comply with federal law are exempt from General Assembly review. Following the notice of proposed regulation and hearing, regulations are submitted to the *State Register* and are effective upon publication.

EFFECTIVE DATE OF REGULATIONS

Final Regulations take effect on the date of publication in the *State Register* unless otherwise noted within the text of the regulation.

Emergency Regulations take effect upon filing with the Legislative Council and remain effective for ninety days. If the original ninety-day period begins and expires during legislative interim, the regulation may be refiled for one additional ninety-day period.

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4527	SR40-2		Consumer Credit Counseling Requirements	1/12/16	Department of Consumer Affairs
4533	SR40-2		South Carolina National Guard College Assistance Program	1/13/16	Commission on Higher Education
4534	SR40-2		South Carolina National Guard Student Loan Repayment Program	1/13/16	Commission on Higher Education
4524	SR40-2		Suspension of Certification Due to Criminal Charges and/or Indictment	1/14/16	South Carolina Criminal Justice Academy
4539	SR40-2		Consumer Electronic Equipment Collection and Recovery	2/01/16	Department of Health and Envir Control
4543	SR40-3		Standards for Licensing Nursing Homes	2/28/16	Department of Health and Envir Control
4552	SR40-4		Horse Meat and Kangaroo Meat; Fairs, Camp Meetings, and Other Gatherings; Camps; Mobile/Manufactured Home Parks; Sanitation of Schools; and Nuisances	3/14/16	Department of Health and Envir Control
4553	SR40-4		Standards for Licensing Hospices	3/27/16	Department of Health and Envir Control
4562	SR40-4		Board of Long Term Health Care Administrators	3/28/16	LLR-Board of Long Term Health Care Administrators
4563	SR40-4		Local Emergency Preparedness Standards	4/05/16	Office of the Governor
4565	SR40-5		Underground Storage Tank Control Regulations	4/25/16	Department of Health and Envir Control
4564	SR40-5		Standards for Licensing Habilitation Centers for Persons with Intellectual Disability or Persons with Related Conditions	4/30/16	Department of Health and Envir Control
4573	SR40-5		Continuing Education in Sterilization and Infection Control	5/11/16	LLR-Board of Dentistry
4574	SR40-5		Pilot Registration	5/11/16	LLR-Commissioners of Pilotage
4567	SR40-5		Crabmeat	5/11/16	Department of Health and Envir Control
4568	SR40-5		Standards for Licensing Tattoo Facilities	5/11/16	Department of Health and Envir Control
4569	SR40-5		Standards for Permitting Body Piercing Facilities	5/11/16	Department of Health and Envir Control
4570	SR40-5		Natural Public Swimming Areas	5/11/16	Department of Health and Envir Control
4585	SR40-5		State Emergency Preparedness Standards	5/11/16	Office of the Governor
4588	SR40-5		Safeguarding Patient Medical Records	5/11/16	LLR-Board of Medical Examiners
4589	SR40-5		Continuing Education, Payment of Fees, Appraisal Experience, and Appraiser Apprentice Requirements	5/11/16	LLR-Reals Estate Appraisers Board
4578	SR40-5		South Carolina Trauma Care Systems	5/11/16	Department of Health and Envir Control
4571	SR40-5		Well Standards	5/11/16	Department of Health and Envir Control
4594	SR40-5		Development of Subdivision Water Supply and Sewage Treatment/Disposal Systems	5/11/16	Department of Health and Envir Control
4591	SR40-5		Onsite Wastewater Systems	5/11/16	Department of Health and Envir Control
4630	SR40-5		Residential Specialty Contractors License	5/13/16	LLR-Residential Builders Commission
4626	SR40-5		Guidelines for Sedation and General Anesthesia	5/13/16	LLR-Board of Dentistry
4627	SR40-5		Fees for Registration and Renewal	5/13/16	LLR-Board of Registration for Foresters
4601	SR40-5		Minimum Requirements for Licensing Cosmetologists as Master Hair Care Specialists	5/13/16	LLR-Board of Barber Examiners
4592	SR40-5		Continuing Competency; Continuing Education Credits	5/13/16	LLR-Panel for Dietetics
4586	SR40-5		Special Education, Education of Students with Disabilities	5/13/16	State Board of Education
4618	SR40-6		Fire Prevention and Life Safety	5/14/16	LLR-Office of State Fire Marshal
4619	SR40-6		Fire Prevention and Life Safety for Special Occupancies	5/14/16	LLR-Office of State Fire Marshal
4621	SR40-6		Hydrogen Facilities	5/14/16	LLR-Office of State Fire Marshal
4623	SR40-6		Portable Fire Extinguishers and Fixed Fire Extinguishing Systems	5/14/16	LLR-Office of State Fire Marshal
4620	SR40-6		Fireworks and Pyrotechnics	5/14/16	LLR-Office of State Fire Marshal
4617	SR40-6		Explosives	5/14/16	LLR-Office of State Fire Marshal
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4603	SR40-6		Alignment of Assessment and Accountability Elements with the No Child Left Behind Act	5/18/16	State Board of Education
4590	SR40-6		Air Pollution Control Regulations and Standards	5/18/16	Department of Health and Envir Control
4622	SR40-6		Liquefied Petroleum (LP) Gas	5/19/16	LLR-Office of State Fire Marshal
4611	SR40-6		Psittacine Birds	5/20/16	Department of Health and Envir Control
4612	SR40-6		Sexually Transmitted Diseases	5/20/16	Department of Health and Envir Control
4613	SR40-6		Solid Waste Management: Used Oil	5/20/16	Department of Health and Envir Control
4606	SR40-6		Test Security	5/20/16	State Board of Education
4602	SR40-6		2015 Edition of International Codes and 2014 Edition of the National Electrical Code	5/20/16	LLR-Building Codes Council
4604	SR40-6		Assessment Program	5/21/16	State Board of Education
4607	SR40-6		Charges for Family Planning Services	5/21/16	Department of Health and Envir Control
4609	SR40-6		Communicable Diseases	5/21/16	Department of Health and Envir Control
4608	SR40-6		Charges for Maternal and Child Health Services	5/21/16	Department of Health and Envir Control
4605	SR40-6		District and School Planning	5/21/16	State Board of Education
4596	SR40-6		Residential Treatment Facilities for Children and Adolescents	5/22/16	Department of Health and Envir Control
4614	SR40-6		Solid Waste Management: Solid Waste Incineration and Solid Waste Pyrolysis Facilities	5/24/16	Department of Health and Envir Control

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4595	SR40-6	X-Rays (Title B)	5/25/16	Department of Health and Envir Control
4593	SR40-6	Program Approval Standards for South Carolina Teacher Education Institutions	5/31/16	State Board of Education
4615	SR40-6	Coastal Division Regulations	6/02/16	Department of Health and Envir Control
4610	SR40-6	Emergency Medical Services	6/02/16	Department of Health and Envir Control
4634		Additional Regulations Applicable to Specific Properties	Withdrawn	Department of Natural Resources
4635		Wildlife Management Area Regulations; and Turkey Hunting Rules and Seasons	Withdrawn	Department of Natural Resources
4636		Accreditation Criteria	Withdrawn	State Board of Education
4637		Certification Requirements	Withdrawn	State Board of Education
4638		Credential Classification	Withdrawn	State Board of Education
4639		Requirements for Additional Areas of Certification	Withdrawn	State Board of Education
4575		Examples of the Application of Tax to Various Charges Imposed by Hotels, Motels, and Other Facilities	Withdrawn	Department of Revenue
4576		Hotels, Motels, and Similar Facilities	Withdrawn	Department of Revenue
4624		Professional Employer Organizations	Withdrawn	Department of Consumer Affairs
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4538		Certification of Need for Health Facilities and Services	Withdrawn	Department of Health and Envir Control
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4581		WIC Vendors		Department of Health and Envir Control
4566		Examination Attempts, Apprenticeship, and Continuing Education Requirements		LLR-Board of Examiners in Opticianry
4628		Classification of Residential Specialty Contractors		LLR-Residential Builders Commission
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The history, status, and full text of these regulations are available on the
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4533	South Carolina National Guard College Assistance Program	Education and Public Works	Education
4534	South Carolina National Guard Student Loan Repayment Program	Education and Public Works	Education
4524	Suspension of Certification Due to Criminal Charges and/or Indictment	Judiciary	Judiciary
4539	Consumer Electronic Equipment Collection and Recovery	Agriculture and Natural Resources	Agriculture and Natural Resources
4543	Standards for Licensing Nursing Homes	Regulations and Admin. Procedures	Medical Affairs
4552	Horse Meat and Kangaroo Meat; Fairs, Camp Meetings, and Other Gatherings; Camps; Mobile/Manufactured Home Parks; Sanitation of Schools; and Nuisances	Regulations and Admin. Procedures	Medical Affairs
4553	Standards for Licensing Hospices	Regulations and Admin. Procedures	Medical Affairs
4562	Board of Long Term Health Care Administrators	Regulations and Admin. Procedures	Medical Affairs
4563	Local Emergency Preparedness Standards	Regulations and Admin. Procedures	General
4565	Underground Storage Tank Control Regulations	Regulations and Admin. Procedures	Medical Affairs
4564	Standards for Licensing Habilitation Centers for Persons with Intellectual Disability or Persons with Related Conditions	Regulations and Admin. Procedures	Medical Affairs
4573	Continuing Education in Sterilization and Infection Control	Regulations and Admin. Procedures	Medical Affairs
4574	Pilot Registration	Regulations and Admin. Procedures	Labor, Commerce and Industry
4567	Crabmeat	Regulations and Admin. Procedures	Agriculture and Natural Resources
4568	Standards for Licensing Tattoo Facilities	Regulations and Admin. Procedures	Medical Affairs
4569	Standards for Permitting Body Piercing Facilities	Regulations and Admin. Procedures	Medical Affairs
4570	Natural Public Swimming Areas	Regulations and Admin. Procedures	Medical Affairs
4585	State Emergency Preparedness Standards	Regulations and Admin. Procedures	General
4588	Safeguarding Patient Medical Records	Regulations and Admin. Procedures	Labor, Commerce and Industry
4589	Continuing Education, Payment of Fees, Appraisal Experience, and Appraiser Apprentice Requirements	Regulations and Admin. Procedures	Labor, Commerce and Industry
4578	South Carolina Trauma Care Systems	Regulations and Admin. Procedures	Medical Affairs
4571	Well Standards	Regulations and Admin. Procedures	Medical Affairs
4594	Development of Subdivision Water Supply and Sewage Treatment/Disposal Systems	Regulations and Admin. Procedures	Medical Affairs
4591	Onsite Wastewater Systems	Regulations and Admin. Procedures	Medical Affairs
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4626	Guidelines for Sedation and General Anesthesia	Regulations and Admin. Procedures	Medical Affairs
4627	Fees for Registration and Renewal	Regulations and Admin. Procedures	Fish, Game and Forestry
4601	Minimum Requirements for Licensing of Cosmetologists as Master Hair Care Specialists	Regulations and Admin. Procedures	Labor, Commerce and Industry
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4586	Special Education, Education of Students with Disabilities	Regulations and Admin. Procedures	Education
4618	Fire Prevention and Life Safety	Regulations and Admin. Procedures	Labor, Commerce and Industry
4619	Fire Prevention and Life Safety for Special Occupancies	Regulations and Admin. Procedures	Labor, Commerce and Industry
4621	Hydrogen Facilities	Regulations and Admin. Procedures	Labor, Commerce and Industry
4623	Portable Fire Extinguishers and Fixed Fire Extinguishing Systems	Regulations and Admin. Procedures	Labor, Commerce and Industry
4620	Fireworks and Pyrotechnic	Regulations and Admin. Procedures	Labor, Commerce and Industry
4617	Explosives	Regulations and Admin. Procedures	Labor, Commerce and Industry
4580	Vital Statistics	Regulations and Admin. Procedures	Medical Affairs
4603	Alignment of Assessment and Accountability Elements with the No Child Left Behind Act	Regulations and Admin. Procedures	Education
4590	Air Pollution Control Regulations and Standards	Regulations and Admin. Procedures	Medical Affairs
4622	Liquefied Petroleum (LP) Gas	Regulations and Admin. Procedures	Labor, Commerce and Industry
4611	Psittacine Birds	Regulations and Admin. Procedures	Agriculture and Natural Resources
4612	Sexually Transmitted Diseases	Regulations and Admin. Procedures	Medical Affairs
4613	Solid Waste Management: Used Oil	Regulations and Admin. Procedures	Medical Affairs
4606	Test Security	Regulations and Admin. Procedures	Education
4602	2015 Edition of International Codes and 2014 Edition of the National Electrical Code	Regulations and Admin. Procedures	Labor, Commerce and Industry
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4605	District and School Planning	Regulations and Admin. Procedures	Education
4596	Residential Treatment Facilities for Children and Adolescents	Regulations and Admin. Procedures	Medical Affairs
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4616	The Evaluation of School Employees for Tuberculosis	Regulations and Admin. Procedures	Medical Affairs
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4 COMMITTEE LIST OF REGULATIONS SUBMITTED TO GENERAL ASSEMBLY

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4610	Emergency Medical Service	Regulations and Admin. Procedures	Medical Affairs
4634	Additional Regulations Applicable to Specific Properties	Regulations and Admin. Procedures	Fish, Game and Forestry
4635	Wildlife Management Area Regulations; and Turkey Hunting Rules and Seasons	Regulations and Admin. Procedures	Fish, Game and Forestry
4636	Accreditation Criteria	Regulations and Admin. Procedures	Education
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4639	Requirements for Additional Areas of Certification	Regulations and Admin. Procedures	Education
4575	Examples of the Application of Tax to Various Charges Imposed by Hotels, Motels, and Other Facilities	Regulations and Admin. Procedures	Finance
4576	Hotels, Motels, and Similar Facilities	Regulations and Admin. Procedures	Finance
4624	Professional Employer Organizations	Regulations and Admin. Procedures	Labor, Commerce and Industry
4625	Licensing Standards for Continuing Care Retirement Communities	Regulations and Admin. Procedures	Medical Affairs
4645	Unemployment Trust Fund Solvency	Regulations and Admin. Procedures	Labor, Commerce and Industry

Resolution Introduced to Disapprove

4551	Certification of Need for Health Facilities and Services	Medical, Military, Pub & Mun Affairs	Medical Affairs
4538	Certification of Need for Health Facilities and Services	Medical, Military, Pub & Mun Affairs	Medical Affairs

Permanently Withdrawn

4581	WIC Vendors	Regulations and Admin. Procedures	Medical Affairs
4566	Examination Attempts, Apprenticeship, and Continuing Education Requirements	Regulations and Admin. Procedures	Medical Affairs
4628	Classification of Residential Specialty Contractors	Regulations and Admin. Procedures	Labor, Commerce and Industry
4629	Residential Specialty Contractors License	Regulations and Admin. Procedures	Labor, Commerce and Industry

Executive Order No. 2016-13

WHEREAS, the State of South Carolina experienced historic flooding in October of 2015, leading to widespread damage to homes across the state; and

WHEREAS, assistance to recover from such damage through a variety of private and public sources including insurance proceeds, direct public assistance, and construction performed by charitable organizations has helped many South Carolinians recover from this damage; and

WHEREAS, unmet housing needs directly resulting from flood damage still exist; and

WHEREAS, the United States Congress appropriated funds for flood-related housing relief and the United States Department of Housing and Urban Development allocated \$96,827,000 in Community Development Block Grant – Disaster Relief funds to address these unmet needs; and

WHEREAS, the responsible administration of such funds requires sound grant allocation policies, effective business processes, and several avenues for individual applicants to receive due consideration of their resource requests.

NOW, THEREFORE, pursuant to the authority vested in me by the Constitution and Statutes of the State of South Carolina, I hereby establish the South Carolina Community Development Block Grant Steering Committee (Committee) to advise the South Carolina Department of Commerce (Department) on the development of the South Carolina State Action Plan (Plan) and oversee its implementation for the disbursement of the Community Development Block Grant – Disaster Relief (CDBG-DR) funds.

FURTHER, I hereby direct the Committee and Department as follows:

1. The Committee shall convene within 10 days of the issuance of this order to organize and receive a briefing from the Department on the current status of Plan formulation.
2. Prior to the submission of the initial Plan, the Department shall receive advice and consent from the Committee regarding allowable activities, resource allocation, and individual eligibility criteria to be included in the Plan and investment strategies for CDBG-DR funds.
3. Once the initial Plan has been submitted to the United States Department of Housing and Urban Development (HUD), the Department shall not amend the Plan without the advice and consent of the Committee.
4. Following submission of the Plan to HUD, the Committee shall meet as needed, but not less than quarterly, to receive reports on the activities funded by the CDBG-DR program and to advise on policy and Plan amendments.

The order shall take effect immediately.

**GIVEN UNDER MY HAND AND THE GREAT
SEAL OF THE STATE OF SOUTH CAROLINA,
THIS 12th DAY OF APRIL, 2016.**

**NIKKI R. HALEY
Governor**

6 EXECUTIVE ORDERS

Executive Order No. 2016-14

WHEREAS, an election was to be held on April 12, 2016, the second Tuesday of the month of April, in the Town of Williams, South Carolina for the offices of Mayor and Town Council; and

WHEREAS, on May 3, 2016, the current Mayor of the Town of Williams, Will Evans, informed me that the election was not held and requested that an election be held for the offices of Mayor and Town Council; and

WHEREAS, pursuant to Section 7-13-1170 of the South Carolina Code of Laws, “When any election official of any political subdivision of this State charged with ordering, providing for, or holding an election has neglected, failed, or refused to order, provide for, or hold the election at the time appointed, or if for any reason the election is declared void by competent authority, and these facts are made to appear to the satisfaction of the Governor, he shall, should the law not otherwise provide for this contingency, order an election or a new election to be held at the time and place, and upon the notice being given which to him appears adequate to insure the will of the electorate being fairly expressed. To that end, he may designate the existing election official or other person as he may appoint to perform the necessary official duties pertaining to the election and to declare the result.”

NOW, THEREFORE, pursuant to the authority vested in me by the Constitution and Statutes of the State of South Carolina, I hereby order a new election to be held for the offices of Mayor and Town Council for the Town of Williams in Colleton County and further order the Colleton County Board of Registration and Elections to perform all necessary official duties pertaining to the election in accordance with applicable constitutional and statutory provisions.

The order shall take effect immediately.

**GIVEN UNDER MY HAND AND THE GREAT
SEAL OF THE STATE OF SOUTH CAROLINA,
THIS 31st DAY OF MAY, 2016.**

NIKKI R. HALEY
Governor

DEPARTMENT OF CONSUMER AFFAIRS
NOTICE OF GENERAL PUBLIC INTEREST

28-90. Discount Medical Plan Certificate of Registration

The South Carolina Department of Consumer Affairs elected to terminate the promulgation process on Regulation Document No. 4647, relating to Discount Medical Plan Certificate of Registration.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
NOTICE OF GENERAL PUBLIC INTEREST

DHEC-Bureau of Land and Waste Management, File #400801
CSXF Bramlette Road Site

**NOTICE OF VOLUNTARY CLEANUP CONTRACT, CONTRIBUTION PROTECTION, AND
COMMENT PERIOD**

PLEASE TAKE NOTICE that the South Carolina Department of Health and Environmental Control (DHEC) intends to enter into a Voluntary Cleanup Contract (VCC) with Duke Energy Carolinas, LLC (Responsible Party). The VCC provides that the Responsible Party, with DHEC's oversight, will fund and perform future response actions at the CSXF Bramlette Road facility located in Greenville County, at 400 E. Bramlette Road, Greenville, South Carolina, and any surrounding area impacted by the migration of hazardous substances, pollutants, or contaminants from the facility property (Site).

Future response actions addressed in the VCC include, but may not be limited to, the Responsible Party funding and performing: a Remedial Investigation (RI) to determine the source, nature, and extent of the release or threat of release of hazardous substances, pollutants, or contaminants and, if necessary, conduct a Feasibility Study (FS) to evaluate alternatives to clean-up the Site. Further, the Responsible Party will reimburse the Department's past costs of response of \$8,491.99 and the Department's future costs of overseeing the work performed by the Responsible Party and other Department costs of response pursuant to the VCC.

The VCC is subject to a thirty-day public comment period consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. § 9613, and the South Carolina Hazardous Waste Management Act (HWMA), S.C. Code Ann. § 44-56-200 (as amended). Notice of Contribution Protection and Comment Period will be provided to known potentially responsible parties via email or US mail. The VCC is available:

- (1) On-line at www.scdhec.gov/Apps/Environment/PublicNotices or
- (2) By contacting Lucas Berresford at 803-898-0747 or berresjl@dhec.sc.gov.

Any comments to the proposed VCC must be submitted in writing, postmarked no later than July 25, 2016, and addressed to: David Wilkie, DHEC-BLWM-SARR, 2600 Bull Street, Columbia, SC 29201.

8 NOTICES

Upon the successful completion of the VCC, the Responsible Party will receive a covenant not to sue for the work done in completing the response actions specifically covered in the Contract and completed in accordance with the approved work plans and reports. Upon execution of the VCC, the Responsible Party shall be deemed to have resolved its liability to the State in an administrative settlement for purposes of, and to the extent authorized under CERCLA, 42 U.S.C. 9613(f)(2) and 9613(f)(3)(B), and under S.C. Code Ann. Section 44-56-200, for the response actions specifically covered in the Contract including the approved work plans and reports. Contribution protection is contingent upon the Department's determination that the Responsible Party has successfully and completely complied with the VCC.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

NOTICE OF GENERAL PUBLIC INTEREST

DHEC-Bureau of Land and Waste Management, File #414343
Marsh Lumber Site

NOTICE OF VOLUNTARY CLEANUP CONTRACT, CONTRIBUTION PROTECTION, AND COMMENT PERIOD

PLEASE TAKE NOTICE that the South Carolina Department of Health and Environmental Control (the Department) intends to enter into a Voluntary Cleanup Contract (VCC) with Marsh Furniture Company (Marsh). Under the VCC, Marsh will perform response actions at the Marsh Lumber facility located at 119 Sixth Avenue, Pamplico (Florence County), South Carolina.

Response actions addressed in the VCC include Marsh funding and performing investigations to delineate groundwater contamination and evaluating cleanup alternatives for the Site under DHEC's oversight. Further, Marsh will reimburse the Department's past response costs of \$343.63 and oversight costs pursuant to the VCC.

The VCC is subject to a thirty-day public comment period consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. Section 9613, and the South Carolina Hazardous Waste Management Act (HWMA), S.C. Code Ann. Section 44-56-200 (as amended). Notice of Contribution Protection and Comment Period will be provided to known potentially responsible parties via email or US mail. The VCC is available:

- (1) On-line at www.scdhec.gov/Apps/Environment/PublicNotices; or
- (2) By contacting Pat L Vincent at 803-898-0840 or vincenpl@dhec.sc.gov.

Any comments to the proposed VCC must be submitted in writing, postmarked no later than July 25, 2016, and addressed to: Pat Vincent, DHEC-BLWM-SARR, 2600 Bull Street, Columbia, SC 29201.

Upon the successful completion of the VCC, Marsh will receive a covenant not to sue for the work done in completing the response actions specifically covered in the VCC and completed in accordance with the approved work plans and reports. Upon execution of the VCC, Marsh shall be deemed to have resolved its liability to the State in an administrative settlement for purposes of, and to the extent authorized under CERCLA, 42 U.S.C. Sections 9613(f)(2) and 9613(f)(3)(B), and under S.C. Code Ann. Section 44-56-200, for the response actions specifically covered in the VCC including the approved work plans and reports.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

ERRATA

State Register Document No. 4564

June 24, 2016

The Department promulgated amendments of Regulation 61-13, *Standards for Licensing Habilitation Centers for Persons with Intellectual Disability or Persons with Related Conditions*, which took effect as final regulations in the State Register May 27, 2016, as Document No. 4564.

This notice is to correct the following scrivener's errors:

In Section 1203.C.5, the word "does" is corrected to "dose" to read as follows:

5. Promptly recording on the medical administration records, as it is administered, the date, time, dose given, mode of administration, and identification of the individual who administered the medication.

In Section 2200.B, the scrivener's error referencing Section 2201.A is corrected to Section 2200.A to read as follows:

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 2200.A.

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

ERRATA

State Register Document No. 4571

June 24, 2016

Effective May 27, 2016 the Department amended R.61-71, *Well Standards*, by publication of Document No. 4571 in S.C. State Register Volume 40 Issue 5. This amendment revised Section 61-71.D.1 to add "S.C. Code Section" before the numerical citation of 40-25-10 for consistency with language style of other legal citations in the Regulation. However, during the drafting of the revision one character in the numerical portion of the citation was inadvertently changed from "3" to "5" and the numerical citation read 40-25-10 rather than 40-23-10. Section 40-25-10 relates to the Practice of Specializing in Hearing Aids Act and is not related to Well Standards. Change of the numerical portion of this statute was not proposed as an amendment, and the statute at this section remains as 40-23-10. This notice of errata is to correct this typographical scrivener's error.

Section 61-71.D.1 is corrected to read:

1. All wells shall be drilled, constructed, and abandoned by a South Carolina certified well driller per S.C. Code Section 40-23-10 et seq.

10 DRAFTING NOTICES

STATE BOARD OF EDUCATION CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, 59-5-65, and 59-59-10 et seq.

Notice of Drafting:

The South Carolina Board of Education proposes to amend Regulation 43-274.1, At-Risk Students.

Interested persons may submit their comments in writing to Jamaal Perry, Education Associate, Office of Student Intervention Services, Division of Federal, State, and Community Resources, 1429 Senate Street, Suite 802, Columbia, SC 29201 or by e-mail to jperry@ed.sc.gov. To be considered, all comments must be received no later than 5:00 p.m. on July 25, 2016.

Synopsis:

Regulation 43-274.1, At-Risk Students, establishes a definition for “at-risk student” and identifies at-risk student indicators, predictors, and barriers. The regulation also sets the parameters schools must use to select, implement, and evaluate at-risk student program models. The regulation must be amended to remove references to the Palmetto Assessment of State Standards (PASS) and the High School Assessment Program (HSAP).

Legislative review is required.

STATE BOARD OF EDUCATION CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, 59-5-65, 59-53-1810, and 20 U.S.C. 2301 et seq.

Notice of Drafting:

The South Carolina Board of Education proposes to amend Regulation 43-236, Career or Technology Centers/Comprehensive High Schools CATE Completer Units.

Interested persons may submit their comments in writing to Ronald Roveri, Director, Office of Career and Technology Education, division of College and Career Readiness, 1429 Senate Street, Room 912-A, Columbia, South Carolina 29201 or by e-mail to rroveri@ed.sc.gov. To be considered, all comments must be received no later than 5:00 p.m. on July 25, 2016.

Synopsis:

Regulation 43-236 governs school districts’ offerings in high schools and/or career or technology centers. The proposed amendment from four units to three units in an approved sequence of CATE coursework is being made in an effort to provide students more flexibility in personalizing their program of study. The amendment will create more opportunities for extended learning opportunities such as Internships and Apprenticeships to better prepare for an industry recognized credential. Furthermore, this amendment from four to three units will align South Carolina with the rest of the states in terms of completing a Career and Technical Program of Study.

Legislative review is required.

STATE BOARD OF EDUCATION

CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, 59-18-110, 59-18-310(B), 59-29-10 et seq., 59-33-30, 59-53-1810, 20 U.S.C. 1232(g), and 20 U.S.C. 6301 et seq.

Notice of Drafting:

The South Carolina Board of Education proposes to amend Regulation 43-234, Defined Program, Grades 9-12 and Graduation Requirements. Interested persons may submit their comments in writing to Darlene Prevatt, Team Leader, Office of Federal and State Accountability, 1429 Senate Street, Room 501-A, Columbia, South Carolina 29201 or by e-mail to dprevatt@ed.sc.gov. To be considered, all comments must be received no later than 5:00 p.m. on July 25, 2016.

Synopsis:

Regulation 43-234 establishes that each school board of trustees must ensure quality schooling by providing a rigorous, relevant curriculum for all students. The regulation also stipulates that each school district must offer a standards-based academic curriculum organized around a career cluster system that provides students with individualized education choices. The regulation also defines the graduation requirements for the state.

The amendment will address Career and Technology Education (CATE) completer requirements, language referencing CATE, and language referencing the Every Student Succeeds Act (ESSA). Language referencing the No Child Left Behind Act (NCLB) will be removed.

Legislative review of this proposal will be required.

STATE BOARD OF EDUCATION

CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, 59-5-65, and 59-59-10 et seq.

Notice of Drafting:

The South Carolina Board of Education proposes to amend Regulation 43-279, Minimum Standards of Student Conduct and Disciplinary Enforcement Procedures to be Implemented by Local School Districts.

Interested persons may submit their comments in writing to Sabrina Moore, Office of Student Intervention Services, Division of Federal, State, and Community Resources, 1429 Senate Street, Room 805, Columbia, South Carolina 29201 or by e-mail to smoore@ed.sc.gov. To be considered, all comments must be received no later than 5:00 p.m. on July 25, 2016.

Synopsis:

Regulation 43-279, Minimum Standards of Student Conduct and Disciplinary Enforcement Procedures to be Implemented by Local School Districts, establishes expectations for student conduct in South Carolina and outlines possible sanctions. The regulation must be amended to include the changes recommended by the Safe Schools Taskforce, which was established by State Superintendent of Education Molly M. Spearman in November of 2015. Dr. Traci Young Cooper, immediate past chair and current member of the South Carolina State Board of Education, co-chaired the taskforce along with Superintendent Spearman. In sum, the amendments will include changes in the levels of misconduct, acts of misconduct, disciplinary enforcement procedures, and possible sanctions.

Legislative review is required.

12 DRAFTING NOTICES

STATE BOARD OF EDUCATION

CHAPTER 43

Statutory Authority: 1976 Code Sections 5-7-12, 16-17-420, 59-5-60, and 59-5-65

Notice of Drafting:

The South Carolina Board of Education proposes to create Regulation 43-210, School Resource Officers.

Interested persons may submit their comments in writing to Sabrina Moore, Office of Student Intervention Services, Division of Federal, State, and Community Resources, 1429 Senate Street, Room 805, Columbia, South Carolina 29201 or by e-mail to smoore@ed.sc.gov. To be considered, all comments must be received no later than 5:00 p.m. on July 25, 2016.

Synopsis:

Regulation 43-210, School Resource Officers, is being created based on recommendations from the Safe Schools Taskforce, which was established by State Superintendent of Education Molly M. Spearman in November of 2015. Dr. Traci Young Cooper, immediate past chair and current member of the South Carolina State Board of Education, co-chaired the taskforce along with Superintendent Spearman. This new regulation establishes a definition of “school resource officers,” along with expectations, roles, and procedures associated with these individuals.

Legislative review is required.

Document No. 4650

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: 1976 Code Sections 48-1-10 et seq.

61-62. Air Pollution Control Regulations and Standards

Preamble:

(1) Pursuant to the South Carolina Pollution Control Act, Section 48-1-10 et seq., along with the federal Clean Air Act, 42 U.S.C. Sections 7410, 7413, and 7416, the Department must ensure national primary and secondary ambient air quality standards are achieved and maintained in South Carolina. No state may adopt or enforce an emission standard or limitation less stringent than these federal standards or limitations. 42 U.S.C. Section 7416. The United States Environmental Protection Agency (EPA) promulgates amendments to the Code of Federal Regulations throughout each calendar year. Recent federal amendments to 40 CFR Parts 51, 52, 60, 61, 63 and 70 include clarification, guidance and technical revisions to SIP requirements promulgated pursuant to 42 U.S.C. 7410 & 7413, New Source Performance Standards (“NSPS”) mandated by 42 U.S.C. 7411, and federal National Emission Standards for Hazardous Air Pollutants (“NESHAP”) for Source Categories.

(2) The Department therefore proposes to amend Regulation 61-62.1, *Section III, Emissions Inventory and Emissions Statements*; Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*; Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*; Regulation 61-62.5, *Standard No. 2, Ambient Air Quality Standards*; and the SIP, to codify federal amendments to these standards promulgated from January 1, 2015, through December 31, 2015.

(3) The Department also proposes to amend: Regulation 61-62.1, *Section II, Permit Requirements*; Regulation 61-62.5, *Standard No.1, Emissions from Fuel Burning Operations*; and Regulation 61-62.5, *Standard 4, Emissions from Process Industries*, to address periods of excess emissions during startup, shutdown, or malfunction (SSM) events as required by the EPA in response to a national petition for rulemaking and to address a finding of substantial inadequacy (referred to as a ‘SIP call’) (80 FR 33840, June 12, 2015).

(4) The Department is also proposing other changes to Regulation 61-62 that include corrections for internal consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

In accordance with 1976 Code Section 1-23-120(H), legislative review is not required because the Department proposes promulgating the amendments to maintain compliance with federal law.

A Notice of Drafting for these proposed amendments was published in the *State Register* on February 26, 2016. The Notice was also sent via the Department list serve to interested stakeholders on February 26, 2016.

Discussion of Proposed Revisions:

SECTION CITATION/EXPLANATION OF CHANGE:

Regulation 61-62.1, *Section II, Permit Requirements*

Regulation 61-62.1, *South Carolina Designated Facility Plan and New Source Performance Standards*: Paragraph L.2. is amended to delete the entire sentence, in order to address the SSM SIP Call rule.

14 PROPOSED REGULATIONS

Regulation 61-62.1, *South Carolina Designated Facility Plan and New Source Performance Standards*: Paragraph L.3. is amended to delete the phrase “The affirmative defense of”; and amended to delete the lowercase “a” in an; and replace with upper case “A”. Paragraph L.3. is also amended to delete the phrase “shall be demonstrated” and replace with “may be documented” to read, “An emergency may be documented through properly signed, contemporaneous operating logs and other relevant evidence that verify.”, in order to address the SSM SIP Call rule.

Regulation 61-62.1, *South Carolina Designated Facility Plan and New Source Performance Standards*: Paragraph L.4. is amended to delete the entire sentence in order to address the SSM SIP Call rule.

Regulation 61-62.1, *South Carolina Designated Facility Plan and New Source Performance Standards*: Paragraphs L.3 through L.5 are renumbered in alpha-numeric order to account for the deleted paragraphs L.2 and L.4 and to ensure clarity and consistency.

Regulation 61-62.1, Section III, Emissions Inventory and Emissions Statements

Regulation 61-62.1, Section III, *Emissions Inventory and Emissions Statements*: Paragraph B.1.a. is amended to delete the word "potential" to ensure clarity within this section of the regulation. Table 1 is revised to lower the point source threshold for lead (Pb) emissions to 0.5 tons per year (tpy) of actual emissions. The purpose of this change is to match requirements of the Pb Ambient Air Monitoring Requirements rule (75 FR 81126; December 27, 2010), which required monitoring agencies to install and operate source-oriented ambient monitors near Pb sources emitting 0.5 tpy or more by December 27, 2011 (80 FR 8787; February 19, 2015). An additional column and a footnote are added to the table to clarify that the Pb threshold is based on actual emissions rather than potential emissions. Table 2 is amended to delete the phrase "(tpy potential to emit¹)" and replace with “(tons per year)” for clarity and consistency within this portion of the regulation.

Regulation 61-62.1, Section III, *Emissions Inventory and Emissions Statements*: Paragraph B.1.b. is amended to delete the word "potential" to ensure clarity within this section of the regulation.

Regulation 61-62.1, Section III, *Emissions Inventory and Emissions Statements*: Paragraph B.1.c. is amended to delete the word "potential" to ensure clarity within this section of the regulation. Table 2 is revised to lower the point source threshold for lead (Pb) emissions to 0.5 tons per year (tpy) of actual emissions by deleting "5" in the table and replacing with "0.5". The purpose of this change is to match requirements of the Pb Ambient Air Monitoring Requirements rule (75 FR 81126; December 27, 2010), which required monitoring agencies to install and operate source-oriented ambient monitors near Pb sources emitting 0.5 tpy or more by December 27, 2011 (80 FR 8787; February 19, 2015). An additional column and a footnote are added to the table to clarify that the Pb threshold is based on actual emissions rather than potential emissions. The footnotes are reordered for clarity and consistency. Table 2 is amended to delete the phrase "(tpy potential to emit¹)" and replace with “(tons per year)” for clarity and consistency within this portion of the regulation.

Regulation 61-62.1, Section III, *Emissions Inventory and Emissions Statements*: Paragraph B.2.e.x. is amended to delete the comma after the phrase "(December 17, 2008)" for correct punctuation and consistency within the regulation.

Regulation 61-62.5, Standard 1, Emissions from Fuel Burning Operations

Regulation 61-62.5, *Standard 1, Emissions from Fuel Burning Operations*: Section I, Paragraph C. is amended to delete the entire first sentence in order to address the SSM SIP Call rule.

Regulation 61-62.5, *Standard 1, Emissions from Fuel Burning Operations*: Section IV, Paragraph A.1. is amended to add a hyphen between the words “Fuel” and “Fired” for consistency within the regulation.

Regulation 61-62.5, *Standard 1, Emissions from Fuel Burning Operations*:

Section IV, Paragraph D.1. is amended to add a hyphen between the words “fuel” and “fired” for consistency within the regulation.

Regulation 61-62.5, *Standard 2, Ambient Air Quality Standards*

Table is revised for consistency with federal National Ambient Air Quality Standard by removing the information for the 1997 Ozone Standard and adding the information for the 2015 Ozone standard.

Regulation 61-62.5, *Standard 3, Waste Combustion and Reduction*

Regulation 61-62.5, *Standard 3, Waste Combustion and Reduction*:

Section IV, Paragraph A.2.g.(i) is amended to replace “analysis” with “analyses” for consistency within the regulation; and add a period to the end of the last sentence for correct punctuation.

Regulation 61-62.5, *Standard 3, Waste Combustion and Reduction*:

Section V, Paragraph J. is amended to replace the words “on site” with the word “on-site” for consistency within the regulation.

Regulation 61-62.5, *Standard 3, Waste Combustion and Reduction*:

Section VI, Paragraph D.3. is amended to add an apostrophe to the word “sources” for correct punctuation and consistency with the rest of the regulation

Regulation 61-62.5, *Standard 3, Waste Combustion and Reduction*:

Section IX, Paragraph A. is amended to replace the words “on site” with the word “on-site” for consistency within the regulation.

Regulation 61-62.5, *Standard 3, Waste Combustion and Reduction*:

Section IX, Paragraph C. is amended to replace the word “operating” with the word “operator” for consistency within this section of the regulation.

Regulation 61-62.5, *Standard 3.1, Hospital/Medical/Infectious Waste Incinerators (HMIWI)*

Regulation 61-62.5, *Standard 3.1, Hospital/Medical/Infectious Waste Incinerators (HMIWI)*:

Section VIII, Paragraph (c)(7), is amended to delete the semicolon and add a period for correct punctuation and consistency with the rest of the regulation.

Regulation 61-62.5, *Standard 3.1, Hospital/Medical/Infectious Waste Incinerators (HMIWI)*:

Section VIII, Paragraph (c)(8), is amended to delete the semicolon and add a period for correct punctuation and consistency with the rest of the regulation.

Regulation 61-62.5, *Standard 3.1, Hospital/Medical/Infectious Waste Incinerators (HMIWI)*:

Section VIII, Paragraph (c)(9), is amended to delete the semicolon and the word “and” and add a period for correct punctuation and consistency with the rest of the regulation.

Regulation 61-62.5, *Standard 3.1, Hospital/Medical/Infectious Waste Incinerators (HMIWI)*:

Section VIII, Paragraph (e), is amended to delete the word “semiannually” and replace with the word “semi-annually” for correct punctuation and consistency with the rest of the regulation.

Regulation 61-62.5, *Standard 3.1, Hospital/Medical/Infectious Waste Incinerators (HMIWI)*:

Section VIII, Paragraph (h)(2), is amended to delete the word “semiannually” and replace with the word “semi-annually” for correct punctuation and consistency with the rest of the regulation.

16 PROPOSED REGULATIONS

Regulation 61-62.5, *Standard 3.1, Hospital/Medical/Infectious Waste Incinerators (HMIWI)*:

Section VIII, Paragraph (k), is amended to delete the word “District” and replace with the word “Regional” for consistency within this section of the regulation.

Regulation 61-62.5, *Standard 3.1, Hospital/Medical/Infectious Waste Incinerators (HMIWI)*:

Section IX, Paragraph (h)(9), is amended to delete the words “Record keeping” and replace with the word “recordkeeping” for consistency with the rest of the regulation.

Regulation 61-62.5, *Standard 4, Emissions from Process Industries*

Regulation 61-62.5, *Standard 4, Emissions from Process Industries*:

Section XI, paragraph D.4 is amended to delete the entire section in order to address the SSM SIP Call rule.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart A, Table, is amended to incorporate federal revisions at 80 FR 13671, March 16, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart F, Table, is amended to incorporate federal revisions at 80 FR 44771, July 27, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart J, Table, is amended to incorporate federal revisions at 80 FR 75178, December 1, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart Ja, Table, is amended to incorporate federal revisions at 80 FR 75178, December 1, 2015, by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart T, Table, is amended to incorporate federal revisions at 80 FR 50385, August 19, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart U, Table, is amended to incorporate federal revisions at 80 FR 50385, August 19, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart V, Table, is amended to incorporate federal revisions at 80 FR 50385, August 19, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart W, Table, is amended to incorporate federal revisions at 80 FR 50385, August 19, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart X, Table, is amended to incorporate federal revisions at 80 FR 50385, August 19, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart AAA, Table, is amended to incorporate federal revisions at 80 FR 13671, March 16, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart OOOO, Table, is amended to incorporate federal revisions at 80 FR 48262, August 12, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*:

Subpart PPPP is added in alpha-numeric order for consistency with federal regulations.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*: Subpart QQQQ, Table, is added to incorporate a newly promulgated federal rule at 80 FR 13671, March 16, 2015 by reference.

Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*: Subpart TTTT, Table, is added to incorporate a newly promulgated federal rule at 80 FR 64509, October 23, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart A is amended to delete the word “Title” for consistency. Subpart A, Table, is amended to incorporate by reference federal revisions at 80 FR 37365, June 30, 2015; 80 FR 50385, August 19, 2015, 80 FR 56699, September 18, 2015; 80 FR 62389, October 15, 2015; 80 FR 65469, October 26, 2015; 80 FR 75178, December 1, 2015; and 80 FR 75817, December 4, 2015.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart N, Table, is amended to incorporate federal revisions at 80 FR 22116, April 21, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart Y, Table, is amended to incorporate federal revisions at 80 FR 75178, December 1, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart AA, Table, is amended to incorporate federal revisions at 80 FR 50385, August 19, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart BB, Table, is amended to incorporate federal revisions at 80 FR 50385, August 19, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart CC, Table, is amended to incorporate federal revisions at 80 FR 75178, December 1, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart DD, Table, is amended to incorporate federal revisions at 80 FR 14247, March 18, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart GG, Table, is amended to incorporate federal revisions at 80 FR 76151, December 7, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart LL, Table, is amended to incorporate federal revisions at 80 FR 62389, October 15, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart NN is amended to add a table to incorporate federal revisions at 80 FR 45279, July 29, 2015 by reference.

18 PROPOSED REGULATIONS

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart DDD, Table, is amended to incorporate federal revisions at 80 FR 45279, July 29, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart NNN, Table, is amended to incorporate federal revisions at 80 FR 45279, July 29, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart RRR, Table, is amended to incorporate federal revisions at 80 FR 56699, September 18, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart UUU, Table, is amended to incorporate federal revisions at 80 FR 75178, December 1, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart XXX, Table, is amended to incorporate federal revisions at 80 FR 37365, June 30, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart LLL, Table, is amended to incorporate federal revisions at 80 FR 44771, July 27, 2015; and 80 FR 54728, September 11, 2015, by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart DDDDD, is amended to add Table and to incorporate federal revisions at 69 FR 55218, September 13, 2004 to 80 FR 72789, November 20, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart JJJJJ, is amended to add Table and to incorporate federal revisions at 68 FR 26690, May 16, 2003 to 80 FR 65469, October 26, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart KKKKK, is amended to add Table and to incorporate federal revisions at 68 FR 26690, May 16, 2003 to 80 FR 65469, October 26, 2015; and 80 FR 75817, December 4, 2015, by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart UUUUU, Table, is amended to incorporate federal revisions at 80 FR 15510, March 24, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart YYYYY, Table, is amended to incorporate federal revisions at 80 FR 36247, June 24, 2015 by reference.

Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*: Subpart DDDDDD, Table, is amended to incorporate federal revisions at 80 FR 5938, February 4, 2015 by reference.

Notice of Public Hearing and Opportunity for Public Comment:

Interested persons are provided an opportunity to submit written comments on the proposed regulations to Caitlan Bell by mail at Bureau of Air Quality, South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201; by facsimile at (803) 898-4487; or by e-mail at bellcl@dhec.sc.gov. To

be considered, comments must be received no later than 5:00 p.m. on July 27, 2016, the close of the comment period. Comments received during the write-in public comment period by the deadline requested above shall be submitted to the Board in a Summary of Public Comments and Department Responses for consideration at the public hearing as noticed below.

Interested members of the public and regulated community are also invited to comment on the proposed amendments to Regulation 61-62, Air Pollution Control Regulations and Standards, at a public hearing to be conducted by the Board of the South Carolina Department of Health and Environmental Control at its regularly-scheduled meeting on September 8, 2016. The public hearing is to be held in room 3420 (Board Room), Third floor, Aycock Building of the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearings will be noted in the Board's agenda to be published by the Department twenty-four hours in advance of the meeting at the following address: <http://www.scdhec.gov/Agency/BoardofDirectors/>. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less, and as a courtesy, are asked to provide written copies of their presentation to the Clerk of the Board for inclusion for the record.

Copies of the proposed regulation for public notice and comment may be obtained by contacting Caitlan Bell at the South Carolina Department of Health and Environmental Control, Bureau of Air Quality, 2600 Bull Street, Columbia, SC 29201; by calling (803) 898-0561; or by emailing bellcl@dhec.sc.gov. A copy may also be obtained on the Department's Regulatory Information Internet Site at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/> in its DHEC Monthly Regulations Development Update. To access this document, click on the Air category, then scan down for this proposed amendment.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION:

Amendment of Regulation 61-62, *Air Pollution Control Regulations and Standards* and the South Carolina Air Quality Implementation Plan ("SIP").

Purpose:

(1) The United States Environmental Protection Agency ("EPA") promulgated amendments to national air quality standards in 2015. The recent federal amendments include clarification, guidance and technical revisions to SIP requirements promulgated pursuant to 42 U.S.C. Sections 7410 & 7413, New Source Performance Standards ("NSPS") mandated by 42 U.S.C. Section 7411, and federal National Emission Standards for Hazardous Air Pollutants ("NESHAP") for Source Categories mandated by 42 U.S.C. Section 7412.

(2) The Department therefore proposes to amend Regulation 61-62.1, Section III, *Emissions Inventory and Emissions Statements*; Regulation 61-62.60, *South Carolina Designated Facility Plan and New Source Performance Standards*; Regulation 61-62.63, *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories*; Regulation 61-62.5, Standard No. 2, *Ambient Air Quality Standards*; and the SIP, to codify federal amendments to these standards promulgated from January 1, 2015, through December 31, 2015.

(3) The Department proposes to amend Regulation 61-62.1, Section II, *Permit Requirements*; Regulation 61-62.5, Standard No.1, *Emissions from Fuel Burning Operations*; and Regulation 61-62.5, Standard No. 4, *Emissions from Process Industries*, to address periods of excess emissions during startup, shutdown, or malfunction ("SSM") events as required by the EPA in response to a national petition for rulemaking and to address a finding of substantial inadequacy (referred to as a "SIP call") (80 FR 33840, June 12, 2015).

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(4) The Department is also proposing other changes to Regulation 61-62 that include corrections for internal consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

Legal Authority:

Pursuant to the South Carolina Pollution Control Act, 1976 Code Section 48-1-10 et seq., along with the federal Clean Air Act, 42 U.S.C. Sections 7410, 7413, and 7416, the Department must ensure national primary and secondary ambient air quality standards are achieved and maintained in South Carolina. No state may adopt or enforce an emission standard or limitation less stringent than these federal standards or limitations pursuant to 42 U.S.C. Section 7416.

Plan for Implementation:

The proposed amendments will take effect upon approval by the Board of Health and Environmental Control and publication in the *State Register*. These requirements are in place at the federal level and are currently being implemented. The proposed amendments will be implemented in South Carolina by providing the regulated community with copies of the regulation, publishing associated information on our website at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/>, sending an email to stakeholders, and communicating with affected facilities during the permitting process.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The EPA promulgates amendments to 40 CFR Parts 51, 52, 60, 61, 63, and 70 throughout each calendar year. Federal amendments in 2015 included new and revised NSPS rules, NESHAPs, and NESHAPs for Source Categories. States are mandated by law to adopt these federal amendments. These amendments are reasonable as they promote consistency and ensure compliance with both state and federal regulations.

DETERMINATION OF COSTS AND BENEFITS:

There is not anticipated increase in costs to the State or its political subdivisions resulting from these proposed revisions. The standards to be adopted are already in effect and applicable to the regulated community as a matter of federal law, thus the regulated community has already incurred the cost of these regulations. The proposed amendments incorporate the revisions to the EPA regulations, which the Department implements pursuant to the authority granted by Section 48-1-50 of the Pollution Control Act. The proposed amendments will benefit the regulated community by clarifying the regulations and increasing their ease of use.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the State or its political subdivisions.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

Adoption of the recent changes in federal regulations through the proposed amendments to Regulation 61-62, *Air Pollution Control Regulations and Standards*, will provide continued protection of the environment and public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED:

The State's authority to implement federal requirements, which are beneficial to the public health and environment, would be compromised if these amendments were not adopted in South Carolina.

Text:

The full text of this regulation is available on the South Carolina General Assembly Home Page: <http://www.scstatehouse.gov/regnsrch.php>. Full text may also be obtained from the promulgating agency.

Document No. 4651

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61**

Statutory Authority: 1976 Code Sections 44-56-10 et seq.

61-79. Hazardous Waste Management Regulations

Preamble:

The Department of Health and Environmental Control (Department) is proposing to amend R.61-79, Hazardous Waste Management Regulations, to adopt two final rules published in the Federal Register by the United States Environmental Protection Agency (EPA). The proposed amendments will support the Department’s goal of promoting and protecting the health of the public and the environment in a more efficient and effective manner. These amendments will: revise the definition of solid waste to conditionally exclude carbon dioxide (CO₂) streams that are hazardous from the definition of hazardous waste, provided these hazardous CO₂ streams are captured from emission sources, are injected into Underground Injection Control (UIC) Class VI wells for purposes of geologic sequestration (GS), and meet certain other conditions; and revise several recycling-related provisions associated with the definition of solid waste used to determine hazardous waste regulation under Subtitle C of the Resource Conservation and Recovery Act. See the Section-by-Section Discussion of Proposed Amendments below and the Statements of Need and Reasonableness and Rationale herein.

A Notice of Drafting for these proposed amendments was published in the *State Register* on November 27, 2015.

Section-by-Section Discussion of Proposed Amendments:

1. The Department is proposing to amend R.61-79 to adopt the “Conditional Exclusion for Carbon Dioxide (CO₂) Streams in Geologic Sequestration Activities,” published on January 3, 2014 at 79 FR 350-364:

260.10 Definitions. Add, in alphabetical order, the following new definition: “Carbon dioxide stream.”

261.4(h). Add new subsection (h) by adding language that describes how carbon dioxide (CO₂) streams that are to be injected into Underground Injection Control (UIC) Class VI wells for purposes of geologic sequestration are excluded from the definition of hazardous waste provided that they comply with applicable Department of Transportation requirements for transportation of the CO₂ streams, applicable UIC Class VI wells requirements, no other hazardous wastes are mixed with or otherwise co-injected with the CO₂ stream, and generators and UIC Class VI well owners or operators claiming the exclusions must sign a certification statement that the conditions of the exclusion were met. This subsection also adds language that describes the length of time the certification must be kept on site and to whom and how it must be made available.

2. The Department is proposing to amend R.61-79 to adopt “Revisions to the Definition of Solid Waste,” published on January 13, 2015 at 80 FR 1694-1814.

Checklist D2 – Definition of Solid Waste exclusions and non-waste determinations.

260.10 Definitions. Add, in alphabetical order, the following new definitions: “Hazardous secondary material generator;” “Intermediate facility;” “Land-based unit.”

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260.10 Definitions. Modify the definition of “Facility” by adding language that includes the management of hazardous secondary materials prior to reclamation. Modify the definition of “Transfer facility” by adding language that includes hazardous secondary materials.

260.30 Heading. Revise by adding “Non-waste determinations and.”

260.30. Revise the introductory text to add a reference to procedures in Section 260.34.

260.30(b). Revise subsection (b) by removing the word “and.”

260.30(d). Add a new subsection (d) by adding language that the Department may determine that hazardous secondary materials that are reclaimed in a continuous industrial process are not solid wastes.

260.30(e). Add a new subsection (e) by adding language that the Department may determine that hazardous secondary materials that are indistinguishable in all relevant aspects from a product or intermediate are not solid wastes.

260.30(f). Add a new subsection (f) by adding language that the Department may determine that hazardous secondary materials that are transferred for reclamation under 261.4(a)(24) and are managed at a verified reclamation facility or intermediate facility where the management of the hazardous secondary materials is not addressed under a RCRA Part B permit or interim status standards are not solid wastes.

260.31(d). Add a new subsection (d) by adding language that the Department may grant requests for a variance for classification as a solid waste those hazardous secondary materials that are transferred under 261.4(a)(24) and are managed at a verified reclamation facility or intermediate facility where the management of the hazardous secondary materials is not addressed under a RCRA part B permit or interim status standards. The Department’s decision will be based on a demonstration: that the facility is legitimate pursuant to 260.43; financial assurance conditions in 261.4(a)(24)(vi)(F) are met; the facility is not subject to a formal enforcement action; proper equipment, personnel training and emergency response requirements are met; reclamation residuals are properly handled; and potential risks to proximate populations from unhandled releases are addressed.

260.33. Revise the introductory text to include applications for non-waste determinations.

260.33(a). Revise this subsection to add non-waste determination and an additional regulatory citation.

260.34. Add a new section “Standards and criteria for non-waste determinations.” This section adds language that requires facilities applying for a non-waste determination to explain or demonstrate why they cannot meet, or should not have to meet, the existing Definition of Solid Waste exclusions in 261.2 or 261.4.

261.1(c)(4). Revise this paragraph to add a reference to 261.4(a)(23) and (24) and language regarding smelting, melting and refining furnaces.

261.2(c)(3). Revise this paragraph to add a reference to 261.4(a)(23), (24) and (27). NOTE: This is the same revision found in Checklist E.

261.2(c)(4) Table 1. Revise column 3 to amend the regulatory citations. NOTE: This is the same revision found in Checklist E.

261.4(a)(23). Revise this section by adding language that describes the conditional exclusion from the definition of solid waste those hazardous secondary materials that are legitimately reclaimed within the United States or its territories and under the control of the generator. This includes: a codified definition of “contained;” adding recordkeeping requirements for same company and toll manufacturing reclamation; making notification a

condition of the exclusion; adding a requirement to document that recycling under the exclusion is legitimate; and adding emergency preparedness and response conditions. In addition, the speculative accumulation provisions have a recordkeeping requirement.

261.4(a)(24). Revise this section by adding language that describes how hazardous secondary material that is generated and then transferred to a verified reclamation facility for the purpose of reclamation is not a solid waste. This includes: showing that the material is not speculatively accumulated, not handled by any person or facility other than the generator, transporter, intermediate facility or reclaimer and is stored and packaged properly; the material is not subject to material-specific management conditions when reclaimed and is not a spent lead-acid battery; reclamation of the material is legitimate; and the generator satisfies conditions regarding containment, transport to a verified reclamation facility and specific record keeping requirements.

Subpart H. Add new Subpart H to R.61-79.261, Subpart H – Financial Requirements for Management of Excluded Hazardous Secondary Materials. This Subpart adds new language regarding financial requirements for owners or operators of reclamation and intermediate facilities managing hazardous secondary materials excluded under 261.4(a)(24).

Subparts K-L. Add new Subparts K-L and reserve them.

Subpart M. Add new Subpart M to R.61-79.261, Subpart M – Emergency Preparedness and Response for Management of Excluded Hazardous Secondary Materials. This Subpart adds new language regarding applicability; preparedness and prevention; emergency procedures for facilities generating or accumulating 6000 kg or less of hazardous secondary material and contingency planning and emergency procedures for facilities generating or accumulating more than 6000 kg of hazardous secondary material.

270.42, Appendix I – Classification of Permit Modification. Add entries 9 and 10 in the table under section A. General Permit Provisions.

Checklist E – Remanufacturing exclusion

260.10 Definitions. Add, in alphabetical order, the following new definition: “Remanufacturing.”

261.2(c)(3). Revise this paragraph to add a reference to 261.4(a)(23), (24) and (27). NOTE: This is the same revision found in Checklist D2.

261.2(c)(4) Table 1. Revise column 3 to amend the regulatory citations. NOTE: This is the same revision found in Checklist D2.

261.4(a)(27). Add a new item (27) by adding language that eighteen (18) spent solvents are eligible for the remanufacturing exclusion. This includes: requirements for notification, a remanufacturing plan, a record of shipments and confirmation of receipts, management in tanks and containers and a prohibition on speculative accumulation.

Subpart I. Add new Subpart I to R.61-79.261, Subpart I – Use and Management of Containers. This Subpart adds new language regarding applicability, condition of containers, compatibility of hazardous secondary materials with containers, management of containers, containment, special requirements for ignitable, reactive hazardous secondary material or incompatible materials and air emission standards.

Subpart J. Add new Subpart J to R.61-79.261, Subpart J – Tank Systems. This Subpart adds new language regarding applicability, assessment of existing tank system’s integrity, containment and detection of releases, general operating requirements, response to leaks or spills and disposition of leaking or unfit-for-use tank systems, termination of remanufacturing exclusion, special requirements for ignitable, reactive and incompatible materials and air emission standards.

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Subpart AA. Add new Subpart AA to R.61-79.261, Subpart AA – Air Emission Standards for Process Vents. This Subpart adds new language regarding applicability, definitions, standards for process vents and closed-vent systems and control devices, test methods and procedures and recordkeeping requirements.

Subpart BB. Add new Subpart BB to R.61-79.261, Subpart BB – Air Emission Standards for Equipment Leaks. This Subpart adds new language regarding applicability, definitions, standards, alternative standards, test methods and procedures and recordkeeping requirements.

Subpart CC. Add new Subpart CC to R.61-79.261 Subpart CC – Air Emission Standards for Tanks and Containers. This Subpart adds new language regarding applicability, definitions, standards for tanks, containers and closed-vent systems and control devices, material determination procedures, inspection and monitoring requirements and recordkeeping requirements.

Notice of Staff Informational Forum and Public Comment Period:

Staff of the Department of Health and Environmental Control invite interested members of the public and regulated community to attend a staff-conducted information forum to be held on July 28, 2016 at 10:00 a.m. in the Wallace Room, Third floor, Aycock Building of the Department of Health and Environmental Control at 2600 Bull Street, Columbia, South Carolina 29201. The purpose of the forum is to present the proposed amendments to the regulations, answer questions, and receive formal public comments on the proposed amendments from interested persons.

Interested persons are also provided an opportunity to submit written comments on the proposed amendments to R.61-79 by writing to David Scaturo by mail at Bureau of Land and Waste Management, South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201; by facsimile at (803) 898-0590; or by e-mail at scaturdm@dhec.sc.gov. To be considered, comments must be received no later than 5:00 p.m. on July 28, 2016, the close of the public comment period.

Comments received at the informational forum and during the public comment period noticed above shall be considered by staff in formulating the final draft proposed amendments for submission to the Board of Health and Environmental Control for consideration at the public hearing noticed below for September 8, 2016. Staff shall submit a summary of public comments received and Department responses to the Board for consideration at the public hearing.

Copies of the proposed amendments for public comment as published in the *State Register* on June 24, 2016 may be obtained online in the DHEC Regulation Development Update at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/RegulationDevelopmentUpdate/>. Click on the Land and Waste Management item and scroll down to the proposed amendments to R. 61-79. A copy can also be obtained by contacting David Scaturo at the above address or by calling (803)898-0290, or by email at scaturdm@dhec.sc.gov.

Notice of Public Hearing and Opportunity for Public Comment:

Interested members of the public and regulated community are invited to make oral and/or written comments on the proposed amendments to R.61-79 at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly scheduled meeting on September 8, 2016. The Board will conduct the public hearing in the Board Room, Third floor, Aycock Building of the Department of Health and Environmental Control at 2600 Bull Street, Columbia, South Carolina 29201. The Board meeting commences at 10:00 a.m. at which time the Board will consider items on its agenda in the order presented. The order of presentation for public hearings will be noted in the Board's agenda published by the Department 24 hours in advance of the meeting at the following address: <http://www.scdhec.gov/Agency/docs/AGENDA.PDF>. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes or less and, as a courtesy,

are asked to provide written copies of their presentation for the record. Due to admittance procedures at the DHEC Building, all visitors should enter through the Bull Street entrance and register at the front desk.

Preliminary Fiscal Impact Statement:

The proposed regulations will have no substantial fiscal or economic impact on the State or its political subdivisions. Implementation of this regulation will not require additional resources beyond those allowed. There is no anticipated additional cost by the Department or State Government due to any inherent requirements of this regulation.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION:

Purpose: The proposed amendments of R.61-79 will support the Department’s goal of promoting and protecting the health of the public and the environment in a more efficient and effective manner. These amendments will: revise the definition of solid waste to conditionally exclude carbon dioxide (CO2) streams that are hazardous from the definition of hazardous waste, provided these hazardous CO2 streams are captured from emission sources, are injected into Underground Injection Control (UIC) Class VI wells for purposes of geologic sequestration (GS), and meet certain other conditions; and revise several recycling-related provisions associated with the definition of solid waste used to determine hazardous waste regulation under Subtitle C of the Resource Conservation and Recovery Act.

Legal Authority: The legal authority for R.61-79 is S.C. Code Section 44-56-30.

Plan for Implementation: The proposed amendments will take effect upon approval by the S.C. General Assembly and publication in the *State Register*. An electronic copy of R.61-79, that includes these latest amendments, will be published on the Department’s Regulation Development website at: <http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/>. At this site, click on the Land and Waste Management category and scroll down to R.61-79. Subsequently, this regulation will be published on the S.C. Legislature website in the S.C. Code of Regulations. Printed copies will be made available at cost by request through the DHEC Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

1. The Department proposes adopting the “Conditional Exclusion for Carbon Dioxide (CO2) Streams in Geologic Sequestration Activities,” published on January 3, 2014 at 79 FR 350-364. The rule revises the definition of solid waste to conditionally exclude carbon dioxide (CO2) streams that are hazardous from the definition of hazardous waste, provided these hazardous CO2 streams are captured from emission sources, are injected into Underground Injection Control (UIC) Class VI wells for purposes of geologic sequestration (GS), and meet certain other conditions.

2. The Department proposes adopting the “Revisions to the Definition of Solid Waste,” published on January 13, 2015 at 80 FR 1694-1814. The rule revises several recycling-related provisions associated with the definition of solid waste used to determine hazardous waste regulation under Subtitle C of the Resource Conservation and Recovery Act. The purpose of these revisions is to ensure that the hazardous secondary materials recycling regulations, as implemented, encourage reclamation in a way that does not result in increased risk to human health and the environment from discarded hazardous secondary material. Sections of the Rule cover Definition

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of Solid Waste exclusions and non-waste determinations, including provisions from the 2008 Definition of Solid Waste Rule and revisions from the 2015 Definition of Solid Waste Final Rule and a remanufacturing exclusion.

The proposed changes are necessary to maintain federally delegated program authority due to recent changes in the applicable federal regulations. The EPA has authorized South Carolina to operate the State Hazardous Waste Program in lieu of the federal program under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. Sections 6901 to 6992k. Because the State Hazardous Waste Program is federally delegated, the EPA continues to exercise oversight including the ability to revoke program authorization to ensure consistency with RCRA. Specifically, the State Hazardous Waste Program must remain equivalent to, consistent with, and no less stringent than the federal program. The EPA periodically promulgates regulations that are either mandatory or optional for the states to adopt. Because the changes proposed herein are optional for states to adopt, legislative approval is required.

DETERMINATION OF COSTS AND BENEFITS:

There should be no increased cost to the State or its political subdivisions resulting from the proposed revisions. Amendments to R.61-79 will revise the definition of solid waste to conditionally exclude carbon dioxide (CO₂) streams that are hazardous from the definition of hazardous waste, provided these hazardous CO₂ streams are captured from emission sources, are injected into Underground Injection Control (UIC) Class VI wells for purposes of geologic sequestration (GS), and meet certain other conditions, and ensure that the hazardous secondary materials recycling regulations encourage reclamation in a way that does not result in increased risk to human health and the environment from discarded hazardous secondary materials.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the State or its political subdivisions.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The proposed revisions to R.61-79 will provide continued protection of the environment and public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

While there would be no detrimental effect on the environment and/or public health if the regulation is not implemented, the State's federally delegated authority to implement the hazardous waste management program in South Carolina would be compromised if the State's regulations are not consistent with or equivalent to the federal program. There could be a detrimental effect if the changes are not adopted because the State Hazardous Waste Management Program is federally delegated, and EPA continues to exercise program oversight. This includes the ability to revoke State program authorization if it determines that a State program is not equivalent to, consistent with, and no less stringent than the federal program.

Statement of Rationale:

R.61-79 contains requirements for hazardous waste management, including identification of waste, standards for generators, transporters, and owners/operators of treatment, storage, and disposal (TSD) facilities, procedures for permits for TSD facilities, investigation and cleanup of hazardous waste, and closure/post-closure requirements. The regulation is promulgated pursuant to the S.C. Hazardous Waste Management Act, Section 44-56-30. As an authorized State program, the regulations must be equivalent to and consistent with the EPA's regulations under RCRA. R. 61-79 has been amended numerous times since it was first promulgated in 1984 to adopt federal regulations that are either mandatory or optional changes for an authorized State to adopt.

Text:

The full text of this regulation is available on the South Carolina General Assembly Home Page: <http://www.scstatehouse.gov/regnsrch.php>. Full text may also be obtained from the promulgating agency.

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Document No. 4603
STATE BOARD OF EDUCATION
CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, and 20 U.S.C. 6301 et seq.

43-307. Alignment of Assessment and Accountability Elements with the No Child Left Behind Act

Synopsis:

State Board of Education (SBE) Regulation 43-307 requires SBE assessments and accountability elements to align with the No Child Left Behind Act (NCLB) with much specificity. The proposed amendment will ensure that South Carolina will comply with federal law without having to amend the regulation each time the NCLB is amended.

Notice of Drafting for the proposed amendments to the regulation was published in the *State Register* on September 25, 2015.

Instructions:

Entire regulation is to be replaced with the following text.

Text:

43-307. Alignment of Assessment and Accountability Elements with the No Child Left Behind Act.

I. The State Board of Education and the South Carolina Department of Education will align its assessment and accountability elements with the measures mandated by federal law.

II. The State Board of Education authorizes the South Carolina Department of Education to develop and amend the State Accountability Workbook as necessary to meet U.S. Department of Education approval.

Fiscal Impact Statement:

None.

Statement of Rationale:

The proposed amendment will ensure that South Carolina will comply with federal law without having to amend the regulation each time the NCLB is amended. The proposed amendment would simply state that South Carolina will follow the requirements of the NCLB.

Document No. 4604
STATE BOARD OF EDUCATION
 CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, 59-18-310, 59-18-320, 59-18-325, 59-18-330,
 59-18-350, 59-18-360, 59-18-900, 59-20-60, and 20 U.S.C. 6301 et seq.

43-262. Assessment Program

Synopsis:

Section 59-18-310 of the Education Accountability Act requires end-of-course tests for gateway courses awarded units of credit in English/language arts, mathematics, science, and social studies. Proposed amendments to Section H of Regulation 43-262, End-of-Course Examination Program (EOCEP), are to permit the State Board of Education to define the courses in which end-of-course tests must be administered and permits the SCDE to work directly with districts concerning testing specific students when unusual circumstances arise.

Notice of Drafting for the proposed amendment of this regulation was published in the *State Register* on August 28, 2015.

Instructions:

Section H. below replaces Section H. currently in law.

Text:

43-262. Assessment Program.

I. STATEWIDE ASSESSMENT PROGRAM

A. The Education Accountability Act of 1998 (EAA), S.C. Code Ann. Section 59-18-310, and the No Child Left Behind Act of 2001 (NCLB), 20 U.S.C. Section 6301, et seq. require that the State Board of Education develop or adopt a statewide assessment program in certain grades and selected content/skill areas.

B. The statewide assessment program will involve testing public school students at selected grade levels and in selected content and skill areas at times specified by the South Carolina Department of Education (SCDE). The grade(s) and content/skill areas to be included in the assessment program are identified by the EAA, NCLB, and State Board of Education regulations.

The statewide assessment program includes assessments administered to assist in the identification of students for participation in programs for the gifted and talented, and assessments administered for accountability purposes, including but not limited to the following:

South Carolina Palmetto Assessment of State Standards (SCPASS),
 South Carolina Alternate Assessment (SC-Alt), and
 End-of-Course Examination Program.

C. The program is funded through an annual appropriation included in the South Carolina General Appropriations Act. The request for such funding is included in the annual budget request of the State Superintendent of Education. Continued operation of the program is contingent upon the availability of funds.

D. The following are responsibilities of the SCDE for assessments in which school districts are required to participate.

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1. Supply all necessary test materials regardless of the testing format, (e.g., paper/pencil, online, customized), scoring, and standard score reports at no cost to the local school districts. Test materials do not include hardware or software for online testing.

2. Pay all shipping costs for the transportation of test materials and score reports between the SCDE, school districts, and scoring service(s).

3. Provide workshops on test administration, interpretation, and utilization for district test coordinators and other selected staff.

4. Report the statewide results of the program to the State Board of Education on an annual basis.

5. The SCDE will report statewide and school district test results as may be necessary for accurate and meaningful interpretation.

6. Test data for individuals shall be released only in a manner that is consistent with the provisions of Section 438 (Privacy Rights of Parents and Students) of the General Education Provisions Act (Title IV of Public Law 90-247, as amended) and any other relevant legislation, including but not limited to Act 200 of 2014.

7. Field/pilot-test, at the discretion of the State Superintendent of Education, new assessment instruments and/or procedures and recommend changes in the Statewide Assessment Program to the State Board of Education, the Education Oversight Committee, and other appropriate policy-making bodies.

E. The participation of local school districts in the statewide testing program is required under Section 59-20-60(7)(c) of the South Carolina Education Finance Act and the South Carolina Education Accountability Act of 1998. The following are responsibilities of local school districts.

1. As used in these regulations, “local school district” shall mean public school districts, the South Carolina Public Charter School District, a public or independent institution of higher learning serving as a charter school sponsor pursuant to the South Carolina Charter Schools Act, as well as other publicly funded educational institutions providing instruction to public school students.

2. Designate one or more district test coordinators (DTCs) who will be the point of contact for the SCDE or its contractors as well as attend the workshops provided by the SCDE. The DTC is responsible for ensuring that school test coordinators (STCs) and test administrators are trained. DTCs and/or STCs are responsible for the distribution, receipt, storage, and return of test materials and reports.

3. Administer the tests (including field/pilot tests) in accordance with procedures and at dates and times specified by the SCDE.

F. Students with disabilities shall be included in the assessment program in compliance with the provisions of South Carolina and federal statutes and regulations.

G. The State Superintendent of Education is authorized to develop and implement such administrative procedures as he or she may deem necessary and appropriate for the purpose of implementing the South Carolina Statewide Assessment Program. Any administrative action taken under this regulation will be presented to the State Board of Education during the next regularly scheduled meeting of the Board.

H. End-of-Course Examination Program (EOCEP)

1. Gateway courses in English/language areas, mathematics, science, and social studies as required in Section 59-18-310 of the EAA will be defined by the State Board of Education. The End-of-Course test for social studies is the United States History and the Constitution.

2. Purposes and Uses

a. The purposes and uses of the end-of-course examinations shall be as follows:

i. The examinations shall encourage instruction in the specific academic standards for the courses, encourage student achievement, and document the level of students' mastery of the academic standards.

ii. The examinations shall serve as indicators of program, school, and school district effectiveness in the manner prescribed by the Education Oversight Committee in accordance with the provisions of the Education Accountability Act of 1998 (EAA).

iii. The examinations shall be weighted 20 percent in the determination of students' final grades in the gateway courses.

b. The examination may be used for such other purposes as the State Board of Education may determine to be appropriate and consistent with the Standards for Educational and Psychological Testing (Joint Standards) of the American Psychological Association, the American Educational Research Association, and the National Council on Measurement in Education.

3. The content of the subject-area examinations that are selected or developed pursuant to the provisions of this policy shall be aligned with the academic standards approved by the State Board of Education.

4. Student performance standards for the examinations shall be established by the SCDE.

5. The academic standards for the examinations shall be reviewed on a schedule that is consistent with the requirements of the EAA. Following any revisions of the academic standards, the examinations will be reviewed and revised as necessary to ensure their continued alignment with the standards.

6. Students who are enrolled in the gateway courses shall be provided with copies of the academic standards that pertain to those particular courses. Students will be advised that the final examination for each gateway course will be based on the skills and content represented in the academic standards. District personnel shall provide this information to students no later than the first day of instruction in the course.

II. NATIONAL ASSESSMENT OF EDUCATIONAL PROGRESS (NAEP)

NAEP tests will be administered annually to samples of students. Schools selected for NAEP will participate in the assessment program as prescribed by NAEP policies.

Fiscal Impact Statement:

None.

Statement of Rationale:

Proposed amendments permit the State Board of Education to define or change the courses in which end-of-course tests must be administered, when needed, in a timely manner and permit the SCDE to work directly with districts concerning testing specific students when unusual circumstances arise.

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Document No. 4605
STATE BOARD OF EDUCATION
CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, 59-18-1300, 59-18-1310, 59-18-1510, 59-20-60, 59-139-05, et seq., and 20 U.S.C. Section 6301, et seq.

43-261. District and School Planning.

Synopsis:

State Board of Education (SBE) Regulation 43-261 (R.43-261) governs the requirements of the districts' strategic plans and schools' renewal plans. These plans are filed every five years and may be amended at any time. The SBE has the power to waive any regulation that may impede a plan.

Notice of Drafting for the proposed amendments to the regulation was published in the *State Register* on August 28, 2015.

Instructions:

Section A(2) below replaces Section A(2) currently in law.
Section C. below replaces Section C. currently in law.

Text:

43-261. District and School Planning.

A. Development of District Strategic Plan and School Renewal Plans

1. Each school district must develop a five-year district strategic plan and each school must develop a five-year school renewal plan as required by the Early Childhood Development and Academic Assistance Act of 1993 and the Education Accountability Act of 1998. District and school plans shall coordinate and align improvement initiatives.

2. New five-year district and school plans shall be submitted to the State Department of Education by April 30, 2005, and every five years thereafter. Plans will become effective on July 1 of the same year. The annual update of the district strategic plan must be submitted to the State Department of Education by April 30 of each year or, if applicable, on the AdvancED plan deadline, whichever is later.

3. The district strategic plan includes the accountability system that directs an annual needs assessment; prioritizes the performance goals; and reports how the district supports schools, students, and families. The district strategic plan and school renewal plans must establish priorities and prioritize efforts to focus on raising student achievement levels for all students, the prevention of academic problems, and reducing the achievement gaps identified on the annual report card. It is imperative that the planning processes demonstrate a commitment to continuous improvement and respond to accountability requirements in both state and federal legislation. The plans must be developed collaboratively by a broad-based group of stakeholders using a consensus process.

4. The district strategic plan, school renewal plans, and annual updates must be reviewed and approved by the local board of trustees and coordinate funding from local, state, federal, and private sources.

5. Districts and schools are urged to follow the model planning process developed by the State Department of Education, although no single planning format is required for district or school plans. Whatever process is used for developing a district strategic plan and school renewal plans must include each of the following components:

- a. comprehensive needs assessment,
- b. performance goals,
- c. interim performance goals,
- d. strategies and action plans,
- e. evaluation of the strategies,
- f. evidence of comprehensive consensus building, and
- g. assurances.

6. Schools that use the Southern Association of Colleges and Schools (SACS) accreditation process may substitute the SACS plan for the school renewal plan provided that it includes the components (a) through (g) listed above and described below.

a. Comprehensive Needs Assessment

The annual needs assessment will provide focus for planning teams to set priorities for the plan. The comprehensive needs assessment must identify targeted areas of discrepancy between the desired performance levels and the current status as indicated by available data. Any discrepancies in the following areas identified by the school and district report cards must be included in the plan:

- (1) achievement,
- (2) achievement by subgroups,
- (3) graduation rates,
- (4) attendance,
- (5) discipline,
- (6) teacher/administrator quality and professional growth, and
- (7) other priority areas.

b. Performance Goals

Measurable performance goals, written in five-year increments, shall be developed to address the major areas of discrepancy found in the needs assessment in key areas reported in the district and school report cards. Performance goals in the district strategic plan and school renewal plans must address:

- (1) student achievement,
- (2) teacher/administrator quality,
- (3) school climate (parent involvement, safe and healthy schools, and other locally identified areas), and
- (4) other innovation initiatives or priorities as identified by districts and schools.

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c. Interim Performance Goals

Interim performance goals will establish annual measurable targets for the five-year performance goals.

d. Strategies and Action Plans

Strategies shall be derived from scientifically-based education research and best practices and shall be designed to meet the performance and interim performance goals. Action plans, which may include innovative initiatives, will provide details (action/activity, person responsible, start and end dates for major action steps, professional development, necessary resources, and progress measures) regarding the implementation of each data-driven strategy to ensure continuous improvement. Staff development shall meet national professional development standards and must provide participants with the knowledge and skills necessary to implement the strategies. Coordination of funding from local, state, federal, and private sources is imperative. Schools visited by an external review team (ERT) must incorporate appropriate recommendations into their annual update.

e. Evaluation of the Strategies

Ongoing evaluation (formative and summative) will assess the progress toward performance goals and annual interim performance goals. Measures of effectiveness must include outcome and process indicators of improvement. The methods of assessing the efficacy of the strategies must provide data regarding the impact of the strategies and whether they should be continued, modified, or terminated. After the initial year of the plan, the evaluation results from the annual update will become a key component of the ongoing needs assessment process.

f. Evidence of Comprehensive Consensus Building

Shared decision making is central to the formulation of a functional plan. Therefore, a collaborative consensus building process shall be used in the development of the district strategic plan and school renewal plans. Stakeholders, including teachers, administrators/principals, parents/guardians, and community representatives, must be actively involved in the district strategic planning and school renewal planning processes. The School Improvement Council must actively participate in the development of the school renewal plan.

g. Assurances

Assurances, signed by the district superintendent, attest that the district and schools comply with all applicable federal and state statutory and fiscal requirements.

B. Review of District Strategic Plan and School Renewal Plans

1. The district strategic plan, school renewal plans, and annual updates shall be submitted to the local board of trustees for review and approval. Five-year plans approved by the local board of trustees must be submitted to the State Department of Education for review and approval by peer review panels convened and trained by the Department.

2. The review panel will do one of the following: (1) approve the plan, (2) provisionally approve the plan pending suggested modifications, or (3) disapprove the plan. The Department shall provide technical assistance, directly or indirectly, to districts and schools with provisionally approved or disapproved plans to ensure that all plans are approved.

3. All district strategic plan updates will be reviewed by the State Department of Education on an annual basis.

C. Waivers

Upon request of a district board of trustees or its designee, the State Board of Education may waive any regulation that would impede the implementation of an approved district strategic plan or school renewal plan. The State Board of Education may delegate to the State Superintendent the ability to waive regulatory requirements for similarly situated school districts and schools. The Superintendent will report regularly to the State Board of Education all waivers issued by the Superintendent. The State Department of Education will maintain a central electronic location of all waivers issued by the State Board of Education and the Superintendent.

Fiscal Impact Statement:

None.

Statement of Rationale:

This amendment to R.43-261 will streamline the waiver process for districts and schools. The amendment delegates SBE power to the State Superintendent on issues that the SBE has ruled on previously.

Document No. 4593

STATE BOARD OF EDUCATION

CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, 59-6-65, and 59-26-20

43-90. Program Approval Standards for South Carolina Teacher Education Institutions

Synopsis:

Regulation 43-90 governs the accreditation requirements for public and private educator preparation programs. The proposed amendments to the regulation would modify language within the regulation. Current language in the regulation is specific to an educator preparation accrediting body, the National Council for Accreditation of Teacher Education (NCATE); however, a new accrediting body, the Council for the Accreditation of Educator Preparation (CAEP) has replaced NCATE. The proposed amendments would eliminate the need for a regulation change any time an accrediting body changes.

Notice of Drafting for the proposed amended regulation was published in the *State Register* on July 24, 2015.

Instructions:

Entire regulation is to be replaced with the following text.

Text:

43-90. Program Approval Standards for South Carolina Teacher Education Institutions.

The South Carolina State Board of Education requires that all teacher education programs meet the standards as established by a national accreditation association with which the South Carolina Department of Education has a partnership agreement. For State Board of Education approval, public institutions must seek and receive national accreditation. Private institutions may seek national accreditation or meet national standards for State Board of Education approval. The South Carolina Department of Education will develop guidelines to assist teacher education programs to meet the national standards. Statutory authority to determine accreditation

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decisions for and impose sanctions against teacher education programs is granted to the State Board of Education.

Fiscal Impact Statement:

No additional state funding is requested. The SCDE estimates that no additional costs will be incurred by the state in complying with the proposed amendments to R.43-90.

Statement of Rationale:

Regulation 43-90 governs the accreditation requirements for public and private educator preparation programs. Language in the current regulation reflects the name of the specific accrediting body. Because accrediting bodies change, the proposed amendments to the regulation will eliminate the need for a regulation change when an accrediting body changes.

Document No. 4606
STATE BOARD OF EDUCATION
CHAPTER 43

Statutory Authority: 1976 Code Sections 59-5-60, 59-1-445, 59-1-447, and 59-18-310(B)

43-100. Test Security

Synopsis:

State Board of Education (SBE) Regulation 43-100 (R.43-100) regulates not only test security, but also includes disciplinary action for educator's breach of professional ethics for violating test security. The amendment is being proposed because failing to test and exempting students from being assessed are breaches and the parental opt-out of testing movement unintentionally jeopardizes an educator's certificate.

Notice of Drafting for the proposed amendments to the regulation was published in the *State Register* on August 28, 2015.

Instructions:

Section IX(P) below replaces Section IX(P) currently in law.

Text:

43-100. Test Security.

I. Tests administered by or through the State Board of Education shall include but are not limited to:

A. The statewide tests, as defined in State Board of Education Regulation 43-262, including field tests and pilot tests;

B. Examinations for admission to teacher education programs and teacher certification examinations;

C. Examinations for admission to programs such as the gifted and talented program; and

D. High school equivalency tests.

II. As used in this regulation, “local school board” means the governing board of a public school district, a public charter school, as well as those of special school districts, special schools, and institutions that utilize tests administered by or through the State Board of Education.

III. Each local school board must develop and adopt a district test security policy. The policy must provide for the security of materials for the entire period of time (before, during, or after testing) the materials are in the district and/or the schools within that district. The policy must address security for paper-based, computer-based, and customized assessments. This also applies to district-owned materials that are the same as those used in any state-operated testing or assessment program. Throughout the time testing materials are under the control of the school district, secure paper-based materials must be stored under lock and key when not in use for approved test administration activities.

IV. Each District Superintendent and the administration from each of the special schools and institutions that utilize tests administered by or through the State Board of Education must designate annually one individual in each district for each mandated assessment who will be the sole individual in the district authorized to procure test instruments that are utilized in testing programs administered by or through the State Board of Education. The name of the designated individual must be provided to the South Carolina Department of Education (SCDE) in writing. When the testing program involves procurement of materials available commercially, the designated individual must be the sole individual in the district authorized to procure commercial test instruments which are utilized in testing programs administered by or through the State Board of Education.

V. Individuals must adhere to all procedures specified in all operating manuals governing the mandated testing programs. Manuals are provided by or through the SCDE.

VI. A. The State Board of Education may invalidate test scores that reflect improbable gains and that cannot be satisfactorily explained through changes in student populations or instruction.

B. In cases where test results are invalidated because of a breach of security or action of the State Board of Education, any programmatic, evaluative, or certification criteria dependent upon the data will be deemed to not have been met.

VII. Any individual(s) who knowingly engage(s) in any activity that results in the invalidation of scores derived from teacher certification examinations, the examinations for admission to teacher education programs, and/or the high school equivalency tests forfeits all opportunities to retake the test(s).

VIII. Any knowing involvement in the presentation of forged, counterfeit, or altered identification for the purpose of obtaining admission to a test administration site for any of the tests administered by or through the State Board of Education will be considered a breach of test security within the meaning of S.C. Code Ann. Section 59-1-445 (1990, 2004). Any individual(s) who knowingly cause(s) or allow(s) the presentation of forged, counterfeit, or altered identification for the purpose of obtaining admission to any test administration site specified in this paragraph forfeits all opportunities to retake the test(s).

IX. Each of the following is considered a breach of professional ethics which may jeopardize the validity of the inferences made on the basis of test data and, as such, are viewed as security violations which could result in criminal prosecution and/or disciplinary action to an educator’s professional certificate.

A. Failing to administer tests on the test dates specified by the SCDE.

B. Failing to maintain an appropriate testing environment, free from undue distractions.

C. Failing to proctor the test to ensure that examinees are engaged in appropriate test-taking activities.

D. Providing examinees with access to test questions or specific test content prior to testing.

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- E. Providing examinees with access to answer keys prior to or during testing.
- F. Keeping, copying, reproducing, or using in any manner inconsistent with the instructions provided by or through the SCDE any test, test question, or specific test content.
- G. Keeping, copying, or reproducing in any manner inconsistent with the instructions provided by or through the SCDE any portion of examinee responses to any item or any section of a secured test.
- H. Coaching examinees, altering examinee responses, or interfering with examinee responses in any way prior to, during, or after testing. This includes hinting to examinees about the correctness of their responses.
- I. Failing to follow instructions specified in the test manuals for the distribution, storage, or return of test materials or failing to account for test materials before, during, or after testing.
- J. Failing to follow all directions pertaining to the administration of a test as specified in the test manuals for that test. This section includes failure to clear the memory of calculators used on a test as directed in the test manual.
- K. Allowing, participating in, assisting in, or encouraging any unauthorized access to test materials prior to, during, or after testing.
- L. Disclosing the contents of any portion of secure materials or discussing the contents of secure tests with examinees, teachers, or other educators before, during, or after testing.
- M. Leaving in view of examinees during test administration materials that are content or conceptually related to the subject areas being assessed.
- N. Providing references or tools other than those specifically allowed in test manuals. Providing references or tools during test administration at times other than those specifically allowed in test manuals.
- O. Failing to provide accommodations and/or customized materials as specified in the student's Individualized Education Program (IEP) or 504 plan. Providing accommodations and/or customized materials not included in the student's IEP or 504 plan.
- P. Excluding examinees or exempting from assessment students who should be assessed; however, this does not include students who opt out of the assessment.
- Q. Failing to return test materials for all examinees.
- R. Engaging in inappropriate test preparation practices that invalidate the test scores. These practices include activities that result in an increase in test scores without a simultaneous increase in the examinee's real achievement or performance in the content area.
- S. Revealing test scores or test performance to anyone not involved in the education of the examinee.
- T. Altering test scores in electronic records or files.
- U. Failing to report a security breach.
- X. The SCDE has the right and responsibility to observe test administration activities without prior notice in order to monitor adherence to test security. Examinees should be made aware that monitoring may occur.
- XI. Any suspected violation of security must be reported to the South Carolina Law Enforcement Division.

XII. If a security breach occurs in a district, or charter school, rendering test forms or test items unusable, funds equivalent to replacement costs may be withheld from the district or charter school by the SCDE at the discretion of the State Board of Education.

XIII. At the discretion of the State Board of Education, an educator may receive a public or private reprimand or the credential of an educator may be suspended or revoked based on evidence of violation of test security provisions.

Fiscal Impact Statement:

None.

Statement of Rationale:

The proposed amendment will ensure that the parental opt-out of testing movement does not unintentionally jeopardize an educator's certificate.

Document No. 4645

DEPARTMENT OF EMPLOYMENT AND WORKFORCE

CHAPTER 47

Statutory Authority: 1976 Code Sections 41-29-110 and 41-31-45(C)

47-501. Unemployment Trust Fund Solvency

Synopsis:

The South Carolina Department of Employment and Workforce proposes to amend Regulation 47-501 in Article 5. Unemployment Trust Fund Solvency, to have the initial rebuilding period remain at five (5) years and to have any and all subsequent rebuilding periods be four (4) years.

Notice of Drafting for the proposed regulation was published in the *State Register* on January 22, 2016.

Section-by-Section Discussion

47-501. Unemployment Trust Fund Solvency.

This section provides details on how the income necessary to be raised each year to set state unemployment insurance tax rates will be determined based on economic conditions. The proposed amendment revises the rebuilding period for subsequent rebuilds from five (5) years to four (4) years.

Instructions:

Replace Regulation 47-501 as shown below.

Text:

47-501. Unemployment Trust Fund Solvency.

Pursuant to South Carolina Code Annotated Section 41-31-45(C) and Section 41-31-50(1)(b), the Department must annually calculate the income necessary to pay benefits and reach the fund adequacy target for the unemployment trust fund. The Department determines the total income needed as follows:

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(1) Projected benefits will be determined for the next tax year in consultation with the United States Department of Labor and with annual data provided by the Congressional Budget Office, subject to subsection (2).

(2) The income needed to pay benefits and return the unemployment trust fund to the fund adequacy target may also include a solvency surcharge. A solvency surcharge shall be in effect for each tax year that the trust fund reserve is less than the fund adequacy target, as of June 30th, subject to 47-501(2)(a). The aggregate amount of the solvency surcharge will be determined for each tax year to be the amount calculated to return the unemployment trust fund to the fund adequacy target within five years subject to the following:

(a) When actual benefits paid in the prior fiscal year are greater than the actual tax collections received in the prior fiscal year, then the cap, as defined in 47-500(7), is triggered. For the purpose of this section, tax collections shall exclude all penalties, interests, contingency surcharges, and recording fees. Once the cap is triggered then:

(i) If projected benefits for the next year are less than the cap, then the solvency surcharge shall be the difference between the cap and the projected benefits.

(ii) If projected benefits for the next tax year are equal to the cap, then no additional solvency surcharge will be added for the next tax year.

(3) The aggregate amount of the solvency surcharge for the trust fund rebuild that began with tax year 2016 will be determined for each tax year to be the amount calculated to return the unemployment trust fund to the fund adequacy target within five years. Once the fund adequacy target has been met pursuant to this item, future fund adequacy targets shall be met pursuant to item (4).

(4) After the fund adequacy target has been reached pursuant to item (3) or after the cap has been triggered, as described in 47-501(2), and in the prior fiscal year, actual benefits paid were less than actual tax collections, then tax rates for the next tax year will be set based on returning the unemployment trust fund to the fund adequacy target within the next four years.

(5) If the balance of the unemployment trust fund, as of the end of the most recently completed fiscal year, is greater than the fund adequacy target, then the Department may use the surplus amount to reduce taxes in the next tax year.

(6) Notwithstanding the provisions of 47-501(2), once the fund adequacy target has been met, in subsequent tax years, the solvency surcharge shall be set in the event the unemployment trust fund balance does not meet the fund adequacy target, as of the end of the most recently completed fiscal year, as shown in the following table:

Percentage the unemployment trust fund balance is below the fund adequacy target	Rebuilding period
More than 0.0000%, but less than 2.5000%	One year
2.5000% or more, but less than 5.0000%	Two years
5.0000% or more, but less than 7.5000%	Three years
7.5000% or more	Four years

(7) In a fiscal year in which the fund adequacy target is reached, the Department will determine tax rates for the following tax year without a solvency surcharge and pursuant to South Carolina Code Annotated Section 41-31-50.

Fiscal Impact Statement:

No additional state funding is requested. The South Carolina Department of Employment and Workforce estimates that no additional costs will be incurred by the state and its political subdivisions in amending Regulation 47-501.

Statement of Rationale:

The purpose of amending Regulation 47-501 is to change the rebuilding period for subsequent rebuilds from five (5) years to four (4) years.

Document No. 4590
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
 CHAPTER 61
 Statutory Authority: 1976 Code Sections 48-1-10 et seq.

61-62. Air Pollution Control Regulations and Standards

Synopsis:

Pursuant to the Clean Air Act, 42 U.S.C. Section 7401 et seq., and the South Carolina Pollution Control Act, 1976 Code Section 48-1-10 et seq., the South Carolina Department of Health and Environmental Control (“Department”) has amended South Carolina Regulation 61-62, Air Pollution Control Regulations and Standards, and the State Implementation Plan (“SIP”), as follows:

1. The Department amended Regulation 61-62.1, Definitions and General Requirements, Section I, Definitions and the SIP in order to add a definition for “Emission.” This revision is a result of comments received from the regulated community in 2013 related to the Department’s “2013 General Assembly Package” revisions approved on June 27, 2014. Because of public notice requirements, the Department was unable to submit this revision for approval at that time, but agreed that the change would be submitted for approval as part of the current set of revisions (2015-2016 General Assembly Package).

2. The Department amended Regulation 61-62.1, Definitions and General Requirements, Section II, Permit Requirements, to remove the requirement of a revised air dispersion modeling analysis for permit renewals. Amendments included additional definitions for clarification and/or corrections for internal consistency, clarification, reference, punctuation, codification, and spelling to improve the overall text of Regulation 61-62.1 as necessary.

3. The Department amended Regulation 61-62.5, Standard No. 4, Emissions from Process Industries, to clarify this regulation is not triggered for sources that the Department has removed Particulate Matter (“PM”) limits (from other sections of this regulation).

4. The Department amended Regulation 61-62.5, Standard No. 5.2, Control of Oxides of Nitrogen (NO_x), to clarify applicability and exemptions as well as corrections for internal consistency, punctuation, codification, and spelling.

5. The Department amended Regulation 61-62.70, Title V Operating Permit Program, to remove appeals language as this is generally defined by statutory law (Code Ann. Section 44-1-60 (Supp. 2012) and is redundant, and to clarify qualification language for administrative amendments.

6. The Department amended Regulation 61-62 to include corrections for consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

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A Notice of Drafting was published in the *South Carolina State Register* on March 27, 2015.

Changes made at the request of the House Regulations and Administrative Procedures Committee
by letter dated February 5, 2016:

Regulation 61-62.1, Definitions and General Requirements

Regulation 61-62.1, Section I, Definitions:

49. Malfunction - Add a comma after “malfunction” for grammatical correctness.

Regulation 61-62.1, Section I, Definitions:

51. Medical/Infectious Waste.c.iv. - Remove a comma after the word “testing” and add a comma after the word “analysis” for grammatical correctness.

Regulation 61-62.1, Section I, Definitions:

66. Plastics/Rubber Recycling Unit - Remove the word “and” after the word “trimming.” for grammatical correctness.

Regulation 61-62.1, Section I, Definitions:

83. Sludge Incinerator - Remove the words “waste water” after “industrial” and replace it with the single word “wastewater” for consistency.

Regulation 61-62.1, Section I, Definitions:

99. Virgin Fuel - Remove the period and the word “Also” after the word “fuel” and replace with the word “and” for grammatical correctness.

Regulation 61-62.1, Section I, Definitions:

101. Waste b. Type 1 - Remove the “s” in the word “papers” for grammatical correctness.

Regulation 61-62.1, Section II, Permit Requirements

Paragraph C.3.m, replace the “.” after “emissions” with a semicolon.

Regulation 61-62.5, Standard No. 5.2, Control of Oxides of Nitrogen (NO_x)

Regulation 61-62.5, Standard No. 5.2, Section II

H. Fuel – after word “fuels” add a comma and delete “or” from first sentence. Delete uppercase “F” and replace with lowercase “f” followed by a comma.

H.(4) add underline.

Regulation 61-62.5, Standard No. 5.2, Section III

Table 1 add hard return before “H_w is the heat input from combustion of wood residue.”

Regulation 61-62.5, Standard No. 5.2, Section IV - MONITORING, RECORD KEEPING, AND REPORTING REQUIREMENTS FOR NEW AFFECTED SOURCES

A.(1)(b) delete comma after “checks”

A.(1)(d)(i) add “s” to “report”

A.(1)(d)(i)(A) delete “.” and insert comma after “emissions” and change uppercase “T” to lowercase “t” in “The”

- A.(1)(d)(i)(B) insert comma after “taken”
- A.(1)(d)(i)(D) add “s” to “report”
- A.(2) delete (i) and recodify (b through d)
- A.(3) delete codification “(a)”
- A.(4) add comma after “40 CFR 63”
- A.(5) delete codification “(a)”
- B.(1) delete sentence (a) and recodify (i) and (ii) to (a) and (b)
- B.(2)(a) insert comma after “Department”
- B.(3)(a) add “s” to “owner” and delete “and/”
- B.(4)(a) delete codification “(a)”
- B.(5)(a) delete codification “(a)”
- C.(1)(b) delete comma after “checks”
- C.(1)(d)(i) add “s” to “report”
- C.(1)(d)(i)(A) delete “.” and insert comma after “emissions” and change uppercase “T” to lowercase “t” in “The”
- C.(1)(d)(i)(B) add comma after “taken”
- C.(1)(d)(i)(D) add “s” to “report”
- C.(2)(a) add comma after “maintain”
- C.(3)(a) change lowercase “s” to uppercase “S” in CEMs
- C.(3)(b) add comma after “recommendations” in both first and last sentences
- C.(3)(d) delete comma after “months”
- C.(5)(a) delete codification “(a)”
- C.(6)(a) delete codification “(a)” and delete “Any” and insert in its place “The” and delete “subject to the provisions of this part”
- D.(3)(a) delete codification “(a)”

Regulation 61-62.5, Standard No. 5.2, Section VII - TUNE-UP REQUIREMENTS FOR EXISTING SOURCES

- A. insert “a” after “of” and before “burner” in second sentence.

Discussion of Revisions:

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SECTION CITATION/EXPLANATION OF CHANGE:

Regulation 61-62.1, Definitions and General Requirements

Regulation 61-62.1, Section I, Definitions:

A definition for emission is inserted as number 27 to specify that a release or discharge into the atmosphere includes “fugitive emissions.”

Regulation 61-62.1, Section I, Definitions:

Definitions are renumbered in alpha-numeric order from definition “27.” to the end to account for newly added definition and to ensure clarity and consistency.

Regulation 61-62.1, Section II, Permit Requirements:

Text in Paragraph A.3 is amended to replace the words “no later than” with the word “within” for consistency within the regulation.

Regulation 61-62.1, Section II, Permit Requirements:

Section C, Construction Permit Applications, Paragraph 3.m is amended to include the wording “as well as buildings that might affect dispersion of any emissions.”

Regulation 61-62.1, Section II, Permit Requirements:

Section E, Synthetic Minor Construction Permits, Paragraph 2.b is amended to replace the words “no later than” with the word “within” for consistency within the regulation.

Regulation 61-62.1, Section II, Permit Requirements:

Section F, Operating Permits, Paragraph 3.b is amended to replace the words “no later than” with the word “within” for consistency within the regulation.

Regulation 61-62.1, Section II, Permit Requirements:

Section G, Conditional Major Operating Permits, Paragraph 4.b is amended to replace the words “no later than” with the word “within” for consistency within the regulation.

Regulation 61-62.1, Section II, Permit Requirements:

Section H, Operating Permits Renewal Requests, Paragraph 3, is amended to replace the words “no later than” with the word “within” for consistency within the regulation.

Regulation 61-62.1, Section II, Permit Requirements:

Section H, Operating Permits Renewal Requests, Paragraph 4.i is amended to replace the requirement of a revised air dispersion modeling analysis for permit renewals with a description of acceptable information.

Regulation 61-62.5, Standard No. 4, Emissions from Process Industries

Regulation 61-62.5, Standard No. 4, Section VIII:

Paragraph A, is amended to add the text “Kraft Pulp and Paper Manufacturing facilities are excluded from Section VIII.”

Regulation 61-62.5, Standard No. 4, Section XII:

Paragraph A, is stricken in its entirety to clarify this regulation is not triggered for sources that the Department has removed PM limits (from other sections of this regulation). The appropriate codification is made for the subsequent paragraphs A through F.

Regulation 61-62.5, Standard No. 5.2, Control of Oxides of Nitrogen (NO_x)

Regulation 61-62.5, Standard No. 5.2, Section I(A):

Section I(A) is amended to add language to explain sources for which this regulation is applicable.

Regulation 61-62.5, Standard No. 5.2, Section I(B):

Section I(B) is amended to strike and add language to clarify sources that are exempt from the requirements of this regulation and ensure internal consistency. The alpha-numeric order was renumbered for clarity and consistency.

Regulation 61-62.5, Standard No. 5.2, Section II:

Section II is amended to strike obsolete definitions and add others to further clarify existing definitions. The alpha-numeric order was edited for clarity and consistency.

Regulation 61-62.5, Standard No. 5.2, Section III:

Section III is amended to add language to further explain the requirements for new affected sources, add clarity to the existing requirements of this regulation, ensure internal consistency, and properly cite items per the 2014 South Carolina Legislative Council's Standards Manual.

Regulation 61-62.5, Standard No. 5.2, Section III, Table 1:

Section III, Table 1 is amended to revise measurement units for control technology and/or emission limit to ensure consistency with the Federal requirements. Revise language to clarify source types, add clarity to the existing requirements of this regulation, and ensure internal consistency.

Regulation 61-62.5, Standard No. 5.2, Section IV, V, and VI:

Section IV, V and VI are amended to strike these Sections addressing requirements for existing sources in their entirety to relocate to the end of this regulation as new Sections V, VI, and VII for ease of use and clarity. Revise and retitle these Sections to clarify the standard requirements, notification requirements, and tune-up requirements for existing affected sources.

Regulation 61-62.5, Standard No. 5.2, Section IV:

This section is revised and retitled to add new language to clearly identify the requirements for "new affected sources" by adding paragraphs "(A) Boilers", "(B) Engines", "(C) Turbines", and "(D) All Other Affected Source Types" to this Section. Further clarify the requirements of this regulation for each of the added paragraphs described above by adding language to define monitoring, record keeping, tune-ups, and reporting requirements.

Regulation 61-62.70, Title V Operating Permit Program

Regulation 61-62.70, Section 70.1, Program overview:

Section 70.1 is amended to strike paragraph "(h), Appeals." in its entirety, as this is generally defined by statutory law (Code Ann. Section 44-1-60 (Supp. 2012) and is redundant.

Instructions:

Amend Regulation 61-62, Air Pollution Control Regulations and Standards, pursuant to each instruction provided below with the text of the amendments.

Text:**Regulation 61-62.1, Definitions and General Requirements**

Regulation 61-62.1, Section I. shall be revised as follows:

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27. Emission – Means a release or discharge to the outdoor (ambient) atmosphere of air contaminants, including fugitive emissions.

28. Emission Data – Means the definition contained in 40 CFR 2.301(a)(2), July 1, 1986, is incorporated by reference.

29. Emission Limitation (and Emission Standard) – Means a requirement established by the state or by the Administrator which limits the quantity, rate, or concentration of emissions of air pollutants on a continuous basis, including any requirements which limit the level of opacity, prescribe equipment, set fuel specifications, or prescribe operation or maintenance procedures for a source to assure continuous emission reduction.

30. Federally Enforceable – Means all limitations and conditions which are enforceable by the Administrator and citizens under the Act, including those requirements developed pursuant to 40 CFR 60, 61, 63, and 70; requirements within the South Carolina State Implementation Plan (SIP); and any permit requirements established pursuant to 40 CFR 52.21 or under regulations approved pursuant to 40 CFR 51 Subpart I, including operating permits issued under an EPA-approved program that is incorporated into the SIP and expressly requires adherence to any permit issued under such program.

31. Fuel Burning Operation – Means use of a furnace, boiler, device, or mechanism used principally, but not exclusively, to burn any fuel for the purpose of indirect heating in which the material being heated is not contacted by and adds no substance to the products of combustion.

32. Fugitive Dust – Means a type of particulate emission that becomes airborne by forces of wind, man's activity, or both, including, but not limited to, construction sites, tilled land, materials storage piles, and materials handling.

33. Fugitive Emissions – Means emissions which could not reasonably pass through a stack, chimney, vent, or other functionally equivalent opening.

34. Garbage – Means animal and vegetable waste resulting from the handling, preparation, cooking, and serving of foods.

35. Hazardous Air Pollutant (HAP) – Means a pollutant which is the subject of National Emission Standards for Hazardous Air Pollutants (NESHAP) promulgated by the EPA by publication in the Federal Register.

36. Hazardous Waste – Means any waste identified as such by Regulation 61-79.

37. Hazardous Waste Fuel – Means hazardous waste that has a heat value greater than 5000 British thermal unit per pound (Btu/lb) and is burned in an industrial or utility boiler or industrial furnace for energy recovery, except for hazardous wastes exempted by Section 266.30(b) of Regulation 61-79.

38. Hazardous Waste Incinerator – Means an incinerator whose primary function is to combust hazardous waste, except for devices which have qualified for exemption as provided in Sections 264.340(b) or 265.340(b) of Regulation 61-79.

39. Hospital – Means any facility which has an organized medical staff, maintains at least six (6) inpatient beds, and where the primary function of the institution is to provide diagnostic and therapeutic patient services and continuous nursing care primarily to human inpatients who are not related and who stay on average in excess of twenty-four (24) hours per admission. This definition does not include facilities maintained for the sole purpose of providing nursing or convalescent care to human patients who generally are not acutely ill but who require continuing medical supervision.

40. Hospital/Medical/Infectious Waste Incinerator or HMIWI or HMIWI Unit – Means any device that combusts any amount of hospital waste and/or medical/infectious waste.

41. Hospital Waste – Means discards generated at a hospital, except unused items returned to the manufacturer. The definition of hospital waste does not include human corpses, remains, and anatomical parts that are intended for interment or cremation.

42. Incinerator – Means any engineered device used in the process of controlled combustion of waste for the purpose of reducing the volume; removing the contamination and/or reducing or removing the hazardous potential of the waste charged by destroying combustible matter leaving the noncombustible ashes, material, and/or residue; and which does not meet the criteria nor classification as a boiler nor is listed as an industrial furnace.

43. Industrial Boiler – Means a boiler that produces steam, heated air, or other heated fluids for use in a manufacturing process.

44. 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 tray furnaces, 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
- l. Such other devices as the Department may determine on a case-by-case basis using one (1) or more of the following factors:
 - i. The design and use of the device primarily to accomplish recovery of material products;
 - ii. The use of the device to burn or reduce raw materials to make a material product;
 - iii. 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;

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iv. The use of the device to burn or reduce secondary materials as ingredients in an industrial process to make a material product;

v. The use of the device in common industrial practice to produce a material product; and

vi. Other factors as appropriate.

45. Industrial Incinerator – Means any incinerator utilized in an industrial plant that does not meet the definition for any other type of incinerator or an incinerator used to combust Type 5 or 6 waste at any site.

46. In Existence – Means that the owner or operator has obtained all necessary construction permits required by this Department and either has:

a. Begun, or caused to begin, a continuous program of physical on-site construction of the source; or

b. Entered into binding agreements or contractual obligations, which cannot be canceled or modified without substantial loss to the owner or operator, to undertake a program of construction of the source to be completed in a reasonable time, or that the owner or operator possesses a valid operating permit for the source prior to the effective date of a regulation or standard.

47. Kraft Pulp Mill – Means any stationary source which produces pulp from wood by cooking (digesting) wood chips in a water solution of sodium hydroxide and sodium sulfide (white liquor) at a high temperature and pressure. Regeneration of the cooking chemicals through a recovery process is also considered part of the kraft pulp mill.

48. Major Source – Means, except as otherwise provided, any source which directly emits, or has the potential to emit, greater than or equal to the major source threshold as defined by applicable federal and state regulations.

49. Malfunction – Means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions. During periods of malfunction, the operator shall operate within established parameters as much as possible, and monitoring of all applicable operating parameters shall continue until all waste has been combusted or until the malfunction ceases, whichever comes first.

50. Mass Emission Rate – Means the weight discharged per unit of time.

51. Medical/Infectious Waste – Means any waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals listed below; and any waste defined as infectious waste in Regulation 61-105, Infectious Waste Management. The definition of medical/infectious waste does not include hazardous waste identified or listed in Regulation 61-79.261; household waste, as defined in Regulation 61-79.261.4(b)(1); ash from incineration of medical/infectious waste, once the incineration process has been completed; human corpses, remains, and anatomical parts that are intended for interment or cremation; and domestic sewage materials identified in Regulation 61-79.261.4(a)(1).

a. Cultures and stocks of infectious agents and associated biologicals, including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

b. Human pathological waste – tissues, organs, body parts, and body fluids that are removed during surgery or autopsy or other medical procedures, and specimens of body fluids and their containers.

c. Human blood and blood products including:

- i. Liquid waste human blood;
- ii. Products of blood;
- iii. Items saturated and/or dripping with human blood; or

iv. Items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers which were used or intended for use in either patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.

d. Sharps – instruments used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

e. Animal waste including contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.

f. Isolation wastes – biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans who are isolated to protect others from highly communicable diseases or isolated animals known to be infected with highly communicable diseases.

g. Unused sharps including the following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

52. Multiple-Chamber Incinerator – Means an incinerator consisting of at least two (2) refractory lined combustion chambers (primary and secondary) in series, physically separated by refractory walls, interconnected by gas passage ports or ducts.

53. Municipal Solid Waste, MSW, or Municipal-type Solid Waste – a. Means household, commercial/retail, and/or institutional waste. Household waste includes material discarded by single and multiple residential dwellings, hotels, motels, and other similar permanent or temporary housing establishments or facilities. Commercial/retail waste includes material discarded by stores, offices, restaurants, warehouses, nonmanufacturing activities at industrial facilities, and other similar establishments or facilities. Institutional waste includes material discarded by schools, nonmedical waste discarded by hospitals, material discarded by nonmanufacturing activities at prisons and government facilities, and material discarded by other similar establishments or facilities. Household, commercial/retail, and institutional wastes include:

- i. Yard waste;
- ii. Refuse-derived fuel; and
- iii. Motor vehicle maintenance materials limited to vehicle batteries and tires.

b. Household, commercial/retail, and institutional waste (MSW) does not include used oil; sewage sludge; wood pallets; construction, renovation, and demolition wastes (which includes, but is not limited to, railroad ties and telephone poles); clean wood; industrial process or manufacturing wastes (including Type 5 or 6 waste);

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medical waste; radioactive contaminated waste; hazardous waste; or motor vehicles (including motor vehicle parts or vehicle fluff).

54. Municipal Waste Combustor, MWC, or Municipal Waste Combustor Unit – Means any setting or equipment that combusts solid, liquid, or gasified municipal solid waste including, but not limited to, field-erected incinerators (with or without heat recovery), modular incinerators (starved-air or excess-air), boilers (for example, steam generating units) and furnaces (whether suspension-fired, grate-fired, mass-fired, or fluidized bed-fired, etc.), air curtain incinerators, and pyrolysis/combustion units. Municipal waste combustors do not include pyrolysis/combustion units located at plastics/rubber recycling units. Municipal waste combustors do not include internal combustion engines, gas turbines, or other combustion devices that combust landfill gases collected by landfill gas collection systems. For the purpose of determining reconstruction or modification, as defined in 40 CFR 60 Subpart A, or Regulation 62.5, Standard No. 3, to a municipal waste combustor, the following applies:

a. The boundaries of a municipal solid waste combustor are defined as follows. The municipal waste combustor unit includes, but is not limited to, the municipal solid waste fuel feed system, grate system, flue gas system, bottom ash system, and the combustor water system. The municipal waste combustor boundary starts at the municipal solid waste pit or hopper and extends through:

i. The combustor flue gas system, which ends immediately following the heat recovery equipment or, if there is no heat recovery equipment, immediately following the combustion chamber;

ii. The combustor bottom ash system, which ends at the truck loading station or similar ash handling equipment that transfers the ash to final disposal, including all ash handling systems that are connected to the bottom ash handling system; and

iii. The combustor water system, which starts at the feed water pump and ends at the piping exiting the steam drum or superheater.

b. The municipal waste combustor unit does not include air pollution control equipment, the stack, water treatment equipment, or the turbine-generator set.

55. NAICS Code – Means North American Industry Classification System (NAICS) Code, a six digit coding system, which attempts to classify all business establishments by the types of products or services they provide.

56. Non-Industrial Boiler – Means any boiler not classified as an industrial boiler.

57. Non-Industrial Furnace – Means any furnace not classified as an industrial furnace.

58. Non-Spec. Oil (Off-Spec. Oil) – See definition of used oil.

59. Opacity – Means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background.

60. 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.

61. Part 70 Permit – Means any permit or group of permits covering a source subject to the permitting requirements of Regulation 61-62.70. The use of the term “Title V Permit” shall be construed to mean “Part 70 Permit.”

62. Particulate Matter – Means any material, except uncombined water, that exists in a finely divided form as a liquid or solid at standard conditions.

63. Particulate Matter Emissions – Means all finely divided solid or liquid material, other than uncombined water, emitted to the ambient air as measured by an applicable reference method described in 40 CFR 60, July 1, 1987, or an equivalent or alternative method approved by the Department, with the concurrence of the EPA.

64. Pathological Waste – Means waste material consisting of only human or animal remains, anatomical parts, and/or tissue; the bags/containers used to collect and transport the waste material; and animal bedding (if applicable).

65. Plant – Means, except as otherwise provided, any stationary source or combination of stationary sources, which is located on one (1) or more contiguous or adjacent properties and owned or operated by the same person(s) under common control.

66. Plastics/Rubber Recycling Unit – Means an integrated processing unit where plastics, rubber, and/or rubber tires are the only feed materials (incidental contaminants may be included in the feed materials) and they are processed into a chemical plant feedstock or petroleum refinery feedstock where the feedstock is marketed to and used by a chemical plant or petroleum refinery as input feedstock. The combined weight of the chemical plant feedstock and petroleum refinery feedstock produced by the plastics/rubber recycling unit on a calendar quarter basis shall be more than seventy (70) percent of the combined weight of the plastics, rubber, and rubber tires processed by the plastics/rubber recycling unit on a calendar quarter basis. The plastics, rubber, and/or rubber tire feed materials to the plastics/rubber recycling unit may originate from the separation or diversion of plastics, rubber, or rubber tires from MSW or industrial solid waste; and may include manufacturing scraps, trimmings, off-specification plastics, rubber, and rubber tire discards. The plastics, rubber, and rubber tire feed materials to the plastics/rubber recycling unit may contain incidental contaminants (for example, paper labels on plastic bottles, metal rings on plastic bottle caps, etc.).

67. PM_{2.5} – Means particulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers emitted to the ambient air as measured by a reference method based on Appendix L of 40 CFR 50 and designated in accordance with 40 CFR 53 or by an equivalent method designated in accordance with 40 CFR 53.

68. PM_{2.5} Emissions – Means finely divided solid or liquid material with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers emitted to the ambient air as measured by a reference method approved by the Department with concurrence of the EPA.

69. PM₁₀ – Means particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers as measured by a reference method based on Appendix J of 40 CFR 50 and designated in accordance with 40 CFR 53 or by an equivalent method designated in accordance with 40 CFR 53.

70. PM₁₀ Emissions – Means finely divided solid or liquid material with an aerodynamic diameter less than or equal to a nominal 10 micrometers emitted to the ambient air as measured by a reference method approved by the Department with concurrence of the EPA.

71. Potential to Emit – Means the maximum capacity of a source to emit a regulated pollutant under its physical and operational design. Any physical or operational limitation on the capacity of the source to emit a regulated pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design only if the limitation or the effect it would have on emissions is federally enforceable. Secondary emissions do not count in determining the potential to emit of a source.

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72. Process Industry – Means any source engaged in the manufacture, processing, handling, treatment, forming, storing, or any other action upon materials except fuel-burning operations.

73. Process Weight – Means the total weight of all materials introduced into a source operation, including air and water where these materials become an integral part of the product and solids used as fuels, but excluding liquids and gases used solely as fuels.

74. Process Weight Rate – a. Means a rate established as follows:

i. For continuous or long-run steady-state source operations, the total process weight for the entire period of continuous operation or for a typical portion thereof, divided by the number of hours of such period or portion thereof.

ii. For cyclical or batch unit operations or unit processes, the total process weight for a period that covers a complete operation or an integral number of cycles, divided by the hours of actual process operation during such a period.

b. Where the nature of any process or operation or the design of any equipment is such as to permit more than one interpretation of this definition, the interpretation that results in the minimum value for allowable emission shall apply.

75. Pyrolysis/Combustion Unit – Means a unit that produces gases, liquids, or solids through the heating of waste; and the gases, liquids, or solids produced are combusted and emissions vented to the atmosphere.

76. Refuse – Means garbage, rubbish, and/or trade waste.

77. Refuse-derived Fuel – Means a type of municipal solid waste produced by processing municipal solid waste through shredding and size classification. This includes all classes of refuse-derived fuel including low-density fluff refuse-derived fuel through densified refuse-derived fuel and pelletized refuse-derived fuel.

78. Retail Business Type Incinerator – Means an incinerator that combusts waste typical of a retail business rather than domestic, commercial, or industrial activities.

79. Rubbish – Means solid wastes from residences and dwellings, commercial establishments, and institutions.

80. Salvage Operations – Means any operation of a business, trade, or industry engaged in whole or in part in salvaging or reclaiming any product or material including, but not limited to, metals, chemicals, shipping containers, drums, or automobiles.

81. Secondary Emissions – Means emissions which would occur as a result of the construction or operation of a major source or major modification but do not come from the major source or major modification itself. Secondary emissions shall be specific, well defined, quantifiable, and shall impact the same general area as the source or modification which causes the secondary emissions. Secondary emissions may include, but are not limited to:

a. Emissions from ships or trains moving to or from the new or modified source.

b. Emissions from any offsite support operation which would not otherwise be constructed or increase its emissions as a result of the construction or operation of the major source or major modification.

82. SIC Code – Means Standard Industrial Classification Codes which are four digit numerical codes designed by the U.S. Department of Labor in order to create uniform descriptions of business establishments.

83. Sludge Incinerator – Means an incinerator that combusts wastes containing more than ten (10) percent (dry weight basis) sludge produced by municipal or industrial wastewater treatment plants or each incinerator that charges more than 2205 pounds per day (lb/day) (dry weight basis) of sludge produced by municipal or industrial wastewater treatment plants.

84. Smoke – Means small gasborne and airborne particles arising from a process of combustion in sufficient number to be observable by a person of normal vision under normal conditions.

85. Solid Fuel – Means a fuel which is fired as a solid such as coal, lignite, and wood.

86. Spec. Oil – See definition of used oil.

87. Stack – Means any flue, conduit, chimney, or opening arranged to conduct an effluent into the open air.

88. Stack Height – Means the vertical distance measured in feet between the point of discharge from the stack or chimney into the outdoor atmosphere and the elevation of the land thereunder.

89. Standard Conditions – Means 760 millimeters of mercury (mmHg) at twenty-five (25) degrees Centigrade (C).

90. Stationary Source – Means any building, structure, installation, or process which emits or may emit an air pollutant subject to regulation by any national or state standard. Use of the term “source” is to be construed to mean “stationary source.”

91. Substantial Loss – Means, generally, a loss which would equal or exceed ten (10) percent of the total initial project cost.

92. Synthetic Minor Source – Means a stationary source that obtains a federally enforceable physical or operational limitation from the Department to limit or cap the stationary source’s potential to emit to avoid being defined as a major source or major modification, as defined by applicable federal and state regulations.

93. Total Reduced Sulfur (TRS) – Means the sum of the sulfur compounds hydrogen sulfide, methyl mercaptan, dimethyl sulfide, and dimethyl disulfide that are released during the kraft pulping operation.

94. Total Suspended Particulate (TSP) – Means particulate matter as measured by the method described in Appendix B, 40 CFR 50, July 1, 1987.

95. Trade Waste – Means all solid, liquid, or gaseous material or rubbish resulting from construction, building operations, or the prosecution of any business, trade, or industry including, but not limited to, plastic products, cartons, paint, grease, oil and other petroleum products, chemicals, and cinders.

96. Untreated Lumber – Means wood or wood products that have been cut or shaped and include wet, air-dried, and kiln-dried wood products. Untreated lumber does not include wood products that have been painted, pigment-stained, or “pressure-treated.” Pressure-treating compounds include, but are not limited to, chromate copper arsenate, pentachlorophenol, and creosote.

97. Used Oil – Means any oil that 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. This also includes absorbent material contaminated with used oil such as oily rags or absorbent blankets. Two (2) types of used oil are defined as follows:

- a. Spec. Oil (Specification Oil) – Used oil that meets the following specifications: *

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- i. Arsenic – 5 parts per million (ppm) maximum;
- ii. Cadmium – 2 ppm maximum;
- iii. Chromium – 10 ppm maximum;
- iv. Lead – 100 ppm maximum;
- v. Nickel – 120 ppm maximum;
- vi. Total halogens – 4000 ppm maximum; and**
- vii. Flash Point – 100 degrees Fahrenheit (F) (37.8 degrees C) minimum.

* This specification does not apply to used oil fuel mixed with a hazardous waste.

** Used oil containing more than 1000 ppm total halogens is presumed to be a hazardous waste. The burden of proof that this is not true rests with the user.

- b. Non-Spec. Oil (Off-Spec. Oil) – Used oil that does not meet the specification above.

98. Utility Boiler – Means a boiler that produces steam, heated air, or other heated fluids for sale or for use in producing electric power for sale.

99. Virgin Fuel – Means unused solid, liquid, or gaseous commercial fuel, and clean wood or bark that has not been processed other than for size reduction excluding clean wood or bark burned in an air curtain incinerator.

100. Volatile Organic Compound (VOC) – a. Means any organic compound which participates in atmospheric photochemical reactions; or which is measured by a reference method (as specified in 40 CFR 60, as of July 1, 1990), an equivalent method, an alternative method, or which is determined by procedures specified under any subpart of 40 CFR 60. This definition does not include compounds that have negligible photochemical reactivity according to the methods employed by the EPA to determine compounds listed in 40 CFR 51.100(s).

b. For purposes of determining compliance with emission limits, VOCs will be measured by the approved test methods. Where such a method also inadvertently measures compounds with negligible photochemical reactivity, an owner or operator may exclude these negligibly reactive compounds when determining compliance with an emissions standard.

c. The following compound(s) are VOCs for purposes of all recordkeeping, emissions reporting, photo-chemical dispersion modeling, and inventory requirements which apply to VOCs and shall be uniquely identified in emission reports, but are not VOCs for purposes of VOC emissions limitations or VOC content requirements: t-butyl acetate (TBAC or TBAC).

101. Waste – Means any discarded material including, but not limited to, used oil, hazardous waste fuel, hazardous waste, medical waste, municipal solid waste (MSW), sludge, waste fuel, and waste classification Types 0 through 6 or any material which 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.

a. Type 0 – Trash, a mixture of highly combustible waste such as paper, cardboard, wood boxes, and combustible floor sweepings from commercial and industrial activities. The mixture contains up to ten (10)

percent by weight of plastic bags, coated paper, laminated paper, treated corrugated cardboard, oily rags, and plastic or rubber scraps.

Typical composition: ten (10) percent moisture, five (5) percent incombustible solids, and has a heating value of approximately 8500 Btu/lb as fired.

b. Type 1 – Rubbish, a mixture of combustible waste such as paper, cardboard cartons, wood scrap, foliage, and combustible floor sweepings from domestic, commercial, and industrial activities. The mixture contains up to twenty (20) percent by weight of restaurant or cafeteria waste, but contains little or no treated paper, plastic, or rubber wastes.

Typical composition: twenty-five (25) percent moisture, ten (10) percent incombustible solids, and has a heating value of approximately 6500 Btu/lb as fired.

c. Type 2 – Refuse, consisting of an approximately even mixture of rubbish and garbage by weight. This type of waste is common to apartment and residential occupancy.

Typical composition: up to fifty (50) percent moisture, seven (7) percent incombustible solids, and has a heating value of approximately 4300 Btu/lb as fired.

d. Type 3 – Garbage, consisting of animal and vegetable wastes from restaurants, cafeterias, hotels, hospitals, markets, and like installations.

Typical composition: up to seventy (70) percent moisture, up to five (5) percent incombustible solids, and has a heating value of approximately 2500 Btu/lb as fired.

e. Type 4 – Human and animal remains, consisting of carcasses, organs, and solid organic wastes from hospitals, laboratories, abattoirs, animal pounds, and similar sources.

Typical composition: up to eighty-five (85) percent moisture, five (5) percent incombustible solids, and having a heating value of approximately 1000 Btu/lb as fired.

f. Type 5 – By-product waste, gaseous, liquid, or semi-liquid, such as tar, paints, solvents, sludge, fumes, etc., from industrial operations. Btu values shall be determined by the individual materials to be destroyed.

g. Type 6 – Solid by-product waste, such as rubber, plastics, wood waste, etc., from industrial operations. Btu values shall be determined by the individual materials to be destroyed.

102. Waste Fuel – Means waste that does not meet hazardous waste criteria but has a heat value greater than 5000 Btu /lb.

103. Yard Waste – Means grass, grass clippings, bushes, shrubs, and clippings from bushes and shrubs that are generated by residential, commercial/retail, institutional, and/or industrial sources as part of maintenance activities associated with yards or other private or public lands. Yard waste does not include construction, renovation, and demolition wastes, which are exempt from the definition of MSW in this section. Yard waste does not include clean wood, which is also exempt from the definition of MSW in this section.

Regulation 61-62.1, Section II, Paragraph A.3 shall be revised as follows:

3. The owner or operator shall submit written notification to the Department of the date construction is commenced, postmarked within thirty (30) days after such date, and written notification of the actual date of initial startup of each new or altered source, postmarked within fifteen (15) days after such date.

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Regulation 61-62.1, Section II, Paragraph C.3.m, shall be revised as follows:

m. Scale drawings showing a plan view of the property lines, the location of the source, all stacks, and other emission points related to the source, as well as buildings that might affect dispersion of any emissions;

Regulation 61-62.1, Section II, Paragraph E.2.b, shall be revised as follows:

b. The owner or operator shall submit written notification to the Department of the date construction is commenced, postmarked within thirty (30) days after such date, and written notification of the actual date of initial startup of each new or altered source, postmarked within fifteen (15) days after such date. A written request to obtain an operating permit shall be submitted to the Department within fifteen (15) days after the actual date of initial startup of each new or altered source in accordance with Section II.F below. A satisfactory compliance inspection by a Department representative may precede the issuance of an operating permit for any newly constructed or modified source.

Regulation 61-62.1, Section II, Paragraph F.3.b, shall be revised as follows:

b. For sources not subject to Regulation 61-62.70, or not yet covered by an effective Title V operating permit, the owner or operator shall submit a written request for a new or revised operating permit to cover any new, or altered source, postmarked within fifteen (15) days after the actual date of initial startup of each new or altered source.

Regulation 61-62.1, Section II, Paragraph G.4.b, shall be revised as follows:

b. A written request to obtain a conditional major operating permit shall be submitted to the Department, postmarked within fifteen (15) days after the actual date of initial startup of each new or altered source. This request shall include any additional information required in Section II.G.6 below. These facilities will be issued conditional major operating permits without further public notice if no substantive changes to limitations are required. A satisfactory compliance inspection by a Department representative may precede the issuance of an operating permit for any newly constructed or modified source.

Regulation 61-62.1, Section II, Paragraph H.3, shall be revised as follows:

3. For sources not subject to Regulation 61-62.70, the owner or operator shall submit an operating permit renewal request to the Department within ninety (90) days prior to the operating permit expiration date. The source may be inspected by the Department in order to decide whether to renew the permit. Past records of compliance and future probability of compliance will be considered in making the decision regarding renewal.

Regulation 61-62.1, Section II, Paragraph H.4.i, shall be revised as follows:

i. A description of stack, vent, or fugitive emission parameters associated with each non-exempt emission source. For each emission point/source, this information should include, as appropriate, Universal Transverse Mercator or latitude and longitude coordinates of the emission location, the minimum height above ground, maximum internal dimensions of the emission point/vent, discharge orientation, emission exit velocity, emission exit temperature, dimensions describing the volume or area of fugitive emissions, existence of any rain protection device or other impediment to vertical dispersion, etc. If existing data supplied to the Department remains correct, identify the document(s) submitted to comply with this requirement; and

Regulation 61-62.5, Standard No. 4, Emissions from Process Industries

Regulation 61-62.5, Standard No. 4, Section VIII.A, shall be revised as follows:

A. Particulate matter emissions where not specified elsewhere shall be limited to the rate specified in Table A (modified using the effect factors (F) of Table B as required). Kraft Pulp and Paper Manufacturing facilities are excluded from Section VIII.

Regulation 61-62.5, Standard No. 4, Section XII.A-G, shall be revised as follows:

An owner or operator of a source listed below shall perform scheduled periodic tests for particulate matter emissions and/or SO₂ every two (2) years except as noted, or on a schedule as stipulated by special permit conditions, and shall ensure that source tests are conducted in accordance with Regulation 61-62.1, Section IV, Source Tests.

A. Rotary kilns, clinker coolers, and rotary dryers of Portland Cement plants.

B. Sulfuric acid plants.

C. Metallurgical furnaces greater than ten (10) tons per hour normal output.

D. Asphalt plants. Asphalt plants that have a baghouse operating in a satisfactory manner with sufficiently low visible emissions may be exempted at the discretion of the Department. Asphalt plants will be required to produce “surface mix” during compliance source testing. “Surface mix” is hot laid asphaltic concrete surface courses (except sand asphalt surface mix) as defined in Section 403 of the 1986 edition of the South Carolina State Highway Department’s “Standard Specifications for Highway Construction” manual. The Department may, at its discretion, waive this requirement if sufficient evidence indicates that less than twenty-five (25) percent of the plant’s total annual production is surface mix.

E. Fertilizer plants.

F. Any other sources which are deemed necessary.

Regulation 61-62.5, Standard No. 5.2, Control of Oxides of Nitrogen (NO_x)

Regulation 61-62.5, Standard No. 5.2, Section I(A) shall be revised as follows:

A. Except as provided in paragraph B. of this part, the provisions of this regulation shall apply to any stationary source that emits or has the potential to emit oxides of nitrogen (NO_x) generated from fuel combustion. A stationary source becomes an affected source under this regulation upon meeting one or more of the criteria specified in paragraphs (A)(1), (A)(2), and (A)(3) below.

(1) Any new source that is constructed after June 25, 2004;

(2) Any existing source where a burner assembly is replaced with another burner assembly after the effective date of this regulation, regardless of size or age of the burner assembly to be replaced shall become an existing affected source and is subject to sections V, VI, and VII below. The replacement of individual components such as burner heads, nozzles, or windboxes does not trigger affected source status.

(3) Any existing source removed from its presently permitted facility (either from in-state or out-of-state) and moved to another permitted facility in-state after the effective date of this regulation shall be considered a new affected source. Any existing sources relocated between permitted facilities within the State under common ownership shall not become an existing affected source until Section I(A)(2) is triggered.

Regulation 61-62.5, Standard No. 5.2, Section I(B) shall be revised as follows:

B. Exemptions:

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The following sources are exempt from all requirements of this regulation unless otherwise specified:

- (1) Any source emitting NO_x listed on the Regulation 61-62.1, Section II(B), Exemptions.
- (2) Any source emitting NO_x listed on the Department maintained list under Regulation 61-62.1, Section II (B)(3).
- (3) Any source which has undergone a Best Available Control Technology (BACT) analysis or Lowest Achievable Emission Rate (LAER) for NO_x in accordance with Regulation 61-62.5, Standard No. 7, and 7.1, respectively.
- (4) Any stationary internal combustion engine with a mechanical power output of less than two hundred (200) brake horsepower (bhp) or 149kW.
- (5) Any device functioning solely as a combustion control device. Waste heat recovery from these combustion control devices shall not be considered primary grounds for exclusion from this exemption.
- (6) Any equipment that has NO_x limits pursuant to the requirements of 40 Code of Federal Regulations (CFR) 60, 61, or 63 where such limits are equivalent to, or more stringent than, the requirements of this regulation.
- (7) Any source that has NO_x limits pursuant to the requirements of Regulation 61-62.96, where such limits are equivalent to, or more stringent than, the requirements of this regulation.
- (8) Any source that has NO_x limits pursuant to the requirements of Regulation 61-62.99.
- (9) Air Curtain Incinerators.
- (10) Engines Test Cells and/or Stands.
- (11) Portable and temporary internal combustion (IC) engines such as those associated with generators, air compressors, or other applications provided that they fall in the categories listed in 40 CFR 89, (Control of Emissions from New and In-Use Nonroad Compression-Ignition Engines), 40 CFR 1039 (Control of Emissions From New and In-Use Nonroad Compression-Ignition Engines), and 40 CFR 1068 (General Compliance Provisions For Highway, Stationary, and Nonroad Programs).
- (12) Combustion sources that operate at an annual capacity factor of ten (10) percent or less per year.
- (13) Special use burners, such as startup/shutdown burners, that are operated less than 500 hours a year are exempt from the existing source replacement requirements.
- (14) Liquor guns on a recovery boiler are only exempt from the standard requirements in Section IV below.
- (15) Portable sources such as asphalt plants or concrete batch plants are considered existing sources only and become existing affected sources when the burner assembly is replaced under Section (1)(A)(2).
- (16) The Department reserves the right to consider any other exemptions from this regulation on a case-by-case basis as appropriate.

Regulation 61-62.5, Standard No. 5.2, Section II shall be revised as follows:

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

A. Annual Capacity Factor: Means the ratio between the actual heat input to a combustion unit from the fuels during a calendar year and the potential heat input to the steam generating unit had it been operated for 8,760 hours during a calendar year at the maximum steady state design heat input capacity.

B. Burner Assembly: Means any complete, pre-engineered device that combines air (or oxygen) and fuel in a controlled manner and admits this mixture into a combustion chamber in such a way as to ensure safe and efficient combustion. A self-contained chamber such as is found on a combustion turbine is not a burner assembly for the purposes of this regulation.

C. Case-by-Case NO_x Control: Means an emissions limitation based on the maximum degree of reduction for NO_x which would be emitted from any new source which the Department, on a case-by-case basis, taking into account energy, environmental, and economic impacts and other costs, determines is achievable for such source through application of production processes or available methods, systems, and techniques. In no event shall application of NO_x control result in emissions of any pollutant which would exceed the emissions allowed by any applicable standard. If the Department determines that technological or economic limitations on the application of measurement methodology to a particular source would make the impositions of an emission standard infeasible, a design, equipment, work practice, operational standard, or combination thereof, may be prescribed instead to satisfy the requirement for the application of NO_x control. Such standard shall, to the degree possible, set forth the emissions reduction achievable by implementation of such design, equipment, work practice or operation, and shall provide for compliance by means which achieve equivalent results.

D. Combustion Control Device: Means, but is not limited to, any equipment that is used to destroy or remove air pollutant(s) prior to discharge to the atmosphere, excluding boilers, process heaters, dryers, furnaces, digesters, ovens, combustors, and similar combustion devices. Such equipment includes, but is not limited to, thermal oxidizers, catalytic oxidizers, and flares.

E. Constructed: Means the on-site fabrication, erection, or installation of the NO_x emitting source.

F. Equivalent Technology: Means any item that is identical or functionally equivalent to the existing component. This component may serve the same purpose or function as the replaced component, but may be different in some respects or improved in some ways.

G. Existing affected source: Means sources constructed on or before June 25, 2004 and that meet the applicability requirements of Section (1)(A)(2).

H. Fuel: Means the following fuels, any combination of the following fuels, or any combustible material the Department determines to be a fuel including, but not limited to:

(1) Virgin fuel, waste, waste fuel, and clean wood (biomass fuel) as defined in Regulation 61-62.1.

(2) Biodiesel: Means a mono-alkyl ester derived from vegetable oil and animal fat and conforming to ASTM D6751.

(3) Biofuel: Means any biomass-based solid fuel that is not a solid waste. This includes, but is not limited to, animal manure, including litter and other bedding materials; vegetative agricultural and silvicultural materials, such as logging residues (slash), nut and grain hulls and chaff (for example, almond, walnut, peanut, rice, and wheat), bagasse, orchard prunings, corn stalks, coffee bean hulls and grounds.

(4) Digester gas: Means any gaseous by-product of wastewater treatment typically formed through the anaerobic decomposition of organic waste materials and composed principally of methane and CO₂.

(5) Fossil Fuel: Means natural gas, petroleum, coal, and any form of solid, liquid, or gaseous fuel derived from such material for the purpose of creating useful heat. Petroleum for facilities constructed, reconstructed, or

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modified before May 4, 2011, means crude oil or a fuel derived from crude oil, including, but not limited to, distillate oil and residual oil. For units constructed, reconstructed, or modified after May 3, 2011, petroleum means crude oil or a fuel derived from crude oil, including, but not limited to, distillate oil, residual oil, and petroleum coke.

(6) Landfill Gas: Means a gaseous by-product of the land application of municipal refuse typically formed through the anaerobic decomposition of waste materials and composed principally of methane and CO₂.

I. New affected source: Means any affected source which has been constructed after June 25, 2004, or meets the applicability requirements of Section (I)(A)(3). A new affected source will not be considered an existing affected source at burner assembly replacement under Section (1)(A)(2).

J. Source: Means an individual NO_x emission unit.

Regulation 61-62.5, Standard No. 5.2, Section III shall be revised as follows:

SECTION III - STANDARD REQUIREMENTS FOR NEW AFFECTED SOURCES

A. Those affected sources as defined in Section I(A)(1) and (A)(3) above shall apply NO_x controls to achieve the limitations provided in Table 1 of this section. Unless otherwise noted, all emission limits for affected sources required to use Continuous Emissions Monitoring (CEMS) shall be based on thirty (30) day rolling averages.

B. An affected source may request an alternate control limitation by submitting a demonstration that the alternate limitation is a Case-by-Case NO_x Control as defined in Section II above.

C. The Department reserves the right to request that the owner or operator submit additional information for those affected sources that request alternate control limitation in accordance with Section III(B) above.

D. Affected sources required to install post combustion technology for the control of NO_x shall be required to use post combustion for the control of NO_x during the ozone season.

Table 1 - NO_x Control Standards

Source Type	Emission Limit
Propane and/or Natural Gas-Fired Boilers	
≥10 million British thermal units per hour (MMBtu/hr) and < 100 MMBtu/hr	Low-NO _x Burners or equivalent technology, shall achieve 0.036 pounds per million metric British thermal units (lb/MMBtu)
≥100 MMBtu/hr	Low-NO _x Burners + Flue Gas Recirculation or equivalent technology, shall achieve 0.036 lb/MMBtu
Distillate Oil-Fired Boilers	
≥10 MMBtu/hr and < 100 MMBtu/hr	Low-NO _x Burners or equivalent technology, shall achieve 0.15 lb/MMBtu
≥100 MMBtu/hr	Low-NO _x Burners + Flue Gas Recirculation or equivalent technology, shall achieve 0.14 lb/MMBtu
Residual Oil-Fired Boilers	
≥10 MMBtu/hr and < 100 MMBtu/hr	Low-NO _x Burners or equivalent technology, shall achieve 0.3 lb/MMBtu
≥100 MMBtu/hr	Low-NO _x Burners + Flue Gas Recirculation or equivalent technology, shall achieve 0.3 lb/MMBtu
Multiple Fuel Boilers	

Source Type	Emission Limit
<p>The emission limits for boilers burning multiple fuels are calculated in accordance with the formulas below. Additional fuels or combination of fuels not otherwise listed in this table shall be addressed on a case-by-case basis.</p>	
<p>≥10 MMBtu/hr and < 100 MMBtu/hr</p>	$E_n = [(0.036 \text{ lb/MMBtu } H_{ng}) + (0.15 \text{ lb/MMBtu } H_{do}) + (0.3 \text{ lb/MMBtu } H_{ro}) + (0.35 \text{ lb/MMBtu } H_c) + (0.2 \text{ lb/MMBtu } H_w)] / (H_{ng} + H_{do} + H_{ro} + H_c + H_w)$ <p>where:</p> <p>E_n is the nitrogen oxides emission limit (expressed as nitrogen dioxide (NO₂)), ng/J (lb/million Btu), H_{ng} is the heat input from combustion of natural gas, H_{do} is the heat input from combustion of distillate oil, H_{ro} is the heat input from combustion of residual oil, H_c is the heat input from combustion of coal, and H_w is the heat input from combustion of wood residue.</p>
<p>≥100 MMBtu/hr</p>	$E_n = [(0.036 \text{ lb/MMBtu } H_{ng}) + (0.14 \text{ lb/MMBtu } H_{do}) + (0.3 \text{ lb/MMBtu } H_{ro}) + (0.25 \text{ lb/MMBtu } H_c) + (0.2 \text{ lb/MMBtu } H_w)] / (H_{ng} + H_{do} + H_{ro} + H_c + H_w)$ <p>where:</p> <p>E_n is the nitrogen oxides emission limit (expressed as NO₂), ng/J (lb/million Btu), H_{ng} is the heat input from combustion of natural gas, H_{do} is the heat input from combustion of distillate oil, H_{ro} is the heat input from combustion of residual oil, H_c is the heat input from combustion of coal, and H_w is the heat input from combustion of wood residue.</p>
<p>Wood Residue Boilers</p>	
<p>All types</p>	<p>Combustion controls to minimize NO_x emissions or equivalent technology, shall achieve 0.20 lb/MMBtu</p>
<p>Coal-Fired Stoker Fed Boilers</p>	
<p>< 250 MMBtu/hr</p>	<p>Combustion controls to minimize NO_x emissions or equivalent technology, shall achieve 0.35 lb/MMBtu</p>
<p>≥ 250 MMBtu/hr</p>	<p>Combustion controls to minimize NO_x emissions or equivalent technology, shall achieve 0.25 lb/MMBtu</p>
<p>Pulverized Coal-Fired Boilers</p>	
<p>< 250 MMBtu/hr</p>	<p>Low-NO_x Burners + Combustion controls to minimize NO_x emissions or equivalent technology, shall achieve 0.35 lb/MMBtu</p>
<p>≥ 250 MMBtu/hr</p>	<p>Low-NO_x Burners + Combustion controls to minimize NO_x emissions + Selective Catalytic Reduction (SCR) or equivalent technology, shall achieve 0.14 lb/MMBtu</p>
<p>Municipal Refuse-Fired Boilers</p>	
<p>< 250 MMBtu/hr</p>	<p>Combustion modifications to minimize NO_x emissions + Flue Gas Recirculation or equivalent technology, shall achieve 195 ppmv at 12 percent CO₂ (0.35 lb/MMBtu)</p>
<p>≥ 250 MMBtu/hr</p>	<p>Staged Combustion and Automatic Combustion Air Control + SCR or equivalent technology, shall achieve 0.18 lb/MMBtu</p>
<p>Internal Combustion Engines</p>	

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Source Type	Emission Limit
Compression Ignition	<i>Timing Retard</i> ≤ 4 degrees + Turbocharger with Intercooler or equivalent technology, shall achieve 490 ppmv at 15 percent O ₂ (7.64 gram per bhp-hour (gm/bhp-hr))
Spark Ignition	Lean-Burn Technology or equivalent technology, shall achieve 1.0 gm/bhp-hr
Landfill or Digester Gas-Fired	Lean-Burn Technology or equivalent technology, shall achieve 1.25 gm/bhp-hr
Gas Turbines	
Simple Cycle – Natural Gas	
< 50 Megawatts	Combustion Modifications (for example, dry low-NO _x combustors) to minimize NO _x emissions or equivalent technology, shall achieve 25 ppmv at 15 percent O ₂ Dry Basis
≥ 50 Megawatts	Combustion Modifications (for example, dry low-NO _x combustors) to minimize NO _x emissions or equivalent technology, shall achieve 9.0 ppmv at 15 percent O ₂ Dry Basis
Combined Cycle – Natural Gas	
< 50 Megawatts	Dry Low-NO _x Combustors or equivalent technology, shall achieve 9.0 ppmv at 15 percent O ₂ Dry Basis
≥ 50 Megawatts	Dry Low-NO _x Combustors + SCR or equivalent technology, shall achieve 3.0 ppmv at 15 percent O ₂ Dry Basis
Simple Cycle – Distillate Oil Combustion	
< 50 Megawatts	Combustion Modifications and water injection to minimize NO _x emissions or equivalent technology, shall achieve 42 ppmv at 15 percent O ₂ Dry Basis
≥ 50 Megawatts	Combustion Modifications and water injection to minimize NO _x emissions or equivalent technology, shall achieve 42 ppmv at 15 percent O ₂ Dry Basis
Combined Cycle - Distillate Oil Combustion	
< 50 Megawatts	Dry Low-NO _x Combustors with water injection or equivalent technology, shall achieve 42 ppmv at 15 percent O ₂ Dry Basis
≥ 50 Megawatts	Dry Low-NO _x Combustors, water injection, and SCR or equivalent technology, shall achieve 10 ppmv at 15 percent O ₂ Dry Basis
Landfill Gas-Fired	Water or steam injection or low-NO _x turbine design or equivalent technology, shall achieve 25 ppmv at 15 percent O ₂ Dry Basis
Fluidized Bed Combustion (FBC) Boiler	
Bubbling Bed	Selective Non-catalytic Reduction (SNCR) shall achieve 0.15 lbs/MMBtu
Circulating Bed	SNCR shall achieve 0.07 lbs/MMBtu
Other	
Recovery Furnaces	Forth (4 th) level or air to recovery furnace/good combustion practices or equivalent technology, shall achieve 100 ppmv at 8 percent O ₂ Dry Basis
Cement Kilns	Low-NO _x burners or equivalent technology, shall achieve 30 percent reduction from uncontrolled levels.
Lime Kilns	Combustion controls or equivalent technology, shall achieve 175 ppmv at 10 percent O ₂ Dry Basis.

Source Type	Emission Limit
Fuel Combustion Sources burning any non-specified fuel not listed in Table above. (Examples include but are not limited to process heaters not meeting the definition of "boiler" in Regulation 61-62.1 Section I, dryers, furnaces, ovens, duct burners, incinerators, and smelters)	Low-NO _x burners or equivalent technology, shall achieve 30 percent reduction from uncontrolled levels.

Regulation 61-62.5, Standard No. 5.2, Section IV shall be stricken and revised as follows:

SECTION IV – MONITORING, RECORD KEEPING, AND REPORTING REQUIREMENTS FOR NEW AFFECTED SOURCES

A. Boilers

With the exception of fuel certification and tune-up requirements, compliance with required NO_x monitoring in 40 CFR 60 shall constitute compliance with the monitoring requirements in this section.

Affected sources that are not subject to 40 CFR 60 shall comply with the applicable requirements in this section.

(1) CEMS

(a) Except as allowed by the Department, the owner or operator of a boiler rated two hundred (200) MMBtu/hr or greater permitted for solid fuel, shall install, calibrate, maintain, and operate CEMS for measuring NO_x, and Oxygen (O₂) or Carbon Dioxide (CO₂) emissions discharged to the atmosphere, and shall record the output of the system.

(b) The CEMS required under this section shall be operated and data recorded during all periods of operation of the affected source except for CEMS breakdowns and repairs. Data is to be recorded during calibration checks and zero and span adjustments.

(c) The CEMS required under this section shall be installed, calibrated, maintained, and operated in accordance with approved methods in Regulation 61-62.60 or 61-62.72, or as approved by the Department.

(d) Excess Emissions

(i) Excess emissions and monitoring systems performance reports shall be submitted semiannually. All reports shall be postmarked by the thirtieth (30th) day following the end of each six (6) month period. Written reports of excess emissions shall include the following information:

(A) The magnitude of excess emissions, any conversion factor(s) used, the date and time of commencement and completion of each time period of excess emissions, and the process operating time during the reporting period.

(B) Specific identification of each period of excess emissions that occurs during startups, shutdowns, and malfunctions of the affected source. The nature and cause of any malfunction (if known), the corrective action taken, or preventative measures adopted.

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(C) The date and time identifying each period during which the continuous monitoring system was inoperative except for zero and span checks and the nature of the system repairs or adjustments.

(D) When no excess emissions have occurred or the continuous monitoring system(s) have not been inoperative, repaired, or adjusted, such information shall be stated in the reports.

(2) Periodic Monitoring and/or Source Test

(a) Unless required to operate a CEMS, testing requirements apply to boilers rated thirty (30) MMBtu/hr or greater permitted for solid fuels and boilers rated greater than one hundred (100) MMBtu/hr permitted for any other fuels.

(b) Except as allowed by the Department, an initial source test for NO_x emissions shall be conducted within one hundred and eighty (180) days after startup.

(c) Periodic source tests for NO_x shall be conducted every twenty-four (24) months, or as determined by the Department on a case by case basis in the permit condition for the affected source. Source tests will be used to show compliance with the NO_x standard.

(d) The Department reserves the right to require periodic source testing for any affected sources. All source testing shall be conducted in accordance with Regulation 61-62.1, Section IV.

(3) Fuel Certification

The owner or operator shall record monthly records of the amounts and types of each fuel combusted and maintain these records on site.

(4) Tune-ups

If the owner or operator of a boiler is required to comply with federal tune-up requirements in 40 CFR 63, then the federal requirements shall meet the compliance requirements of this paragraph.

(a) The owners or operator shall perform tune-ups every twenty-four (24) months in accordance with manufacturer's specifications or with good engineering practices.

(b) All tune-up records are required to be maintained on site and available for inspection by the Department for a period of five (5) years from the date generated.

(c) The owner or operator shall develop and retain a tune-up plan on file.

(5) Other Requirements

The owner or operator shall maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected source; any malfunction of the air pollution control equipment; and any periods during which a continuous monitoring system or monitoring device is inoperative.

B. Internal Combustion Engines

With the exception of fuel certification and tune-up requirements, compliance with required NO_x monitoring in 40 CFR 60 shall constitute compliance with the monitoring requirements in this section.

Affected sources that are not subject to 40 CFR 60 shall comply with all applicable requirements in this section.

The owner or operator of an affected source shall comply with either (B)(1) or (B)(2) below.

(1) Manufacturer's Certification

(a) Operate and maintain the stationary internal combustion engine and control device according to the manufacturer's emission-related written instructions;

(b) Change only those emission-related settings that are permitted by the manufacturer.

(2) Periodic Monitoring and/or Source Test

(a) Except as allowed by the Department, an initial source test for NO_x shall be conducted within one hundred eighty (180) days after startup.

(b) Periodic source tests for NO_x shall be conducted every twenty-four (24) months, or as determined by the Department on a case by case basis in the permit condition for the affected source. Source tests will be used to show compliance with the NO_x standard.

(c) The owner or operator shall operate the affected source(s) within the parameter(s) established during the most recent compliant source tests. A copy of the most recent Department issued source test summary letter(s) that established the parameter(s) shall be maintained with the required permit.

(d) The Department reserves the right to require periodic source testing for any affected sources. All source testing shall be conducted in accordance with Regulation 61-62.1, Section IV.

(3) Tune-Ups

If the owner or operator of an internal combustion engine is required to comply with federal requirements in 40 CFR 63 for the internal combustion engine, then the federal requirements shall meet the tune-up requirements of this section.

(a) The owner or operator shall perform tune-ups every twenty-four (24) months in accordance with manufacturer's specifications or with good engineering practices.

(b) All tune-up records are required to be maintained on site and available for inspection by the Department for a period of five (5) years from the date generated.

(c) The owner or operator shall develop and retain a tune-up plan on file.

(4) Fuel Certification

The owner or operator shall record monthly the amounts and types of each fuel combusted by the affected sources and maintain these records on site.

(5) Other Requirements

The owner of operator shall maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected source; any malfunction of the air pollution control equipment; and any periods during which a continuous monitoring system or monitoring device is inoperative.

C. Turbines

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With the exception of fuel certification and tune-up requirements, compliance with required NO_x monitoring in 40 CFR 60 shall constitute compliance with the monitoring requirements in this section.

Affected sources that are not subject to 40 CFR 60 shall comply with all applicable requirements in this section.

The owner or operator of an affected source shall comply with either (C)(1) or (C)(2) below.

(1) CEMS

(a) Except as allowed by the Department, the owner or operator shall install, calibrate, maintain, and operate CEMS on the turbine for measuring NO_x, and Oxygen (O₂) or Carbon Dioxide (CO₂) emissions discharged to the atmosphere, and shall record the output of the system.

(b) The CEMS required under this section shall be operated and data recorded during all periods of operation of the affected source except for CEMS breakdowns and repairs. Data is to be recorded during calibration checks and zero and span adjustments.

(c) The CEMS required under this section shall be installed, calibrated, maintained, and operated in accordance with approved methods in Regulation 61-62.60 or 61-62.72, or as approved by the Department.

(d) Excess Emissions

(i) Excess emissions and monitoring systems performance reports shall be submitted semiannually. All reports shall be postmarked by the thirtieth (30th) day following the end of each six (6) month period. Written reports of excess emissions shall include the following information:

(A) The magnitude of excess emissions, any conversion factor(s) used, the date and time of commencement and completion of each time period of excess emissions, and the process operating time during the reporting period.

(B) Specific identification of each period of excess emissions that occurs during startups, shutdowns, and malfunctions of the affected source. The nature and cause of any malfunction (if known), the corrective action taken, or preventative measures adopted.

(C) The date and time identifying each period during which the continuous monitoring system was inoperative except for zero and span checks and the nature of the system repairs or adjustments.

(D) When no excess emissions have occurred or the continuous monitoring system(s) have not been inoperative, repaired, or adjusted, such information shall be stated in the reports.

(2) Parametric Monitoring

(a) Unless required to operate a CEMS, the owner or operator using water or steam injection to control NO_x shall install, calibrate, maintain, and operate a continuous monitoring system to monitor and record the fuel consumption and the ratio of water or steam to fuel being fired in the turbine.

(b) Unless required to operate a CEMS, the owner or operator using a diffusion flame turbine without add-on selective catalytic reduction controls (SCR) to control NO_x, shall define at least four parameters indicative of the unit's NO_x formation characteristics and shall monitor these parameters continuously.

(c) Unless required to operate a CEMS, for any lean premix stationary combustion turbine, the owner or operator shall continuously monitor the appropriate parameters to determine whether the unit is operating in low-NO_x mode.

(d) Unless required to operate a CEMS, for any turbine that uses SCR to reduce NO_x, the owner or operator shall continuously monitor appropriate parameters to verify the proper operation of the emission controls.

(3) Periodic Monitoring and/or Source Test

(a) This requirement only applies to turbines not required to operate a CEMS.

(b) The steam or water to fuel ratio or other parameters that are continuously monitored as described in this section shall be monitored during the performance test required under this section to establish acceptable values and ranges. The owner or operator may supplement the performance test data with engineering analyses, design specifications, manufacturer's recommendations, and other relevant information to define the acceptable parametric ranges more precisely. The owner or operator shall develop and keep on-site a parameter monitoring plan which explains the procedures used to document proper operation of the NO_x emission controls. The plan shall include the parameter(s) monitored and the acceptable range(s) of the parameter(s) as well as the basis for designating the parameter(s) and acceptable range(s). Any supplemental data such as engineering analyses, design specifications, manufacturer's recommendations, and other relevant information shall be included in the monitoring plan.

(c) Except as allowed by the Department, an initial source test for NO_x emissions shall be conducted within one hundred eighty (180) days after startup.

(d) Periodic source tests for NO_x shall be conducted every twenty-four (24) months or as determined by the Department on a case by case basis in the permit condition for the affected source. Source tests will be used to show compliance with the NO_x standard.

(e) The Department reserves the right to require periodic source testing for any affected sources. All source testing shall be conducted in accordance with Regulation 61-62.1, Section IV.

(4) Tune-Ups

(a) The owner or operator shall perform tune-ups every twenty-four (24) months in accordance with manufacturer's specifications or with good engineering practices.

(b) All tune-up records are required to be maintained on site and available for inspection by the Department for a period of five (5) years from the date generated.

(c) The owner or operator shall develop and retain a tune-up plan on file.

(5) Fuel Certification

The owner or operator shall record monthly the amounts and types of each fuel combusted by the affected sources and maintain these records on site.

(6) Other Requirements

The owner or operator shall maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected source; any malfunction of the air pollution control equipment; or any periods during which a continuous monitoring system or monitoring device is inoperative.

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D. All Other Affected Source Types

With the exception of fuel certification and tune-up requirements, compliance with required NO_x monitoring in 40 CFR 60 shall constitute compliance with the monitoring requirements in this section.

If the owner or operator is not required to comply with federal requirements in 40 CFR 60 for monitoring NO_x, then the monitoring requirements for the affected source shall be established on a case by case basis.

(1) Tune-Ups

(a) The owner or operator of a combustion source shall perform tune-ups every twenty-four (24) months in accordance with manufacturer's specifications or with good engineering practices.

(b) All tune-up records are required to be maintained on site and available for inspection by the Department for a period of five (5) years from the date generated.

(c) The owner or operator shall develop and retain a tune-up plan on file.

(2) Periodic Monitoring and/or Source Test

(a) Except as allowed by the Department, an initial source test for NO_x shall be conducted within one hundred eighty (180) days after startup.

(b) Periodic source tests for NO_x shall be conducted every twenty-four (24) months, or as determined by the Department on a case by case basis in the permit condition for the affected source. Source tests will be used to show compliance with the NO_x standard.

(c) The Department reserves the right to require periodic source tests for any affected sources. All source testing shall be conducted in accordance with Regulation 61-62.1, Section IV.

(3) Fuel Certification

The owner or operator shall record and maintain monthly records of the amounts and types of each fuel combusted by the affected sources and maintain these records on site.

Regulation 61-62.5, Standard No. 5.2, Section V shall be revised as follows:

SECTION V - STANDARD REQUIREMENTS FOR EXISTING AFFECTED SOURCES

A. For those affected sources subject to the requirements of this regulation as defined in Section I(A)(2) above where an existing burner assembly is replaced after the effective date of this regulation, the burner assembly shall be replaced with a low-NO_x burner assembly or equivalent technology, and shall achieve a thirty (30) percent reduction from uncontrolled NO_x emission levels based upon manufacturer's specifications. An exemption from this requirement shall be granted when a single burner assembly is being replaced in an affected source with multiple burners due to non-routine maintenance.

B. For those sources defined in Section I(A)(2) above where an existing burner assembly is replaced after the effective date of this regulation, the owner or operator shall notify and register the replacement with the Department in accordance with Section VI below.

C. An affected source may request an alternative control methodology to the one specified in paragraph (A) above of this section provided that they can demonstrate to the Department why the NO_x control limits specified are not economically or technically feasible for this specific circumstance. The Department reserves the right to

request that the owner or operator submit additional information as necessary for the alternative control methodology determination. Alternative control methodologies granted under this part are not effective until notification is submitted to and approved by the Department.

Regulation 61-62.5, Standard No. 5.2, Section VI shall be revised as follows:

SECTION VI - NOTIFICATION REQUIREMENTS FOR EXISTING AFFECTED SOURCES

A. Burner Assembly Replacement Notifications for Existing Affected Sources

(1) Except for those affected sources that wish to request an alternative control methodology as specified in Section V(C) above, the notification requirements specified in this section shall apply only to existing affected sources as defined in Section I(A)(2) above where an existing burner assembly is replaced after the effective date of this regulation.

(2) Within seven (7) days of replacing an existing burner assembly, the owner or operator shall submit written notification to register the replacement unit with the Department.

(3) Notification shall satisfy the permitting requirements consistent with Regulation 61-62.1, Section II(a).

(4) Notification shall contain replacement unit information as requested in the format provided by the Department. Replacement unit information shall include, at a minimum, all affected units at the source and the date the replacement unit(s) commenced operation.

(5) Those affected sources that wish to receive an emission reduction credit for the control device will be required to submit a permit application prior to replacement of the burner assembly(s).

Regulation 61-62.5, Standard No. 5.2, Section VII shall be added as follows:

SECTION VII – TUNE-UP REQUIREMENTS FOR EXISTING SOURCES

A. The owner or operator shall perform tune-ups every twenty-four (24) months in accordance with manufacturer's specifications or with good engineering practices. The first tune-up shall be conducted no more than twenty-four (24) months from start-up of operation for affected new sources and no more than twenty-four (24) months from replacement of a burner assembly for affected existing sources. Each subsequent tune-up shall be conducted no more than twenty-four (24) months after the previous tune-up.

B. All tune-up records are required to be maintained on site and available for inspection by the Department for a period of five (5) years from the date generated.

C. The owner or operator shall develop and retain a tune-up plan on file.

Regulation 61-62.70, Title V Operating Permit Program

Regulation 61-62.70, Section 70.1, h, shall be stricken as follows:

Fiscal Impact Statement:

The Department estimates that there will be no increased costs to the State or its political subdivisions as a result of the amendments to Regulation 61-62, Air Pollution Control Regulations and Standards, which are being made to streamline State requirements and therefore reduce economic burden.

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Statement of Need and Reasonableness:

This Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION:

Purpose: The amendments to Regulation 61-62, Air Pollution Control Regulations and Standards, will support the Department's goal of promoting and protecting the health of the public and the environment in a more efficient and effective manner. These amendments will expand and clarify definitions applicable to air pollution control regulations and standards; streamline permitting options; clarify reporting requirements; and provide corrections for consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62.

Legal Authority: The legal authority for Regulation 61-62, Air Pollution Control Regulations and Standards is S.C. Code Section 48-1-10 et seq.

Plan for Implementation: The amendments will take effect upon approval of the South Carolina General Assembly and publication as final regulations in the State Register. A copy of Regulation 61-62, Air Pollution Control Regulations and Standards that incorporates these amendments, will be made available electronically on the Department's website at <http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/Air/>. The Department will also send an email to stakeholders and will communicate with affected facilities during the permitting process.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department amended Regulation 61-62.1, Definitions and General Requirements, Section I, *Definitions*, to add clarity to definitions by specifying that a release or discharge into the atmosphere includes fugitive emissions.

The Department amended Regulation 61-62.1, Definitions and General Requirements, Section II, Permit Requirements, to remove the requirement of a revised air dispersion modeling analysis for permit renewals. Amendments included clarification and/or corrections for internal consistency to improve the overall text of Regulation 61-62.1 as necessary.

The Department amended Regulation 61-62.5, Standard No. 4, Emissions from Process Industries, to clarify this regulation is not triggered for sources that the Department has removed particulate matter (PM) limits (from other sections of this regulation).

The Department amended Regulation 61-62.5, Standard No. 5.2, Control of Oxides of Nitrogen (NO_x), to clarify applicability and exemptions, as well as to make corrections for internal consistency, punctuation, codification, and spelling.

The Department amended Regulation 61-62.70, Title V Operating Permit Program, to remove appeals language as this is generally defined by statutory law (Code Ann. Section 44-1-60 (Supp. 2012) and is redundant, and to clarify qualification language for administrative amendments.

The Department amended Regulation 61-62 to include corrections for consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

The intent of these amendments is to simplify and correct certain issues in our regulatory guidelines to support the Department's goal of promoting and protecting the health of the public and the environment in a more

efficient and effective manner. There would be no detrimental effect on the environment and public health if these amendments to Regulation 61-62, Air Pollution Control Regulations and Standards, and SIP are adopted.

DETERMINATION OF COSTS AND BENEFITS:

There is no anticipated increased cost to the State or its political subdivisions resulting from this revision. Amendments to Regulation 62-61, Air Pollution Control Regulations and Standards, and the SIP will help streamline state requirements to conform to current Prevention of Significant Deterioration, New Source Review, and Title V Permit Program standards. These revisions may potentially save money for the regulated community by providing clarification on exemptions and permitting requirements, as well as eliminating potentially redundant record keeping and reporting requirements, source tests, and modeling demonstrations while continuing to ensure environmental protection.

The amendments will benefit the regulated community by clarifying the regulations and increasing their ease of use which will reduce economic burden.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the State or its political subdivisions. Rather these revisions seek to provide clarity to the regulated community and reduce redundancy between state and federal requirements.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The amendments to Regulation 61-62, Air Pollution Control Regulations and Standards, seek to provide continued protection of the environment and public health.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment and/or public health associated with these revisions. To the contrary, the State's delegated authority to implement programs beneficial to public health and the environment may be compromised if these amendments were not adopted. Permit streamlining and regulatory text clarification seek to have a positive effect on both the environment and public health.

Statement of Rationale:

The Department began the process to amend South Carolina Regulation 61-62, Air Pollution Control Regulations and Standards, by developing an internal workgroup to evaluate the existing air quality regulations to provide clarification, delete or update obsolete requirements, and correct typographical errors as necessary; in response to comments received.

The Department also held external stakeholder meetings to take recommendations and comments on those regulatory amendments identified by the workgroup. Several comments were received during the external stakeholder process and they were taken into consideration in developing the amendments to Regulation 61-62 and the SIP. These regulatory amendments will provide clarity and specificity to the existing regulations, omit obsolete requirements, and provide additional permitting options to the regulated community.

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Document No. 4607

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 61

Statutory Authority: 1976 Code Section 44-1-180

61-89. Charges for Family Planning Services

Synopsis:

The Department has conducted a review of its family planning regulations and, in the interest of good government and efficiency, repeals R.61-89 because it is no longer needed. See detailed information in the Statement of Need and Reasonableness and Statement of Rationale herein.

A Notice of Drafting for this repeal was published in the *State Register* on April 24, 2015.

Instructions: Repeal R.61-89, Charges for Family Planning Services, in its entirety.

Text:

61-89. [Repealed]

Fiscal Impact Statement:

This repeal of R.61-89 will have no substantial fiscal or economic impact on the State and its political subdivisions.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: Purpose: Repeal of R.61-89, Charges for Family Planning Services.

Legal Authority: Section 44-1-180, S.C. Code of Laws, 1976, as amended.

Plan for Implementation: Upon final approval of the S.C. General Assembly and publication in the State Register as a final regulation repeal, this regulation will be repealed. It will be shown as repealed in Chapter 61 of the S.C. Code of Regulations and in the Department's Regulation Development Update..

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION REPEAL BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Regulation 61-89 was promulgated pursuant to Title 44, Chapter 1, "Department may establish charges for health care." Regulation 61-89 is not necessary because the items it regulates are currently addressed in federal law. The Department, as a condition of receiving funds under Title X of the Public Service Act, must follow federal regulations with respect to the subject matter covered by R.61-89. Therefore, in the interest of good government and efficiency, the Department has repealed this regulation because it is no longer needed.

DETERMINATION OF COSTS AND BENEFITS:

This repeal of Regulation 61-89 will have no substantial fiscal or economic impact on the State and its political subdivisions or the regulated community.

UNCERTAINTIES OF ESTIMATES:

No known uncertainties.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

There will be no environmental or public health effect.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There will not be a detrimental effect on the environment or public health. However, repeal of this regulation is necessary to clarify it is no longer valid.

Statement of Rationale:

Upon review of Department regulations and the status of Regulation 61-89 pursuant to Sections 44-1-180, S.C. Code of Laws, 1976, it was determined that this regulation should be repealed because it is no longer necessary.

Document No. 4608

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**CHAPTER 61**

Statutory Authority: 1976 Code Section 44-1-180

61-88. Charges for Maternal and Child Health Services

Synopsis:

The Department has conducted a review of its maternal and child health regulations and, in the interest of good government and efficiency, repeals Regulation 61-88 because it is no longer needed. See detailed information in the Statement of Need and Reasonableness and Statement of Rationale herein.

A Notice of Drafting for the proposed repeal was published in the *State Register* on April 24, 2015.

Instructions: Repeal Regulation 61-88, Charges for Maternal and Child Health Services, in its entirety.

Text:

61-88. [Repealed]

Fiscal Impact Statement:

The Department does not anticipate substantial fiscal or economic impact on the state and its political subdivisions resulting from repeal of Regulation 61-88.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness was determined by staff analysis pursuant to 1976 Code Section 1-23-115(C)(1)-(3) and (9)-(11).

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DESCRIPTION OF REGULATION:

Repeal of Regulation 61-88, Charges for Maternal and Child Health Services.

Purpose: In the interest of good government and efficiency, the Department repeals Regulation 61-88 which describes charges for maternal and child health services. Regulation 61-88 is no longer necessary because the items regulated therein are currently addressed in state statute and federal regulation and the Department no longer provides maternity services.

Legal Authority: 1976 Code Section 44-1-180 and Sections 502(2)(D) and 501(b)(2) of the Social Security Act, as amended, effective October 1, 1981.

Plan for Implementation: None. Upon approval of the South Carolina General Assembly and publication as a final regulation repeal in the State Register, this regulation will be repealed. Regulation 61-88 will be shown as repealed in Chapter 61 of the S.C. Code of Regulations.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION REPEAL BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Regulation 61-88 was promulgated pursuant to S.C. Code Section 44-1-180. Regulation 61-88 is not necessary because the regulated items therein are currently governed by state statute and federal regulations. Moreover, the Department no longer provides maternity services. As such, in the interest of effective and efficient government administration, the Department has repealed this regulation because it is no longer needed.

DETERMINATION OF COSTS AND BENEFITS;

The Department does not anticipate substantial fiscal or economic impact on the state or its political subdivisions from the repeal of Regulation 61-88. The Department also does not anticipate cost to the regulated community. The repeal benefits the regulated community by adding clarity to which laws are applicable and have legal effect.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The Department anticipates no environmental or public health effect.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION REPEAL IS NOT IMPLEMENTED:

The Department anticipates no detrimental effect on the environment or public health. Repeal of this regulation is necessary to indicate it is no longer valid.

Statement of Rationale:

Upon review of regulations and the status of Regulation 61-88 pursuant to S.C. Code Section 44-1-180 and Sections 505(2)(D) and 501(b)(2) of the Social Security Act, as amended, effective October 1, 1981, the Department determined R.61-88 should be repealed as it is no longer necessary.

Document No. 4615

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**CHAPTER 30**

Statutory Authority: 1976 Code Sections 48-39-10 et seq.

- 30-1. Statement of Policy
- 30-5. Exceptions
- 30-9. Other Provisions
- 30-13. Specific Project Standards for Beaches and the Beach/Dune System
- 30-15. Activities Allowed Seaward of Baseline

Synopsis:

These regulatory changes will amend certain Coastal Division regulations related to permitting in the beaches and beach/dune critical areas of the coastal zone. In 2010, the Board of Health and Environmental Control appointed a Blue Ribbon Committee on Shoreline Management and charged the Committee with developing specific recommendations to guide the stewardship of South Carolina's beachfront shorelines. Comprised of representative stakeholders, elected officials, and leading legal and academic experts, the Committee worked over two years to evaluate the previous two decades of experiences under the South Carolina Beachfront Management Act (1976 Code Section 48-39-250 et seq.). The Committee examined current conditions, considered outcomes of an ad hoc technical committee on shoreline change, and recommended improvements in the management of the State's beachfront jurisdictional area. These amendments are based on the Blue Ribbon Committee's final recommendations.

These regulatory changes will amend definitions, provide clarity and specific standards to be utilized in the evaluation of beachfront permit applications and notifications, and provide specific standards, conditions and administrative procedures for issuance of emergency orders within the State's beachfront jurisdiction. The amendments will provide more clarification to the regulations, enabling Department staff to administer more effectively the regulatory program of the Coastal Division.

Amendments will also modify specific procedures under R.30-13 and R.30-15 for issuance of emergency orders for golf courses to comply with Act No. 147 that took effect April 7, 2014 and was codified as 1976 Code Section 48-39-135.

A Notice of Drafting for these amendments was published in the *State Register* on February 27, 2015.

**Discussion of Changes requested by the Senate Agriculture and Natural Resources Committee
requested by letter dated February 25, 2016**

R.30-1.D(20)

Modify the definition of "emergency order" to retain language specifying state authorities responsible for the issuance of emergency orders.

R.30-5.A(1)

Modify to retain language specifying state authorities responsible for the issuance of emergency orders.

R.30-5.B(1)

Add language to specify state authorities allowed to issue emergency orders.

R.30-5.B(1)(b)

Add language to clarify the conditions that must apply for authorities allowed to issue emergency orders.

R.30-5.B(2)

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Add language to specify state authorities allowed to issue emergency orders.

R.30-9.B

Delete amendments to the section regarding bonding requirements for emergency orders.

R.30-15.H

Modify language specifying authorities responsible for the issuance of emergency orders. Add language to clarify the requirements to notify the U.S. Army Corps of Engineers of the issuance of emergency orders. Add language to clarify that the recipient of an emergency orders may be required to obtain additional permits and agency reviews from other local, state or federal agencies.

R.30-15.H(1)

Add language to specify state authorities allowed to issue emergency orders.

R.30-15.H(2)(a)

Add language to specify state authorities allowed to issue emergency orders.

R.30-15.H(2)(b)

Delete item regarding bonding requirements for emergency orders.

R.30-15.H(2)(c)

Delete subitem (i) referring to a plan for relocation or removal of a structure. Renumber to (b) for proper codification and modify language regarding options to provide a plan for renourishment as a mean to extend the time allowed to use sandbags for temporary protection.

R.30-15.H(2)(d)

Renumber item to (c) for proper codification. Delete language referring to a plan for removal or relocation of a structure.

R.30-15.H(2)(e)

Renumber item to (d) for proper codification.

R.30-15.H(2)(f)

Delete item referring to the relocation or removal of a structure as a mean to extend the time allowed to use sandbags for temporary protection.

R.30-15.H(3)(c)

Modify language to clarify when sandbags may be used to retard normal shoreline movement.

R.30-15.H(3)(f)

Add new item (f) to specify an additional consideration when evaluating the effectiveness of sandbag placement.

R.30-15.H(3)(f)

Renumber item to (g) for proper codification.

R.30-15.H(3)(g)

Renumber item to (h) for proper codification.

R.30-15.H(3)(h)

Renumber item to (i) for proper codification.

R.30-15.H(4)

Add language to specify state authorities allowed to issue emergency orders.

R.30-15.H(5)

Add language to specify state authorities allowed to issue emergency orders.

**Section-by-Section Discussion of Revisions of Coastal Division Regulations
submitted originally to the General Assembly for review by the
Department of Health and Environmental Control on January 21, 2016:**

R.30-1.D(20)

The definition of “emergency order” is revised to clarify that emergency orders are issued in response to an emergency, and add reference to the section regarding notification requirements of emergency orders.

R.30-5.A(1)

Language is added to clarify the authorities responsible for the issuance of emergency orders.

R.30-5.B

The title of this section is revised to provide clarity and new subsection B(1) is added to specify the authorities allowed to issue emergency orders and the conditions that must apply. Existing B(1) is renumbered to B(2) and language is modified to specify which emergency order activities require notification to the Department. Existing B(2) is renumbered to B(3) and language is added to clarify the timeframe for notifying the Department of issued emergency orders, and add reference to the items required within the notification. Existing B(3) is renumbered to B(4).

R.30-9.B

The title of this section is revised to provide clarity. Language is added to include emergency orders as activities for which the Department may require a bond or proof of financial responsibility.

R.30-13.Q(1)

Language is added to provide additional emergency options as temporary protection for golf courses to comply with Act No. 147 of 2014, and add reference to the subsections regarding emergency order provisions.

R.30-15.F(4)

Language is added to specify an additional condition to consider when evaluating a request for a special permit. Stylistic changes are made to the serial order of conditions to correspond with other sections of the regulation.

R.30-15.H

This section is revised to amend the definition of imminent danger, clarify the authorities allowed to issue emergency orders, and clarify that all activities authorized under emergency orders need review prior to performance during turtle nesting season. Language is added to specify that requirements of the section can be applied to new technologies.

R.30-15.H(1)

This subsection is revised to clarify the authorities allowed to issue emergency orders and the conditions that must apply, define ‘critical infrastructure’, and delete items (a) through (g).

R.30-15.H(2)

New subsection is added to specify the process for issuing emergency orders for sandbags and the requirements of the property owner for securing an emergency order.

R.30-15.H(3)

New subsection is added to specify criteria to be used when issuing emergency orders for sandbags.

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R.30-15.H(4)

Existing H(2) is renumbered to H(4) and language is added to specify the authorities allowed to issue emergency orders for sand scraping and the conditions that must apply. New item (b) is added to allow sand scraping as an emergency option for temporary protection of golf courses to comply with Act No. 147 of 2014, and remaining items are renumbered. New item (h) is added to specify what funding is available for sand scraping.

R.30-15.H(5)

Existing subsection H(3) is renumbered to H(5) and language is added to specify the authorities allowed to issue emergency orders for renourishment and the conditions that must apply. Language is added to item (a) to specify standards for compatible sand. Correction is made in item (c) to the section referenced for permit requirements for sand fencing and beach vegetation. Language is added to (d) to provide clarity. New item (e) is added to clarify that renourishment may be used as temporary protection for golf courses to comply with Act No. 147 of 2014. New item (f) is added to specify what funding is available for emergency renourishment.

Instructions: Amend Coastal Regulations 30-1, Statement of Policy; 30-5, Exceptions; 30-9, Other Provisions; 30-13, Specific Project Standards for Beaches and the Beach/Dune System; and 30-15, Activities Allowed Seaward of Baseline pursuant to each individual instruction provided with the text below.

Text:

Revise R.30-1.D(20) definition of ‘Emergency Orders’:

(20) Emergency Orders - orders issued in response to an emergency as defined in Section 48-39-10(U), by the Department or upon written notification to the Department by an appointed official of a county or municipality or of the state acting to protect the public health and safety. With regard to the beach/dune critical area, only the use of sandbags, sand scraping, renourishment, or a combination of them, in accordance with R.30-5 and R.30-15.H, is allowed pursuant to emergency orders.

Revise R.30-5.A(1):

(1) The accomplishment of emergency orders issued by the Department or by an appointed official of a county or municipality or of the state acting to protect the public health and safety. With regard to the beach/dune critical area, only the use of sandbags, sand scraping, renourishment, or a combination of them is allowed, in accordance with R.30-5.B and R.30-15.H.

Replace R.30-5.B to read:

B. Notification of Emergency Orders to the Department:

(1) As required in R.30-5.A(1) and R.30-15.H, emergency orders for sandbags, sand scraping or renourishment may be issued by an appointed official of a county or municipality or of the state provided:

(a) the emergency conditions conform with the definition of emergency in Section 48-39-10(U);

(b) the order is issued to protect health, safety or resources of the residents of the State as provided in Section 48-39-10(U); and

(c) the order is issued in accordance with R.30-15.H.

(2) The Department must be notified of the issuance of an emergency order by an appointed official of a county or municipality or of the state. Notification to the Department must be made in writing prior to commencement of the activity, if possible, and must state the following:

- (a) the nature of the emergency;
- (b) the substance of the emergency order;
- (c) the time the order will be issued, or if circumstances preclude prior notice, when the order was issued;
- (d) the name of the local official executing the order and the authority under which that person is acting;
- (e) the location of the activity ordered;
- (f) the estimate of when such order shall be withdrawn.

(3) The Department shall be notified within seventy-two hours of the issuance of the emergency order. If the Department is not notified the official issuing such order or ordering such emergency action shall be in violation of the Act and these rules and regulations. Within seventy-two hours after the issuance of the emergency order, the official ordering the emergency action shall put the elements under R.30-5.B(2)(a)-(f) in writing and file them with the Department.

(4) The official issuing the emergency order shall be deemed in violation of the Act if the emergency conditions do not conform with the definition of emergency in Section 48-39-10(U).

Replace R.30-13.Q(1) to read:

(1) Golf Courses are allowed seaward of the baseline because they can adjust to a changing shoreline more readily than other types of land uses. The use of sandbags is allowed as temporary protection for golf courses located seaward of the baseline if the golf course existed prior to May 24, 1991 and if the emergency condition conforms with the definition of emergency in Section 48-39-10(U), in accordance with R.30-15.H(1). Sand scraping or renourishment may be used as temporary protection for golf courses in accordance with R.30-15.H(4) and (5).

Replace R.30-15.F(4) to read:

(4) In determining whether or not a permit is contrary to the public health, safety or welfare, the Department shall consider:

- (a) whether or not the proposed structure would be constructed on renourished beach;
- (b) the erosion rate at the site;
- (c) how soon the structure will be located on the active beach;
- (d) whether or not the proposed structure meets American National Standards Institute building standards; and/or
- (e) the potential cumulative effect that similar structures will have upon the beach/dune system.

Replace R.30-15.H to read:

H. Emergency Orders: Emergency situations before or after a storm event may prompt the Department, or an appointed official of a county or municipality or of the state to issue emergency orders under R.30-5, allowing property owners to construct temporary barriers against wave uprush. A structure is determined to be in imminent danger when the erosion comes within twenty feet of that structure. In an effort to protect Loggerhead turtle nesting sites, emergency orders issued between April 15th and November 1st must be reviewed by the

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Department prior to actual performance of the activity authorized by the emergency order. The U.S. Army Corps of Engineers must be notified within seventy-two hours of the issuance of an emergency order by the Department if the Department issued the emergency order. If the emergency order is issued by an appointed official such notification must be accomplished by the issuing official. The property owner or other recipient of the emergency order must obtain any additional permit(s) and agency review(s) that may be required by other local, state or federal agencies. All required permits and reviews must be obtained prior to the commencement of work pursuant to the issued emergency order. Unless otherwise approved by the Department, emergency sandbagging, sand scraping and renourishment shall be performed using the criteria established in this section. The Department may apply any requirements under this section to any Department-approved technology that is authorized under an emergency order.

(1) Emergency orders for sandbags may be issued by the Department, or upon written notification to the Department by an appointed official of a county or municipality or of the state acting to protect public health and safety. Sandbags shall only be used to construct temporary protection for existing habitable structures and critical infrastructure if the Department or appointed official determines a structure to be in imminent danger and emergency conditions conform with the definition of emergency in Section 48-39-10(U), or as allowed in R.30-13.Q(1). In this section, "critical infrastructure" shall mean utilities, roadways and associated infrastructure necessary to provide for public health and safety, communication, and transportation.

(2) Emergency orders for sandbags shall be subject to the following process:

(a) The Department or an appointed official of a county or municipality or of the state may issue emergency orders for areas specifically included under a state emergency declaration or at the request of a local government or property owner.

(b) Within one hundred twenty days of the issuance of an emergency order for sandbags, the property owner may provide the Department with evidence that their community has a feasible and financially viable renourishment plan for the affected area that is consistent with their approved Local Comprehensive Beachfront Management Plan.

(c) If the property owner has not provided the Department with an acceptable plan for renourishment within one hundred twenty days of the issuance of an emergency order for sandbags, then the emergency order shall expire at the end of the one hundred twentieth day, and the sandbags shall be removed at the property owner's expense.

(d) If the property owner's plan is acceptable and calls for renourishment, then a renourishment permit application shall be submitted to the Department within eighteen months of the issuance of the emergency order.

(i) If the Department approves the renourishment permit, sandbags shall be allowed to remain in place for up to twelve months after the permit is issued to allow sufficient time for the project to be completed, but must be removed at the property owner's expense prior to the placement of renourishment sand at the property, or at the end of the twelve month period, whichever occurs first.

(ii) If the Department denies the renourishment permit application, the sandbags shall be removed within ninety days of the final agency decision, including all appeals, at the property owner's expense.

(iii) If a renourishment permit application is not submitted to the Department within eighteen months of the issuance of the emergency order, the emergency order shall expire at the end of the eighteenth month, and the sandbags shall be removed at the property owner's expense.

(3) To maintain the temporary nature that is intended for the use of sandbags, the following criteria shall be used when issuing emergency orders for sandbags:

(a) The bags shall be commercially manufactured for the purpose of holding sand. Biodegradable bags may be required if deemed appropriate by the Department.

(b) The bags, when filled, shall be a maximum size of one cubic yard.

(c) The bags may be placed no farther seaward than is necessary to protect the existing habitable structure, critical infrastructure or golf course qualified under R.30-13.Q(1). In no case may sandbags be used to protect a dune. Sandbags may not retard normal shoreline movement unless used to protect an existing habitable structure, critical infrastructure or golf course qualified under R.30-13.Q(1).

(d) All sandbags are to be placed parallel to the shoreline. Excavation shall not be allowed below existing beach grade. The toe of the sandbags shall not be buried. At no time shall the sandbags be buried or covered with sand.

(e) Sandbags shall generally be limited to a maximum height of six feet above the beach. The sandbags shall be stacked at an angle no steeper than forty-five degrees.

(f) The Department may consider site specific engineering reports which will improve the effectiveness of sandbag placement for site specific situations.

(g) Sandbag fill material must be from an upland source and compatible in grain size and color with the native beach sand and should contain no more than a minimal amount of organic material. Only clean sand may be placed in the bags.

(h) The property owner is responsible for the day-to-day maintenance of the sandbags to ensure that they remain in the location authorized by the emergency order, above grade and in good repair. Failure to maintain the sandbags may result in the Department requiring the removal of the sandbags at the property owner's expense.

(i) A copy of the issued emergency order shall be in the possession of anyone performing the placement of sandbags.

(4) Emergency orders for sand scraping may be issued by the Department, or upon written notification to the Department by an appointed official of a county or municipality or of the state acting to protect public health and safety. Sand scraping may be used to construct temporary protection if the Department or local official determines a structure to be in imminent danger and emergency conditions conform with the definition of emergency in Section 48-39-10(U). The following criteria shall be used when issuing emergency orders for sand scraping:

(a) Sand scraping may only be ordered and performed to protect existing structures. Sand scraping shall not be allowed in front of erosion control structures unless it can be proven that the erosion control structure is itself in danger of collapsing and is within ten feet of the habitable structure.

(b) Sand scraping may be used to provide temporary protection for golf courses pursuant to the requirements of this subsection.

(c) Sand may only be scraped from the intertidal beach and only between extended property lines of the structure receiving the sand. The depth of scraping may not exceed one foot below the existing beach level.

(d) Sand may be placed against an eroded scarp or to replace an eroded dune that is seaward of a threatened structure. The dune shall not exceed six feet above grade or twenty feet in width as measured from dune toe to dune toe.

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(e) No sand may be placed landward of an existing, functional erosion control device.

(f) Sand scraping may be performed one time only per property for each emergency order issued by the local official without prior approval by the Department.

(g) A copy of the issued emergency order shall be in the possession of anyone performing sand scraping.

(h) Sand scraping activities shall generally be accomplished through private or local funding unless a state of emergency is declared, then state funding is not precluded.

(5) Emergency orders for renourishment may be issued by the Department, or upon written notification to the Department by an appointed official of a county or municipality or of the state acting to protect public health and safety. Renourishment may be used to construct temporary protection if the Department or local official determines a structure to be in imminent danger and emergency conditions conform with the definition of emergency in Section 48-39-10(U). The following criteria shall be used when issuing emergency orders for renourishment:

(a) Renourishment sand must originate from an upland source and be approved by the Department as compatible in grain size and color with the native beach sand and should contain no more than a minimal amount of organic material.

(b) Sand placed on the beach must be located between the extended property lines of the property receiving the sand.

(c) Sand may be stabilized with sand fencing and beach vegetation pursuant to the permitting requirements in R.30-13.L.

(d) A copy of the issued emergency order shall be in the possession of anyone performing authorized renourishment activities.

(e) Renourishment activities conducted under an emergency order may be used to provide temporary protection for golf courses pursuant to the requirements of this subsection.

(f) Renourishment activities conducted under an emergency order shall generally be accomplished through private or local funding unless a state of emergency is declared, then state funding is not precluded.

Fiscal Impact Statement:

The Department estimates minimal additional cost will be incurred by the State or its political subdivisions as a result of the promulgation, approval, and implementation of these amendments; therefore, no additional state funding is being requested. Existing staff and resources have been utilized in preparation of these amendments and will further be utilized in the regulatory administration resulting from the amendments.

Statement of Need and Reasonableness:

The Statement of Need and Reasonableness was determined by staff analysis pursuant to 1976 Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF REGULATION:

R.30-1. Statement of Policy

R.30-5. Exceptions

R.30-9. Other Provisions

R.30-13. Specific Project Standards for Beaches and the Beach/Dune System

R.30-15. Activities Allowed Seaward of Baseline

Purpose: These regulatory changes will amend the Department's Coastal Division regulations related to permitting in the beaches and beach/dune critical areas of the coastal zone. These changes would amend definitions, provide clarity and specific standards to be utilized in the evaluation of beachfront permit applications and notifications, and provide specific standards, conditions, and administrative procedures for issuance of emergency orders within the State's beachfront jurisdiction. Amendments will also modify specific procedures for the issuance of emergency orders for golf courses to comply with Act No. 147 of 2014, codified as 1976 Code Section 48-39-135. These amendments will provide more clarification to the regulations, enabling Department staff to administer more effectively the regulatory program of the Coastal Division.

Legal Authority: 1976 Code Section 48-39-10 et seq.

Plan for Implementation: These regulatory changes will amend the Coastal Division regulations upon approval of the General Assembly, and publication in the State Register. These amendments will be implemented, administered, and enforced by existing staff and resources.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

These amendments are based on the Blue Ribbon Committee on Shoreline Management's final recommendations and to comply with Act No. 147 of 2014, codified as 1976 Code Section 48-39-135. They are reasonable and necessary to manage the long-term health and sustainability of the State's beaches and beach/dune systems. These amendments clarify existing regulations that enables Department staff to more effectively (1) implement 1976 Code Section 48-39-130, which addresses the permitting of activities in the critical area; and (2) implement the stated policies of the South Carolina Beachfront Management Act (1976 Code Section 48-39-260).

DETERMINATION OF COSTS AND BENEFITS:

1) Promulgation and administration of these amendments are estimated to have minimal economic impacts to the State. Benefits to the State will include improved management of coastal resources through increased clarity of the regulations and better protection of important habitats.

2) Promulgation and administration of these amendments are estimated to have no significant economic impacts to entities regulated or result in cost increases to the general public. Public benefits will be evident in improved management of coastal resources through increased clarity of the regulations and better management of public trust lands.

See Fiscal Impact Statement.

UNCERTAINTIES OF ESTIMATES:

Minimal.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

These amendments will refine the Department's ability to manage public usage of the State's beaches and beach/dune system and will enable the Department to provide a more effective response to those seeking to utilize the public trust areas of the coastal zone.

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DETRIMENTAL EFFECTS ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment and/or public health associated with these amendments. Implementation of the regulations seek to benefit the environment by providing more clarity to the Department's Coastal Division statutory directives to manage the State's beaches and beach/dune critical areas for its citizens.

Statement of Rationale:

These revisions will ensure effective management of the beaches and beach/dune system critical areas of the coastal zone. They provide additional clarity and specificity to the existing regulations that address the management of the State's beaches and beach/dune system, evaluation of beachfront permit applications and notifications, and administrative procedures for issuance of emergency orders within the State's beachfront jurisdiction. The revisions are based on the recommendations of two broad-based stakeholder committees, the Blue Ribbon Committee on Shoreline Management and the Shoreline Change Advisory Committee. Amendments related to the issuance of emergency orders for golf courses are necessary to comply with Act No. 147 of 2014, codified as 1976 Code Section 48-39-135. The development of the revisions relied on the experience and professional judgment of the Department's staff, as well as the suggestions of the stakeholder committees.

Document No. 4609

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL CHAPTER 61

Statutory Authority: 1976 Code Sections 44-1-110, 44-1-140 and 44-29-10 et seq.

61-20. Communicable Diseases

Synopsis:

The Department has conducted a review of its regulations pertaining to public health concerns of communicable disease reporting, investigation, and mitigation to prevent spread of disease. As a result of the review, the Department has substantially amended Regulation 61-20, Communicable Diseases. The amendments removed obsolete sections, improved the clarity and readability of the regulation, provided definitions, references, codification and improved the grammar and punctuation of the regulation. The regulation has been replaced in entirety with these amendments.

A Notice of Drafting for the regulations was published in the *State Register* on April 24, 2015. It was replaced by a Notice of Drafting that was published in the *State Register* on July 24, 2015.

See Statements of Need and Reasonableness and Rationale herein for these amendments.

Section-by-Section Discussion of Amendments:

Regulation 61-20. Communicable Diseases.

The existing Regulation 61-20 Sections 1 – 17 have been substantively changed and substantially reorganized. The amendments incorporate stylistic changes, which include corrections for clarity, readability, grammar, punctuation and overall improvement of the text; the addition of definitions for improving precision; and reference changes necessitated by changes in related statutes as well as Department organization and structure. The changes also align the Department with advancements and best practices in disease investigation and prevention. As a result, the entire existing regulation has been replaced.

TABLE OF CONTENTS:

The table of contents was added for overall improvement of the regulation.

61-20, Section 1. Disease Reporting

Current Section 1 has been revised and moved to new Section 2. New Section 1 now includes an entirely new Definitions section for the purpose of defining terminology in the amendments and to bring clarity to regulation.

61-20, Section 2. Householders, Heads of Families, etc., Shall Report Contagious Diseases.

Current Section 2 has been deleted in its entirety. In its place is former Section 1 (Disease Reporting), which has been substantially revised to better define disease reporting requirements. Subsection B has been added to New Section 2 in order to specify the consequences for failing to report diseases to the Department, including the criteria the Department will consider in assessing penalties. Subsection C has also been added to New Section 2 to provide a safe harbor to those who have failed to report as required. Under the safe harbor provision, a required reporter may notify the Department of a failure to properly report without fear of penalties, provided he or she meets certain criteria. The safe harbor provision is intended to encourage the reporting of communicable diseases and to assist the Department in protecting the public health.

61-20, Section 3. Nurses and Midwives Shall Report Redness or Inflammation of Eyelids to Health Authorities.

Current Section 3 has been deleted in its entirety as the reporting requirements in Section 3 are included as part of new Section 2. In its place is former Section 13 (Health Authorities to investigate reported cases). Former Section 13 (New Section 3) has been substantially revised to bring the section up to date with current Department organization and procedures and to clarify the steps the Department may take in investigating communicable diseases.

61-20, Section 4. Local Health Authorities Shall Keep Records of Contagious Diseases.

Current Section 4 has been deleted in its entirety as it is unnecessary to codify the Department's record-keeping requirements. In its place is former Section 5 (Regulations relating to control measures, isolation and quarantine to be observed by all health providers). Former Section 5 (New Section 4) has been substantially revised to clarify the Department's responsibility and authority for controlling the spread of communicable diseases, to emphasize the mitigation measures available to it, and to reiterate the statutory penalties associated with failure to abide by Department directives and orders for the control and prevention of communicable diseases. The revisions are also stylistic for the purpose of improving the overall text.

61-20, Section 5. Regulations Relating to Control Measures, Isolation and Quarantine to be Observed by All Health Providers.

Current Section 5 has been substantially revised and moved to Section 4. In its place is former Section 7 (Health authorities are to assume control of quarantine, isolation and other control measures). Former Section 7 (New Section 5) has been revised to clarify that it is the Department's responsibility for assuming control of quarantine, isolation and control measures and to delete the antiquated term "local health authorities."

61-20, Section 6. Placards Shall Not Be Destroyed or Removed.

Current Section 6 has been revised and moved to Section 8. In its place is former Section 8 (Authorized health officers may pass through quarantine lines). Former Section 8 (New Section 6) has been revised to better define who may pass through quarantine lines and access restricted areas by using the defined term "Authorized Health Officer" and to bring the section up to date with current Department organization, including the use of the term "Director" rather than "Commissioner."

61-20, Section 7. Health Authorities Are to Assume Control of Quarantine, Isolation and Other Control Measures.

Current Section 7 has been revised and moved to Section 5. In its place is former Section 15 (Premises designated as infectious shall be placarded). Former Section 15 (New Section 7) has been revised to clarify that it is the

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Department's responsibility for determining if a building, place or premises poses a risk to the public health and to provide a more modern example of language for any Public Health Notice.

61-20, Section 8. Authorized Health Officers May Pass through Quarantine Lines.

Current Section 8 has been revised and moved to Section 6. In its place is former Section 6 (Placards shall not be destroyed or removed). Former Section 6 (New Section 8) has been revised to incorporate the defined term "Public Health Notice" and to establish the duration by which Public Health Notices shall remain attached or posted to buildings, places or premises.

61-20, Section 9. Person Forbidden Going to or Leaving Contagious Disease Premises.

Section 9 has been revised to clarify who may and who may not enter or leave contaminated premises.

61-20, Section 10. Persons Affected with or Exposed to Contagious Diseases Shall Obey Health Authorities.

Current Section 10 has been revised and moved to Section 11. In its place is former Section 14 (Premises occupied by persons with contagious diseases to be rendered non-infectious). Former Section 14 (New Section 10) has been revised to clarify the types of buildings, places or premises to which the regulation applies and to clarify that it is the Department's responsibility to supervise the rendering of a building, place or premises as non-infectious.

61-20, Section 11. Children with Contagious Diseases Shall Not Attend School or Childcare in Out-of-Home Settings.

Current Section 11 has been combined with former Section 12 and moved to Section 12. In its place is the combined former Sections 10 (Persons affected with or exposed to contagious diseases shall obey health authorities) and 16 (Persons suffering from reportable diseases shall not work where food products are produced). Former Sections 10 and 16 (New Section 11) have been combined and substantially revised to simplify requirements and responsibilities for individuals affected with or exposed to communicable diseases and who are required to follow Department directives. The revisions also modernize the language of the regulation by deleting specific references to smallpox, scarlet fever, dysentery and typhoid fever.

61-20, Section 12. Contacts Exposed to an Excludable Disease in Relation to School Attendance or Childcare Attendance in Out-of-Home Settings.

Section 12 has been combined with former Section 11 and substantially revised. The two sections have been combined in order to address in one section the exclusion of students and adults from school settings and to clarify when such individuals can return. The revisions are also stylistic, intended to improve readability and clarity.

61-20, Section 13. Health Authorities to Investigate Reported Cases.

Current Section 13 has been revised and moved to Section 3. In its place is former Section 17 (These regulations not to prevent local laws). Former Section 17 (New Section 13) has been revised to include more modern language, including the use of "health laws" as opposed to "local laws."

61-20, Section 14. Premises Occupied by Persons with Contagious Diseases to be Rendered Non-infectious.

Current Section 14 has been moved to Section 10. In its place is an entirely new section (Public Health Orders, Law Enforcement and Appeal Process). The purpose of New Section 14 is to clarify the Department's ability to issue orders to enforce the provisions of Regulation 61-20, the assistance required of law enforcement in enforcing such orders, and to provide an appeals process for anyone affected by such orders.

61-20, Section 15. Premises Designated as Infectious Shall be Placarded.

Current Section 15 has been revised and moved to Section 7. There is no new Section 15.

61-20, Section 16. Persons Suffering from Reportable Diseases Shall Not Work Where Food Products Are Produced.

Current Section 16 has been combined with former Section 10, revised and moved to Section 11. There is no new Section 16.

61-20, Section 17. These Regulations Not to Prevent Local Laws.

Current Section 17 has been revised and moved to Section 13. There is no new Section 17.

Instructions: Replace 61-20 in its entirety with this amendment.

Text:

61-20. Communicable Diseases.

(Statutory Authority: 1976 Code Section 44-1-110, 44-1-140 and 44-29-10 et seq.)

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- SECTION 5. The Department Is to Assume Control of Quarantine, Isolation and Other Control Measures.
- SECTION 6. Authorized Health Officers May Pass Through Quarantine Lines and Access Restricted Areas.
- SECTION 7. Buildings, Places and Premises Designated as Infectious.
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- SECTION 10. Premises at Risk for Transmission of Contagious Diseases to be Rendered Non-infectious.
- SECTION 11. Persons Affected with or Exposed to Communicable Diseases Shall Comply with Department Directives.
- SECTION 12. Official School and Child Care Exclusion List of Contagious or Communicable Diseases.
- SECTION 13. Health Laws of Cities, Towns and Counties.
- SECTION 14. Public Health Orders, Law Enforcement and Appeal Process.

SECTION 1. Definitions.

A. When capitalized, and for the purposes of this regulation:

(1) "Authorized Health Officer" means an individual designated by the Director of the South Carolina Department of Health and Environmental Control or his or her designee as an individual who may act as a health officer pursuant to these regulations.

(2) "Case" means an instance of a particular disease, injury, or other Condition.

(3) "Carrier" means a person or animal that harbors a specific Infectious Agent without discernible clinical disease or manifests symptoms and serves as a potential source of spread of the infection to others.

(4) "CDC" means the United States Centers for Disease Control and Prevention.

(5) "Communicable Disease" means an Infectious Disease that can be transmitted from one source to another.

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(6) “Condition” means a disease, illness or injury; an illness or abnormality in the body that interferes with a person's usual activities or feeling of wellbeing; any illness or health condition that may be caused by chemical terrorism, bioterrorism, radiological terrorism, epidemic or pandemic disease, or novel and highly infectious agents and might pose a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability.

(7) “Contact” means an individual known to have been exposed to an infected person or animal or a contaminated environment, if the exposure is sufficient to acquire that particular disease.

(8) “Contagious Disease” means a Communicable Disease capable of spreading easily from one person to another by contact or close proximity. A Contagious Disease can be transmitted from person to person or from animal to person through many means including, but not limited to, direct contact, inhalation of airborne droplets, exchange of bodily fluids, animal or insect bites, and needle-sticks.

(9) “Department” means the South Carolina Department of Health and Environmental Control.

(10) “Director” means the Director of the South Carolina Department of Health and Environmental Control.

(11) “Event” means an occurrence of public health importance due to the possibility of substantial risk of human morbidity or mortality.

(12) “Excludable Disease” means a Communicable Disease for which an individual infected with or exposed to the disease has to be removed from an environment to prevent further transmission.

(13) “Infectious Agent” means an organism, such as a virus or bacteria, capable of producing infection or Infectious Disease.

(14) “Infectious Disease” means a disease caused by an Infectious Agent potentially transferable to individuals. An Infectious Disease may or may not be communicable. An example of a non-communicable, but Infectious Disease is a disease caused by toxins from food poisoning or infection caused by toxins in the environment, such as tetanus.

(15) “Isolation” means the physical separation of persons or animals infected with a Communicable or Infectious Disease from others in such places and under such conditions so as to prevent or limit the direct or indirect transmission of the Infectious Agent.

(16) “Outbreak” means the occurrence of more Cases than normally expected within a specific place or group of people over a given period of time.

(17) “Post-exposure Prophylaxis” means a preventive medical treatment provided to a Contact after the exposure to a disease-causing pathogen in order to prevent the development of the disease.

(18) “Public Health Notice” means a note, card, poster, placard or the like issued by an authorized public health authority conveying information or a warning regarding a known or potential risk to the public health.

(19) “Quarantine” means the restriction of activities and movements of well persons or animals who have been exposed to a Communicable Disease for the purpose of preventing disease transmission during the incubation period should infection occur. Quarantine differs from Isolation in that Isolation applies to persons who are known to be infected with a Communicable Disease. Quarantine applies to those who have been exposed to a Communicable Disease, but who are not yet infected.

(20) “Reportable Condition” means any of the diseases, Conditions or Events identified and published in the Department’s Official List of Reportable Conditions of which known or suspected Cases are required to be reported to the Department.

SECTION 2. Disease Reporting.

A. The Department shall publish in January of each year, and may amend as often during each year as needed, an Official List of Reportable Conditions for which known or suspected Cases are to be reported to the Department. All physicians and healthcare practitioners, all healthcare institutions, facilities and providers, all coroners and medical examiners, all designated reporting coordinators, and all laboratories in or out of South Carolina, shall report to the Department all known or suspected Cases of Reportable Conditions occurring in South Carolina and shall do so in accordance with the timeframes, form and manner set forth in the Official List of Reportable Conditions.

B. Failure to report known or suspected Cases to the Department in accordance with Subsection (A) above may result in criminal or civil penalties as provided by South Carolina law and at the Department’s discretion. Factors to be considered by the Department when assessing penalties will include, but not be limited to:

- (1) The reason for the failure to report;
- (2) Whether the failure to report was discovered by the Department or self-reported by the reporter;
- (3) Whether the failure to report was intentional or willful;
- (4) Prior measures taken by the reporter to ensure compliance with reporting requirements, including training and the implementation of policies and procedures.

C. To encourage reporting, any person or entity required to report under Subsection (A) above that fails to do so may notify the Department of the failure without risk of criminal or civil penalties, provided all of the following criteria are met:

- (1) There is no record with the Department of the reporter having previously failed to report a known or suspected Case or Cases as required or of having previously utilized this subsection to avoid criminal or civil penalties;
- (2) The reporter has not intentionally or willfully failed to report;
- (3) The reporter makes a full disclosure to the Department of all previously unreported Cases;
- (4) The reporter agrees to make its records open to the Department for review at the Department’s discretion; and
- (5) The reporter agrees to remedial measures, including training and the implementation of policies and procedures, to ensure compliance with reporting requirements going forward.

SECTION 3. The Department Shall Investigate Reported Cases.

The Department shall investigate a known or suspected Case of a Reportable Condition within the state and within the designated time frame for the Condition in accordance with CDC or Department protocols. For purposes of report verification and epidemiological investigation, the Department may conduct appropriate follow-up of reports of positive tests, Conditions, clusters of diseases, or Events. Such verification and investigation may include, but may not be limited to: confirmation of test results or reports; collection and confirmation of other information required to be reported; review of healthcare records; and interviews of

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patients, Contacts, physicians and other appropriate healthcare staff. If the person infected with the Condition is incompetent, incapacitated or deceased, the Department may interview the guardian, next of kin, and/or spouse.

SECTION 4. Mitigation Measures, Isolation and Quarantine to be Observed by All Health Providers.

A. The Department has responsibility and authority for specifying and directing the methods of control of Communicable and Infectious Diseases and Conditions that could threaten the public health. The Department shall adopt the methods of control applicable to any such disease or Condition necessary to prevent spread of the disease or Condition including, but not limited to, Isolation and Quarantine of individuals or animals and restriction of ingress and egress to buildings, places and premises.

B. When necessary to protect the public health, the Department will make recommendations, issue directives and/or enforce or prescribe orders regarding the suppression or prevention of the spread of Communicable or Infectious Diseases and shall adopt accepted national public health recommendations or shall make such other policies as needed to meet any emergencies or conditions not provided for by general rules for the purpose of protecting public health. National public health resources may include, but may not be limited to, American Public Health Association's "Control of Communicable Diseases Manual," American Academy of Pediatrics' "Red Book," and CDC and Food and Drug Administration (FDA) Guidelines.

C. The Department may direct or order a person or entity to publish or disseminate such public health information as the Department deems necessary to protect the public health and/or prevent the spread of Communicable and Infectious Diseases. The Department has the authority to specify the content, manner and means of the publication, including, but not limited to, requiring the posting of a Public Health Notice.

D. All persons and entities shall comply with Department directives and orders to protect the public health from the spread of Communicable and Infectious Diseases. Any person or entity who, after notice, violates a directive or order of the Department issued pursuant to this section is subject to a civil penalty not to exceed one thousand dollars a day for each violation, with every day of noncompliance considered a separate violation.

SECTION 5. The Department Is to Assume Control of Quarantine, Isolation and Other Control Measures.

In all cities, towns and counties of this state, the Department shall assume control and management of all Outbreaks of Communicable Diseases and exposures to Infectious Agents and shall see that appropriate control measures, including, but not limited to, Isolation and Quarantine, are carried out in all jurisdictions. It shall be the duty of the Department to institute proper methods and control and to coordinate securing any buildings, places and premises in a manner following Communicable Disease control practices and standards as necessary to protect the public health.

SECTION 6. Authorized Health Officers May Pass Through Quarantine Lines and Access Restricted Areas.

All Authorized Health Officers shall have the privilege and shall be allowed to pass through all Quarantine lines and access restricted areas after first identifying themselves as properly Authorized Health Officers and after presenting proper identification. The Director shall specify a method of identification that such officers must carry to verify their authority.

SECTION 7. Buildings, Places and Premises Designated as Infectious.

Whenever the Department determines that a building, place or premises may pose a risk to the public health, the Department shall cause a Public Health Notice to be placed upon the outside entrance or entrances of the building, place or premises in order to warn the public of the risk. The Public Health Notice shall be in a manner comparable to the following:

“These premises may pose a risk to the public health and may not be again occupied until order of the S.C. Department of Health and Environmental Control. This notice must not be removed under penalty of law, except by an Authorized Health Officer.”

SECTION 8. Public Health Notices Shall Not Be Destroyed or Removed.

No person or persons shall alter, deface, remove, destroy or tear down any Public Health Notice, including posters, signs, or cards, posted by the Department or its designees. The occupant or person having possession or control of any building, place or premises upon which a Quarantine or other Public Health Notice has been placed shall, within twenty-four hours after destruction or removal of such by other than the proper authorities, notify the Department of such destruction or removal. All Public Health Notices shall remain as posted by the Department until such time as the Department determines there is no longer a risk to the public health.

SECTION 9. Persons Forbidden Entering or Leaving Contaminated Premises.

After the Department has declared a building, place, or premises as contaminated by a Communicable Disease or Infectious Agent and a risk to the public health, all persons, except those designated by the Department, are prohibited from entering or leaving the building, place or premises or from removing or causing to be removed any object or material whereby such Communicable Disease or Infectious Agent may be transmitted.

SECTION 10. Premises at Risk for Transmission of Contagious Diseases to be Rendered Non-infectious.

No person shall offer for rent, sale or lease, or cause or permit anyone to occupy any building, place or premises, including, but not limited to, houses, apartments, condominiums, office buildings and warehouses, that are confirmed or suspected to be a risk for transmission of any Communicable Disease or Infectious Agent until such building, place or premises has been rendered non-infectious under the supervision of the Department.

SECTION 11. Persons Affected with or Exposed to Communicable Diseases Shall Comply with Department Directives.

Any person affected with or exposed to any Communicable Disease or Infectious Agent and who the Department determines is a threat to the public health shall strictly observe such instructions, directives and orders as are given to him or her by the Department. It shall be lawful for the Department to require any person thus affected or exposed to remain within designated premises and/or to refrain from entering designated premises or workplaces for such length of time as the Department prescribes. Those persons excluded from the workplace shall not be permitted to return to work until the workplace has implemented mitigation measures or the Department has determined there is no public health risk.

SECTION 12. Official School and Child Care Exclusion List of Contagious or Communicable Diseases.

A. The Department shall publish an Official School and Child Care Exclusion List of Contagious or Communicable Diseases for which known or suspected Cases and those exposed to certain Communicable Diseases, whether symptomatic or not, shall not be permitted to attend any private, public, parochial or church school or any childcare center or facility. This Exclusion List shall include specific conditions for duration of school or childcare exclusion as well as criteria for return, and it applies to both students and staff.

B. No superintendent, principal or teacher of any school, no provider of childcare as defined in S.C. Code Ann. Section 63-13-20, and no parent or guardian of any child or minor shall permit any child or minor having or suspected of having any of the Communicable Diseases published in this Exclusion List to attend any private, public, parochial, or church school or childcare center or facility until such time as the published conditions for return have been met.

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C. No administrator, faculty member, teacher, staff member, volunteer, custodian or any other person having or suspected of having any of the Communicable Diseases published in this Exclusion List shall attend any private, public, parochial, or church school or childcare center or facility until such time as the published conditions for return have been met.

D. Any person who has been exposed to certain Communicable Diseases referenced in this Exclusion List, but who is not symptomatic, shall be excluded from the school or childcare setting and shall not be permitted to attend school or child care until the attending physician or the Department states in writing that the person may return to school or child care and he or she meets one or more of the following criteria:

- (1) determined not to have been exposed to the Excludable Disease during the period of communicability;
- (2) proven to be immune to the disease;
- (3) determined not to be a Carrier of the disease;
- (4) has been provided appropriate Post-exposure Prophylaxis;
- (5) has exceeded the maximum incubation period of the disease from the last exposure; or
- (6) the Department concludes disease transmission has ceased and no longer presents a risk to the public.

SECTION 13. Health Laws of Cities, Towns and Counties.

Nothing contained in these regulations shall be construed to prevent any city, town or county from making such health laws as they may think necessary for the preservation of public health; provided that said laws are not inconsistent with the laws approved by the Board of Health and Environmental Control. It shall be the duty of any city, town or county proposing a health law to at once furnish the Department of Health and Environmental Control with a copy of any proposed law for the approval of the Board of Health and Environmental Control before it shall become law.

SECTION 14. Public Health Orders, Law Enforcement and Appeal Process.

A. In addition to its authority provided for by statute or as otherwise provided for by regulation, the Department may issue separate orders to enforce the provisions of this regulation for the purpose of suppressing nuisances, Communicable, Contagious and Infectious Diseases, and other dangers to the public health.

B. The Director or his or her designee may request assistance from state and local law enforcement authorities in enforcing orders issued pursuant to this regulation, who must aid and assist the Director and the Department in carrying out such orders.

C. Except as otherwise provided by law, any person to whom an order is directed under this regulation may appeal the order of the Department to any court having jurisdiction. At any hearing on appeal, the person shall be provided the opportunity to present and to cross-examine witnesses. The person appealing from such order may be represented by an attorney of his or her choosing. The person or his or her attorney shall have access to any documents relied upon by the Department in issuing the order. Any order which is appealed shall remain in full force and effect throughout the pendency of the appeal.

Fiscal Impact Statement:

The Department does not anticipate substantial fiscal or economic impact on the State and its political subdivisions resulting from amending Regulation 61-20.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness is based on an analysis of the factors listed in S.C. Code Sections 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: Regulation 61-20, Communicable Diseases.

Purpose: Amendment of Regulation 61-20, Communicable Diseases.

Legal Authority: 1976 Code Sections 44-1-110, 44-1-140 and 44-29-10 et seq.

Plan for Implementation: Upon final approval of the S.C. General Assembly and publication in the State Register as final, these amendments will take effect as law. In addition to publication in the State Register, notice will also be provided to interested persons on the Department's website in the DHEC Regulation Development Update. Also, a copy of this amended regulation will be published on the Department's Laws and Regulations website and subsequently in the Code of Regulations in the S.C. Code of Laws.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Regulation 61-20 was promulgated pursuant to 1976 Code Sections as listed above. Amendment of Regulation 61-20 is necessary because the items it regulates are currently governed by state statute and federal law. Reporting of cases of communicable disease is important in the planning and evaluation of disease prevention and control programs, in the assurance of appropriate medical therapy, and in the detection of common-source outbreaks. In the United States, the authority to require notification of cases of disease resides in the respective state legislatures.

DETERMINATION OF COSTS AND BENEFITS:

The Department does not anticipate substantial fiscal or economic impact on the State and its political subdivisions resulting from amending Regulation 61-20. The Department also does not anticipate cost to the regulated community.

UNCERTAINTIES OF ESTIMATES:

No known uncertainties.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The Department anticipates no environmental or public health effect.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

The Department anticipates no detrimental effect on the environment or public health.

Statement of Rationale:

Upon internal review of Regulation 61-20, the amendments deleted sections that were obsolete and no longer applicable to the reporting of, investigation of and control/mitigation of communicable diseases; to incorporate stylistic changes, which include corrections for clarity, readability, grammar, punctuation and overall improvement of the text; to add a section of definitions for improving precision; to bring the regulation into

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consistency with changes in related statutes as well as Department organization and structure; and to align the regulation with advancements and best practices in disease investigation and prevention.

Document No. 4610
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: 1976 Code Section 44-7-260

61-7. Emergency Medical Services.

Synopsis:

Regulation 61-7 has not been substantively updated since 2006. The amendments herein incorporate statutory requirements for EMT certification and training, update the vehicle equipment list to current accepted industry standards, modify the ground ambulance requirements to reflect the most current standards, change the air ambulance requirements to reflect the latest statutory amendments, incorporate requirements for ambulance drivers, modify the name of first responder agencies to rapid response vehicles, add and amend definitions, and rewrite the certification and training requirements. The Department also made corrections for clarity and readability, grammar, punctuation, codification, and overall improvement to the text of the regulation.

A Notice of Drafting was published in the *State Register* on August 28, 2015.

This Regulation was withdrawn and resubmitted with changes described below at the request of the House of Representatives Regulations and Administrative Procedures Committee by Letter dated May 9, 2016.

A Section-by-Section Discussion of Committee Changes is shown below:

References to Paramedic, Medical Control Physician, Special Purpose EMT, and Medical Control Option were capitalized throughout the document for consistency.

References to EMT-Intermediate, and variations thereof, were amended to EMT-I for consistency and clarity throughout the document.

Updated lists throughout the document with correct usage of semicolons and conjunctions for clarity and consistency.

Updated references to "email" to include "email address" at Section 401.

Amended Section 404 to change "must" to "shall."

Updated the document to include and/or clarify acronyms where appropriate for brevity and consistency.

Amended section references within the document to proper codification standards.

Updated references to single use items as "single-use" throughout the document for consistency.

Amended Section 907.F for clarity and consistency.

Changed "Devises" to "Device" at Sections 1202.D.3.g and 1202.E.2.f.

Changed "USP" to "U.S. Pharmacopeia" at Section 1204.C for clarity.

Changed "&" to "and" at Section 1402.E pursuant to drafting standards.

Below is a Section-by-Section Discussion of Amendments submitted to the S.C. General Assembly for review by the Department of Health and Environmental Control on January 21, 2016:

Title

Statutory Authority: Edited statutory authority to reflect current parlance.

Table of Contents. The Table is revised to bring it current with changes in the text.

Non-substantive changes were made throughout the regulations where applicable to improve outlining, codification, and wording for overall improvement and to avoid conversion problems in electronic publications.

Section 100. Scope and Purpose.

No changes.

Section 200. Definitions

Section 200.A. was revised to change “drugs” to “medications” and update the definition to include levels of care.

Section 200.B. was revised to change the name of EMT Intermediate to AEMT, to change “drug” to “medication,” to update clinical parlance, and to eliminate the “80 percent” rule.

Section 200.C. was revised to expand the definition of air ambulance to include fixed wing and rotorcraft.

Section 200.D. was revised to include BIADs and defibrillation capability, and for clarity and consistency.

Section 200 E. new definition for Commission on Accreditation of Allied Health Education Program (CAAHEP) was added.

Section 200.F. new definition for Committee on Accreditation of Educational Programs (CoAEMSP) was added.

Existing Section 201.E. was renumbered to Section 200.G. and revised to correct grammar.

Section 200.F. was renumbered to Section 200.H.

Section 201.G. was deleted because it no longer meets the current standards.

Added Section 200.I. to add definition for Credentialing Information System (CIS).

Added Section 200.J. to add a definition for Driver.

Added Section 200.K. to add a definition for Electronic Patient Care Report (ePCR).

Added Section 200.L. to add a definition for Emergency and amended for grammar.

Existing Section 201.H. was renumbered to Section 200.M. No substantive changes.

Existing Section 201.I. renumbered to new Section 200.N. and is revised to define the certification levels of the Emergency Medical Technicians (EMT) to match national standards.

Existing Section 201.J. renumbered to Section 200.O. EMT First Responder Service is revised to change in title to EMT Rapid Responder Agency.

Existing Section 201.K. was renumbered to Section 200.P. No substantive changes.

Existing Section 201.L. was deleted. Text was incorporated as appropriate in Section 200.C.1.

Existing Section 201.M. was renumbered to Section 200.Q. and removes roadside pickup language.

New Section 200.R. definition of Ground Ambulance was added.

Existing Section 201.O. was renumbered to Section 200.V. and added subsections which were moved from existing Sections R and S to Subsections 1 and 2.

New Section 200.S. definition of Health Insurance Portability and Accountability Act (HIPAA).

Existing Section 201.N. was renumbered to Section 200.T. and was revised to add the AEMT and change the EMT-Paramedic to Paramedic. Also added new parlance and eliminated the “80 percent” rule.

Existing Section P. was renumbered Section W. No substantive changes.

New Section 200.U. was added to define the Joint Policy Statement on Equipment for Ground Ambulances (JPS).

Section 201.O. was renumbered to 200.V. Added subsections under Section U. Changed “unit’s” to “licensed agency’s.”

Existing Section 201.P. was renumbered to Section 200.W. No substantive changes.

New Section 200.X. was added to define National Emergency Medical Services Information System (NEMSIS).

New Section 200.Y. definition of National Registry of Emergency Medical Technicians (NREMT) was added.

Existing Section 201.Q. was renumbered to 200.Z. and added “the patient” to the convenience clause for nonemergency transports.

Existing Sections 201.R. and 201.S. were moved under Section 200.U as 1 and 2.

Added new Section 200.AA. to define Patient.

Added new Section 200.BB. to define Prehospital Care.

Added new Section 200.CC. to define Prehospital Medical Information System (PreMIS).

Existing Section 201.T. renumbered to Section 200.DD. and amended to four (4) years for certificates.

Existing Section 201.U. was deleted and incorporated as appropriate in 200.C.2.

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Added Section 200.EE. to define Special Purpose EMT.

Added Section 200.FF. to define Specialty Care and replace outdated 201.V. Special purpose ambulance.

Added Section 200.GG. to define the “Star of Life” mentioned later in the Regulation.

Existing 201.V. Special purpose ambulance deleted.

Existing Section 201.W. was renumbered to 200.HH. No substantive changes.

Existing Section 201.X. was renumbered to 200.II. No substantive changes.

Added Section 200.JJ. to define Vocational School.

Added Section 200.KK. to define Volunteer EMS Provider.

Section 300. Enforcing Regulations.

Section 301.A. was revised to add medical control physicians.

Section 302.B. was amended to include permitted vehicles and equipment.

Section 302.C. was revised to update the language/technology.

Section 303 was revised add the location of the fines/monetary penalties in Section 1500 and to add that the Department may seek other actions if appropriate (for example: remediation).

Section 304.A. Added “other employees and the general public”, corrected punctuation, and edited for clarity.

Section 304.B. as revised to correct grammar, to add “other employees and the general public”, and for clarity.

Section 304.C. was revised for clarity.

Section 304.D. was added to denote the new Class IV violations related to re-inspection failures.

Existing Section 304.D. was renumbered to 304.E. and added Class IV language.

Existing Section 304.E was renumbered 304.F. and added “other employees and the general public.”

Added new Section 304.G. to indicate new location of fine schedule in Regulation.

Existing Section 304.F. was deleted and content incorporated in Section 1501.B.

Existing Section 304.G. was renumbered to 304.H.

Section 400. Licensing Procedures

Section 401.A.3 added a requirement to provide a business license.

Existing Section 401.A.3 was renumbered to 401.A.4 and added VIN and rapid response vehicles.

Existing Section 401.A.4 was renumbered to 401.A.5 and revised to meet national standards and added “or contraction.”

Existing Section 401.A.5 was renumbered to 401.A.6 and revised language to add "employees, contractors and affiliates" for those that need listed on the CIS roster.

Existing Section 401.A.6 was renumbered to 401.A.7. No substantive changes.

Existing Section 401.A.7 was renumbered to 401.A.8 and revised to add email address instead of mail address as part of the contact information.

Existing Section 401.A.8 was renumbered to 401.A.9 and revised to name more specifically positions of responsibility.

Existing Section 401.A.9 was renumbered to Section 401.A.10. and changed “units” to “vehicles” and “transporting station” to “fixed station location.”

Existing Section 401.A.10 was renumbered to Section 401.A.11 and revises the required limits of insurance coverage.

Section 401.A.12 was added to meet a federal mandate.

Existing Section 401.A.11 was renumbered to 401.A.13 and revised to enforce per statutory requirements.

Section 401.A.14 was added to meet federal regulation.

Existing Section 401.A.12 was renumbered to 401.A.15 and revised to add the word "make" to correct sentence grammar/structure.

Section 401.C. was revised to clarify inspection frequency and operating procedures; changed “ambulances” to “vehicles.” The table with the schedule of fines was moved to Section 1501.B.

Section 401.D., E., F remain unchanged.

Section 401.G. was deleted for clarity.

Section 401.H. was deleted because the exemption is already in the regulation (redundancy).

Existing Section 401.I was renumbered to Section 401.G. No substantive changes.

Section 402 was revised to capitalize all references to Medical Control Physician.

Section 402.A. was revised to insert acronyms for quality assurance and in-service training.

Section 402.A.2 changed “tapes” to “recordings.”

Section 402.A.4 corrected grammar.

Section 402.C. was revised to clarify a requirement of the medical control physician.

Section 402.D. was revised for clarity and changes “drug” to “medication.”

Section 402.E. was revised for clarity.

Section 402.F. was revised to add “or responsibilities.”

Section 402.H. was added that the medical control physician shall complete appropriate continuing education.

Section 402.I. was added to give the medical control physician authority to be on scene calls and to function as medical providers.

Section 402.J. was added to account for multiple Medical Control Physicians.

Added New Section 403 to add requirements of a Non-Credentialed Ambulance Operator or Driver.

Section 403.B. was amended to require a national accredited safety driving course, such as CEVO.

Renumbered existing Section 403 to Section 404 and revised title to match other parallel sections.

Section 404.A. was revised to delete the clause “or can be permitted.” This inadvertently allowed agencies to continue services by using unpermitted trucks.

Section 404.B. was revised for clarity of the requirement.

Section 404.C. was revised to make “on site” into one word “onsite”, to change “calls” to “responses”, and take out the redundant phrase and corrected grammar in sentence.

Section 404.C.1. was renumbered Section 404.D. and was revised for clarity and direction for all services on emergency responses and transports.

Section 404.C.2. was deleted.

New Section 404.E. was added to define minimum staffing and equipment standards to provide at least basic life support on all ambulances.

Existing Section 404.E. was renumbered to Section 404.G. and was revised to add “or rapid response” capability to industries providing emergency medical services, and to update the reference within the amended Regulation.

Section 404.F. was renumbered to Section 404.H; revised so that providers maintain “accurate” records which must also include CIS rosters; revised for grammatical clarity; revised to correct a section reference; and revised to change “ambulance run reports” to “patient care reports.”

Section 404.G. was amended to refer to rapid medical response.

Renumbered Existing Section 404 to Section 405.

Section 405. AEMT was added to the Intermediate requirement to reflect pending National Registry updates. Airway equipment required was amended to reflect new national standards; added defibrillation capability to meet national standards and best practices; eliminated the “80 percent rule” after January 1, 2018, and amended to ninety-five percent (95%).

Added Section 405.B. to allow for an ILS licensed provider to participate in a tiered response system and delineated requirements for BLS personnel operating on an ILS equipped ambulance.

Renumbered existing Section 405 to Section 406.

Section 406. was revised to remove “EMT” and to update clinical parlance on defibrillation; eliminated the “80 percent rule” after January 1, 2018, and amended to ninety-five percent (95%).

Added Section 406.B. to allow for an ALS licensed provider to participate in a tiered response system, and amended to allow for BLS personnel to upgrade to ALS capabilities.

Renumbered Section 406 to Section 407.

Section 407.A. was amended to correct a section reference.

Section 407.D. was amended to allow for the medical control physician to approve the list of special purpose equipment carried on special purpose ambulances.

Renumbered existing Section 407 to Section 408.

Section 408. was revised to remove “EMT” and add an additional subsection, thus A and B.

Section 408.B. was added to define the staffing requirement of an ALS transport unit to include two certified personnel and further amended to address transports above the BLS level.

Renumbered Section 408 to Section 409.

Section 409. title was revised to add penalty type II.

Renumbered existing Section 409 to Section 410.

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Section 410. title was revised from First to Rapid Responder. (II).

Section 410.A. was revised to change “first” to “rapid” , and to clarify the requirement for rapid responder service.

Section 410.B. was revised to change “first” to “rapid” and to clarify the requirements for rapid responder service. Change “on site” to “onsite” for grammatical clarity.

Section 410.C. was revised to correct a section reference.

New Section 411 was added to delineate requirements for Special Exemptions for Volunteer EMS Providers.

Section 411.B. was amended for grammar.

Section 500. Permits, Ambulance (I)

Section 501.B. was revised to change “lower” to “upper.” Added “interior” to windshield for permit placement.

Section 501.E. was revised to clarify the instructions for permit sticker removal and added to clarify when to return a permit.

Section 501.F. was added to notify the Department within 72 hours if a licensed provider’s vehicle or aircraft is involved in an accident that caused bodily harm.

Section 501.G. was added to cover unlicensed agencies seeking a vehicle or aircraft permit, and to require that the provider be credentialed at a level determined by the local medical control physician and equipped with locally adopted and medical control physician authorized equipment, also in accordance with the level of credentialing as determined by the medical control physician.

Section 501.H. was added to prohibit permitting of vehicles or aircraft that are unlicensed EMS providers in South Carolina.

New Section 502. was added to cover temporary assets.

Section 600. Standards for Ambulance Permit.

Section 601. introductory paragraph was amended to remove an unnecessary word.

Section 601.A. was revised to add “NFPA 1917, (or similar specification standards accepted by the Department)” federal ambulance standard and to delete “the most current edition” comment which is superfluous. Deleted section on four-wheel drive recommendation.

Section 601.B. was deleted.

Existing Section 601.C. was renumbered to Section 601.B.

Section 601.B.2.a was deleted.

Section 601.B.2.b was renumbered Section 601.B.2.a.

Section 601.B.2.c was renumbered Section 601.B.2.b.

Section 601.B.2.d was deleted.

New Section 601.B.2.c is added to require out-of-state ambulances to meet the same requirements as in-state.

Section 601.B.3. was amended to correct a section reference.

Section 601.D. was renumbered to Section 601.C.

Section 601.E. was renumbered to Section 601.D.

Section 601.D.1.c is revised to clarify the separation partition standard in the ambulance.

Section 601.D.2.d. was revised to add “if carried” in reference to spare tire.

Section 601.F. was renumbered to Section 601.E.

Section 601.G. was renumbered to Section 601.F.

Section 601.F.1. was amended to clarify the required foot candles for exterior flood lights.

Sections 601.F.3 and 4 were moved to Section 701.CC and DD respectively.

Section 601.H. was renumbered to Section 601.G.

Section 601.G.1. was edited to clarify the armrest requirement in driver compartment seats.

Section 601.I. was renumbered to Section 601.H. and to remove references to “stretchers” and replace with “cot.”

Section 601.H.4.a was revised to correct grammar.

Section 601.J. was renumbered to Section 601.I.

New Section 601.I.5. was added to regulate for temperature extremes and drug adulteration based on USP and AAA standards and to exclude oxygen from medications requiring controlled temperatures.

Existing Section 601.I.5. was renumbered to Sections 601.J.6.

Section 601.K was renumbered to Section 601.J.

Section 601.J. added NFPA 1917 (or similar specification standards accepted by the Department) standard to be consistent with the other reference in the document; also added “interior cabinets” to clarify equipment in question.

Section 601.L. was renumbered to Section 601.K. No substantive changes.

Section 601.M was renumbered to Section 601.L.

Section 601.L. added the word “minimum” for clarity.

Section 601.N. was renumbered to 601.M.

Section 601.M. deleted rooftop requirement for mounted antenna.

Section 601.O. was renumbered to Section 601.N. No substantive changes.

New Section 601.O. is added to prohibit smoking and tobacco products.

New Section 601.P. was added to delineate requirements for out-of-service vehicles.

Section 700. Equipment (II).

Section 700 was rewritten in its entirety due to technological advancements since last Regulation revision in 2006 and to match accepted national prehospital care standards.

Section 701. amends the definition of child as one (1) year old to eighteen (18).

Sections 701.B.1. and 701.B.2. were amended to remove references to the JPS.

Section 701.C.1. was amended to require two (2) oxygen cylinders, one (1) in service and one (1) full and sealed.

Section 701.C.5. was amended to require that Special Purpose Ambulance maintain infant pulse oximetry capabilities.

Section 701.M.3. has been amended to remove the requirement of local option for cardboard splints as a primary splinting device.

Section 701.N.5. has been amended to remove the requirement of nine (9) foot straps.

Section 701.S.2. was amended to require stethoscopes that are adult and pediatric capable to allow for stethoscopes with dual capability.

Section 701.X. was amended to include the correct ANSI reference.

Section 701.CC. was amended to require three (3) reflective triangles, in accordance with DOT standards.

Section 800. Sanitation Standards for Licensed Providers.

Section 802.A. was corrected for grammar.

Section 802.E. was amended to refer to sodium hypochlorite.

Section 802.G. was revised to delete an unnecessary word.

Section 802.H. was revised for clarity and grammar and to refer to sodium hypochlorite.

Section 802.J. was added to require that all licensed providers carry sufficient and appropriate cleaning supplies.

Section 803.B. was revised to replace “stretchers” with “cots.”

Section 803.D.1. was revised to include towels and sheets.

Section 804.A. was revised to clarify the use and disposal of single-use oxygen administration devices.

Section 804.C. was deleted and the requirements were incorporated into Section 804.A.

Section 804.D. was added requiring all units that carry portable oxygen must have a non-sparking oxygen wrench in order to use on the oxygen regulators in that unit.

Section 805.A. was revised to allow for additional equipment needed to facilitate the use of a bag valve mask and to require that additional equipment needed to facilitate use of a bag valve mask shall be stored with the bag mask assembly. Section 805.A. further delineates requirements for cleaning mask assemblies and requirements with respect to single-use equipment.

Sections 805.B. and 805.C. were deleted and incorporated into Section 805.A.

Section 805.B. was added to meet national disinfectant standards and to refer to sodium hypochlorite.

Section 806.A. was revised to require single-use equipment.

Section 806.D. was revised to require single-use equipment and added “sealed” to requirement.

Section 806.E. was revised include reference to Section 805.D.

Section 807.A. was revised to correct grammar replacing “and” with “or.”

Section 807.F. was added that requires all splints must be in functional working order with the recommended manufacturer's attachments.

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Section 807.G. was added to require single-use equipment.

Section 808.A. was revised to correct grammar.

Section 808.B. was revised to include references to cots.

Section 808.E. and F. were revised to address spinal immobilization board construction.

Section 809.C. revised to make burn dressings single use only.

Section 809.D. was revised to state single-use equipment.

Section 810.B. was revised to state single use OB kits.

Section 810.C. was added that individual item that have an expiration date in OB kits may be replaced if the rest of the other items are individually sealed and sterile.

Section 811 was revised to eliminate sterilization of oral airways and laryngoscopes.

Section 812.A. was revised changing language to national standards and standard practice.

Section 812.B. was revised to refer to a cot instead of stretcher.

Section 815.A. was revised to add non-certified drivers to meet same dress requirements as certified personnel and deleted “neat” from requirement.

Section 815.C. was revised to delete “neat” from requirement and to update regulation with OSHA parlance and accepted practice.

Section 900. Training and Certification.

Section 900 was rewritten in its entirety to meet 2010 State statutory requirements and national standards.

Section 901. was amended to include references to EMTIs.

Section 901.B. was amended to allow for students under the supervision of an appropriately credentialed preceptor to practice advanced skills.

Section 907.A.7. has been amended to address classes which are closed due to associated security concerns and/or requirements.

Section 907.C.1. was amended for grammar.

Section 907.H.2. was amended to change a reference of “South” to “South Carolina.”

Section 1000. Personnel Requirements (I)

Section 1000.A. was revised to change the name of the certification levels to reflect the current nomenclature.

Section 1000.B was revised to correct grammar and to add physicians to the exception.

Section 1000.B.1. was amended to match the current parlance of “scope of practice”.

Section 1000.B.2. was amended to correct grammar and to change “home” to “residence”.

Section 1000.D. was amended to correct a section reference.

Section 1100. Revocation.

Section 1100.A.1 was revised to correct grammar.

Section 1100.B. the Misconduct section was revised in its entirety to correct grammar and flow of the document; and to bring the wording in line with the language in the EMS Act.

Section 1100.B.11. was amended for grammar.

New Section 1100.C. was added to prescribe the Department’s enforcement actions.

New Section 1100.E. was added to require that any adverse action or event related to credentialed personnel shall be reported as required to the National Practitioner Data Bank, in accordance with federal law.

Section 1200. Air Ambulances.

Section 1201.A. is revised in its entirety for clarification. Each item required is now delineated for clarity and better understanding of the license and insurance requirements.

Section 1201.A.3. was amended for grammar.

Section 1201.A.4. was amended to include a section reference.

Section 1201.A.7. was amended for clarity.

Section 1201.B.1 text was deleted due to being obsolete.

New Section 1201.B.1 was added to reflect 44-61 that out of the air ambulances are required to have a South Carolina in order to engage in operations in South Carolina.

New Section 1201.B.3 is added for consistency with other ambulance provider patient care reporting requirements.

Existing Section 1201.C.1 was deleted because it was superfluous. This activity is captured by prehospital air transports.

Section 1201.C.2 was renumbered to Section 1201.C.1 and revised to improve the sentence clarity in this section. Section 1201.C.3 was renumbered to Section 1201.C.2. and revised to reflect new nomenclature and to clarify the purpose of a specific purpose air ambulance.

Section 1201.D. was revised in its entirety to bring required configurations in line with national standards for air medical aircraft and to update language.

Section 1201.E. was rewritten in its entirety to reflect current national standards and accepted industry practices. Section 1201.E.1.c. was amended for grammar.

Section 1201.F.6. was revised to add “requirements” and the section of the regulations which delineates those requirements for Medical Control.

Section 1201.G.1 and G.2 were revised to include South Carolina.

Section 1201.G.2 and G.3 were revised to change advance life support to “prehospital”, to remove "EMT".

Sections 1201.G.4 and G.5 were added to crew member requirements.

Section 1202 was rewritten in its entirety in accordance with national and industry standards with recommendations from the air ambulance providers.

Section 1202.D.9.d. was amended to refer to sodium hypochlorite.

Section 1202.E.2.c. was amended to update the required endotracheal tubes for consistency within the regulation.

Section 1203 title was changed eliminating the interfacility air ambulances and the content was edited to match ALS Prehospital Care Ambulance requirements.

Section 1204 was deleted in its entirety and its content incorporated into Section 1202.

Section 1205 was renumbered to Section 1204.

New Section 1204 was revised to add “fluid or blood product” to items needing medical control approval for use in an air transport by registered nurse or physician; replaced the word “drug” with “medication.”

New Sections 1204.A. through 1204.D. were added to bring air ambulance medication requirements in line with ground ambulance requirements.

Section 1206 was renumbered to Section 1205.

Section 1205 introductory paragraph was amended to clarity.

Section 1300. Patient Care Reports.

Section Title – Added (III) for emphasis. This section is already a Class III violation.

New Section 1301 was added to define and regulate patient care reports.

Existing Section 1301 was renumbered to Section 1302 and renamed to Data Manager since all patient care reports are now digitally submitted and stored.

Section 1302.A. was revised to define the role of the Data Manager which replaced the Forms Control Officer.

Section 1302.B. was amended to reflect the role name change from Forms Control Officer to Data Manager.

Added new Section 1302.C. to add a requirement that each ePCR submitted must reflect all the attendants on the incident including a non-certified driver (if applicable).

Existing Section 1302, renumbered to Section 1303.

Existing Section 1303.B. was renumbered to 1303.A. and revised to include “all providers on call” to be part of the patient care report.

Section 1303.C. was renumbered to 1303.B. and revised to change the wording that patient care reports should be written coherently and should include all providers on the call.

Added new Section 1303.C. to provide guidance for documenting refusal calls.

Added new Section 1303.D. to delineate the requirements for data submissions from ePCR software and to state that ePCR information shall be sent no later than twenty-four (24) hours from completion of the call.

Existing Section 1303, renumbered to Section 1304, added new section 1304.A. to include PreMIS information.

Existing Section 1303.A. renumbered to Section 1304.B. was revised to delete space and supplies which are no longer necessary.

Existing Section 1303.B. renumbered to Section 1304.C. and was revised to meet new entry data requirements.

Existing Sections 1303.C., D. and E. were renumbered to Sections 1304.D., E. and F. respectively.

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Existing Section 1303.F. was deleted because it was no longer relevant.

Section 1304.G. was revised for clarity changing “their” to “the.”

Section 1304.H. was revised for drafting standards.

Section 1400. Do Not Resuscitate Order.

Section 1401.A. was amended for grammar.

Section 1401.C. was amended for clarity.

Section 1402.B. was amended for clarity.

Section 1403.C. was added to prohibit an individual under eighteen (18) years of age from requesting or receiving a DNR in accordance with state law.

Section 1406.F. was amended to add the clarification “(ONLY withheld in the face of cardiac arrest)” for the restriction of continuous cardiac monitoring.

Section 1407.A. was revised for clarity: “suction” to “suctioning.”

Section 1407.D. was revised for grammar since more than one medication is meant.

Section 1500. Fines and Monetary Penalties.

New Section 1500 was added.

New Section 1501.A. contains a schedule of monetary penalties for class violations. The table related to monetary penalties was moved from existing Section 304.F with no changes to the penalty amounts.

New Section 1501.B. also incorporates the schedule of fines for failed reinspections of permitted ambulances or the new Category IV violations. The table was moved from existing Section 401.C.1 with defined fine amounts based on failed points accrued.

New Section 1501.C. was added to delineate actions for multiple occurrences of violations.

Section 1600. Severability.

This section was renumbered to 1600. No substantive changes were made.

Section 1700. General.

This section was renumbered to 1700. No substantive changes were made.

Instructions: Replace Regulation 61-7, Emergency Medical Services, in its entirety.

Text:

61-7. Emergency Medical Services.

Statutory Authority: 1976 Code Sections 44-61-30 and 44-78-65

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SECTION 100.

SCOPE AND PURPOSE

Section 101. Scope of Act 1118 of 1974 as amended.

- A. Establishment of EMS program.
- B. General licensing, certification, inspection and training procedures.
- C. Establishment of an Emergency Medical Service Council and duties of the Council.
- D. Establishment of the Department of Health and Environmental Control authority for enforcement of these rules and regulations.

SECTION 200.

DEFINITIONS

A. Advanced Life Support (ALS): An advanced level of prehospital, interhospital, and emergency service care which includes but is not limited to the treatment of life-threatening medical emergencies through the use of techniques such as endotracheal intubation, administration of medications or intravenous fluids, cardiac monitoring, and electrical therapy by a qualified person pursuant to these regulations.

B. Advanced Life Support Service: A service provider that in addition to basic life support minimum standard, provides at least two (2) EMTs, one of which is a Paramedic and demonstrates the capability to provide IV therapy, advanced airway care, approved medication therapy, cardiac monitoring and defibrillation capability.

C. Air ambulance: Any aircraft that is intended to be used for and is maintained or operated for transportation of persons who are sick, injured or otherwise incapacitated.

1. Fixed Wing: Any aircraft that uses fixed wings to allow it to take off and fly.

2. Rotorcraft: A helicopter or other aircraft that uses a rotary blade to allow vertical and horizontal flight without the use of wings.

D. Basic Life Support Service: A service provider that meets all criteria for basic life support minimum standard and is able to provide one EMT to one hundred percent (100%) of all calls and the ability to provide blind insertion airway devices (BIADs) and defibrillation capability.

E. Commission on Accreditation of Allied Health Education Programs (CAAHEP): A programmatic accreditor in the health sciences field. In collaboration with its Committees on Accreditation, CAAHEP reviews and accredits educational programs in health science occupations.

F. Committee on Accreditation of Educational Programs for the Emergency Medical Service Professionals (CoAEMSP): The national accreditation organization specific to Paramedic education programs. Paramedic education programs must have CoAEMSP accreditation or a letter of review from CoAEMSP in order for their students to qualify for the National Registry examination.

G. Condition Requiring an Emergency Response: The sudden onset of a medical condition manifested by symptoms of such sufficient severity, including severe pain, which a prudent layperson who possesses an average knowledge of health and medicine could reasonably expect without medical attention, to result in:

1. Serious illness or disability;
2. Impairment of a bodily function;
3. Dysfunction of the body; or
4. Prolonged pain, psychiatric disturbance, or symptoms of withdrawal.

H. Continuing Education: An educational program designed to update the knowledge and skills of its participants by attending conventions, seminars, workshops, educational classes, labs, symposiums, and the like. Points toward recertification may be awarded for successful completion of approved activities.

I. Credentialing Information System (CIS): Database managed by EMS Performance Improvement Center (EMSPIC) which tracks EMS information and data such as certifications, licenses, permits, and inspections.

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J. Driver: In the EMS context, the vehicle operator of an ambulance. This person may be a certified EMT of any level or an uncertified individual who meets the minimum requirements as a driver by this regulation in Section 403.

K. Electronic Patient Care Reports (ePCR): Patient care reports authored and submitted electronically into PreMIS which is compliant with the National EMS Information System (NEMSIS).

L. Emergency: For the purposes of this regulation, an emergency is an acute situation in which a prudent layperson has identified a potential medical threat to life or limb such that the absence of immediate medical attention could reasonably be expected to result in placing the individual's health in serious jeopardy, serious impairment of bodily functions, or serious dysfunction of bodily organs.

M. Emergency Transport: Services and transportation provided after the sudden onset of a medical condition manifesting itself by acute symptoms of such severity, including severe pain, that the absence of medical attention could reasonably be expected to result in the following:

1. Placing the patient's health in serious jeopardy;
2. Causing serious impairment of bodily functions or serious dysfunction of bodily organ or part; or
3. A situation resulting from an accident, injury, acute illness, unconsciousness, or shock, for example, requiring oxygen or other emergency treatment, or requiring the patient to remain immobile.

N. EMT: Emergency Medical Technician. When used in general terms for emergency medical personnel, an individual possessing a valid EMT, Advanced EMT (AEMT), or Paramedic certificate issued by the State of South Carolina pursuant to the provisions of this regulation and applicable governing statute.

1. Emergency Medical Technician (EMT): Formerly called an "EMT-Basic," this nationally credentialed level of prehospital emergency medical providers is a person who is specially trained and certified to administer basic emergency services to victims of trauma or acute illness before and during transportation to a hospital or other healthcare facility.

2. Emergency Medical Technician – Intermediate (EMT-I): A nationally credentialed mid-level of prehospital emergency medical providers. The EMT-I is intended to deliver augmented prehospital critical care and provide rapid on-scene treatment, working in conjunction with EMTs and Paramedics. The EMT-I is authorized to provide more advanced medical treatment than the EMT. According to the NREMT, after March 31, 2017, EMT-I certifications are being replaced by the Advanced Emergency Medical Technician (AEMT) credential with a greater scope of practice than the EMT-I.

3. Advanced Emergency Medical Technician (AEMT): A nationally credentialed mid-level of prehospital emergency medical providers. The AEMT is intended to deliver augmented prehospital critical care and provide rapid on-scene treatment, working in conjunction with EMTs and Paramedics. The AEMT is authorized to provide more advanced medical treatment than the EMT.

4. Paramedic: The highest nationally credentialed level of prehospital emergency medical providers. The Paramedic is intended to provide leadership and to deliver prehospital emergency care and provide rapid on-scene treatment. The Paramedic is authorized to provide the highest level of prehospital care in accordance with standards set by the Department.

O. EMT Rapid Responder Agency: Formerly known as "EMT First Responder Service," a licensed agency providing medical care at the EMT level or above as a nontransporting rapid responder.

P. FAA: Federal Aviation Administration. The agency of the federal government that governs aircraft design, operations, and personnel requirements.

Q. Flight Nurse: A licensed registered nurse who is trained in all aspects of emergency care who has been so designated by the Department.

R. Ground Ambulance: A vehicle maintained or operated by a licensed provider who has obtained the necessary permits and licenses for the transportation of persons who are sick, injured, wounded, or otherwise incapacitated. Ambulances provide both emergent and non-emergent transport.

1. Special purpose ambulance: An ambulance equipped and designated to transport by medical necessity only patients in need of specific specialized types of care and staffed by appropriate specialty care attendant(s). Examples may include special purpose ambulances such as neonatal units, and critical care ambulances.

S. HIPAA: Health Insurance Portability and Accountability Act of 1996.

T. Intermediate Life Support Service: A service provider that, in addition to basic life support minimum standard, provides at least two (2) EMTs, one of which is an EMT-I, AEMT or Paramedic and demonstrates the capability to provide IV therapy, blind insertion airway devices (BIADs), and defibrillation capability.

U. Joint Policy Statement on Equipment for Ground Ambulances (JPS): National document drafted and published on January 1, 2014, by the American Academy of Pediatrics, American College of Emergency Physicians, American College of Surgeons Committee on Trauma, Emergency Medical Services for Children, Emergency Nurses Association, National Association of EMS Physicians, and the National Association of State EMS Officials to serve as a referenced standard for equipment needs of emergency ground ambulance services in the United States.

V. Medical Control: Medical Control is usually provided by a licensed agency's physician who is responsible for the care of the patient by the provider's medical attendants. Actual medical control may be direct by two-way voice communications (on-line) or indirect by standing orders or protocols (off-line) control.

1. Off-Line Medical Control Physician: A provider's Medical Control Physician who actually takes responsibility for treatment of patients in the prehospital setting by standing orders, protocols, or patient care guidelines.

2. On-Line Medical Control Physician: The physician who directly communicates with EMTs regarding appropriate patient care procedures en-route or on-scene. An on-line Medical Control Physician must be available for all EMTs performing procedures designated by the Department.

W. Moral Turpitude: Behavior that is not in conformity with and is considered deviant by societal standards.

X. National Emergency Services Information System (NEMSIS): NEMSIS is the national repository of EMS data that is collected from across the United States. The data is used to define EMS and prehospital care, improve patient care, determine the national standard of care, and help design EMS curriculum.

Y. National Registry of Emergency Medical Technicians (NREMT): A national certification agency which establishes uniform standards for training and examination of personnel active in the delivery of prehospital emergency care. Individuals possessing a valid NREMT certification have successfully demonstrated competencies in their level of prehospital provider.

Z. Nonemergency Transport: Services and transportation provided to a patient whose condition is considered stable. A stable patient is one whose condition by caregiver consensus can reasonably be expected to remain the same throughout the transport and for whom none of the criteria for emergency transport has been met.

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Prearranged transports scheduled at the convenience of the service, the patient, or medical facility will be classified as a nonemergency transport.

AA. Patient: A patient is defined as any person who meets any of the following criteria:

1. Receives basic or advanced medical or trauma treatment;
2. Is physically examined;
3. Has visible signs of injury or illness or has a medical complaint;
4. Requires EMS specific assistance to change locations and/or position;
5. Identified by any party as a possible patient because of some known, or reasonably suspected illness or injury;
6. Has a personal medical device evaluated or manipulated by EMS; or
7. Requests EMS assistance with the administration of personal medications or treatments.

BB. Prehospital Care: Assessment, stabilization, and care of a patient, including, but not limited to the transportation to an appropriate receiving facility.

CC. Prehospital Medical Information System (PreMIS): A state mandated internet based EMS information system that collects data on each EMS call report made within South Carolina.

DD. Revocation: The Department has permanently voided a license, permit, or certificate and the holder no longer may perform the function associated with the license, permit, or certificate. The Department will not reissue the license, permit, or certificate for a period of two (2) years for a license or permit and four (4) years for a certificate. At the end of this period, the holder may petition the Department for reinstatement.

EE. Special Purpose EMT: A state credentialed prehospital emergency medical provider. This person is a South Carolina licensed registered nurse (RN) or a Nurse Licensure Compact (NLC) State RN who works in a critical care hospital setting such as neonatology, pediatrics, or cardiac care. These Special Purpose EMTs provide a continuance of critical care during transport while aboard special purpose ambulances permitted by the State and equipped for their specialty area.

FF. Specialty Care: Advanced care skills provided by an appropriately credentialed attendant in their specific specialty area. These may include but are not limited to Paramedics, Special Purpose EMTs in their area of specialty, RNs, and respiratory therapists.

GG. "Star of Life": A six (6) barred blue cross outlined with a white border of which all angles are sixty (60) degrees and upon which is superimposed the staff of Aesculapius in white. This is a registered trademark of the U.S. Department of Transportation.

HH. Suspension: The Department has temporarily voided a license, permit, or certificate and the holder may not perform the function associated with the license, permit, or certificate until the holder has complied with the statutory requirements and other conditions imposed by the Department.

II. The Department: The administrative agency known as the South Carolina Department of Health and Environmental Control.

JJ. Vocational School: Also called a trade school, is a higher-level learning institution that specializes in providing students with the vocational education and technical skills they need in order to perform the tasks of a particular job.

KK. Volunteer EMS Provider: A not-for-profit EMS provider which serves its local community with emergency medical service coverage at any level and is staffed by at least ninety percent (90%) non-paid staff. For the purpose of this regulation, token stipends received by volunteer EMS providers are not considered paid remuneration or a primary wage.

SECTION 300.

ENFORCING REGULATIONS

Section 301. General.

A. The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding an EMT, training facility, instructor, Medical Control Physician, or provider in order to enforce these regulations.

B. The Department reserves the right to make exceptions to these regulations where it is determined that the health and welfare of those being served would be compromised.

Section 302. Inspections and Investigations.

A. An inspection shall be conducted prior to initial licensing of a provider and subsequent inspections conducted as deemed appropriate by the Department.

B. All providers, permitted vehicles, equipment used for rapid response by licensed agencies, EMTs, training facilities, and instructors 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, equipment, and records, and have the authority to require that entity to make photo and/or electronic copies of those documents required in the course of inspections or investigations. These copies 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.

Section 303. Enforcement Actions.

When the Department determines that an EMT, provider, instructor, or training facility 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 certification, license, or authorization or take other actions deemed appropriate by the Department. The schedule of fines and monetary penalties is noted in Section 1501.

Section 304. 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 persons being served, other employees, or the general public; or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more

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practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be considered a subsequent violation.

B. Class II violations are those other than Class I violations the Department determines to have a negative impact on the health, safety or well-being of those being served, other employees, or the general public. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists 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. A physical condition or one or more practices, means, methods, operations, or lack thereof may constitute such a violation. Each day such violation exists may be considered a subsequent violation.

D. Class IV violations are those that are specific to vehicle reinspection failures. These violations can escalate based on frequency and point value accrued per deficiency identified in the vehicle inspections conducted by the Department.

E. 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, respectively. Standards not so annotated are considered Class III violations. Class IV violations are specific to vehicle reinspections which may escalate to Class III violations.

F. 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 the health, safety, or well-being of those being served, other employees and the general public, efforts by the EMT, provider, training facility or instructor to correct cited violations; behavior of the entity in violation that reflects negatively on that entity’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.

G. A schedule of all monetary penalties is delineated in Section 1501.

H. Any enforcement action taken by the Department may be appealed pursuant to the Administrative Procedures Act beginning with S.C. Code Section 1-23-310.

SECTION 400.

LICENSING PROCEDURES

Section 401. Application.

A. Application for license shall be made to the Department by private firms, public entities, volunteer groups or non-federal governmental agencies. The application shall be made upon forms in accordance with procedures established by the Department and shall contain the following:

1. The name and address of the owner of the licensed provider or proposed licensed provider;
2. The name under which the applicant is doing business or proposes to do business;
3. A copy of the licensed provider or proposed licensed provider’s business license (if applicable) for the location of the service;

4. A description of each ambulance, and/or rapid response vehicle, including the make, Vehicle Identification Number (VIN), model, year of manufacture or other distinguishing characteristics to be used to designate applicant's vehicle;

5. The location and description of the place or places from which the licensed provider is intended to operate. The Department shall be notified within five (5) working days of any expansion or contraction of the service, level of care (upgrade or downgrade), or if the headquarters, director or any substation locations are changed;

6. Personnel roster representing all employees, volunteers, and affiliates associated with the service including but not limited to EMTs, non-certified drivers (if applicable), pilots, RNs, certification numbers and expiration dates of their South Carolina and NREMT credentials (if applicable);

7. Type of license applied for;

8. Name, email address, and phone number of Medical Control Physician;

9. Name, email address, and phone number of the following, if applicable;

a. EMS Director;

b. EMS Assistant Director;

c. Training Officer;

d. Data Manager; and

e. Infection Control Officer.

10. Number of vehicles and level of service provided from each fixed station location;

11. Insurance information, to include name of insurance company, agent, phone number and type of coverage. A copy of insurance policy(ies) shall be furnished to the Department upon request. The minimum limits of coverage shall be six hundred thousand dollars (\$600,000) liability and three hundred thousand dollars (\$300,000) malpractice per occurrence.

12. A copy of the EMS Non-dispensing Drug Permit from the South Carolina Board of Pharmacy. If out-of-state provider, the respective home state equivalent;

13. A copy of the agency's current Drug Enforcement Agency license (both South Carolina and federal), when applicable. If out-of-state provider, the respective home state equivalent;

14. A copy of the agency's Clinical Laboratory Improvement Act (CLIA) waiver from the Centers for Medicare & Medicaid Services (CMS) if agency is providing field laboratory testing such as blood glucose readings or cardiac markers; and

15. Such other information as the Department shall deem reasonable and necessary to make a determination of compliance with this regulation.

B. The Department shall issue a license valid for a period of two (2) years when it is determined that all the requirements of this regulation have been met. If disapproved, the applicant may appeal in a manner pursuant to the Administrative Procedures Act beginning with S.C. Code Section 1-23-310.

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C. Subsequent to issuance of any license, the Department shall cause to be inspected each licensed provider (vehicles, equipment, personnel, records, premises, and operational procedures) whenever that service is initially licensed. Thereafter, services will be inspected by the Department on a random basis. These random inspections may be conducted dependent upon past compliance history. The schedule of fines and monetary penalties is noted in Section 1501.

D. The Department is herein authorized pursuant to S.C. Code Section 44-61-70, to suspend or revoke a license so issued at any time it determines that the holder no longer meets the requirements prescribed for operating as a licensed provider.

E. Renewal of any license issued under the provision of this Act shall require conformance with all the requirements of this Act as upon original licensing.

F. The Department shall be notified within five (5) working days when changes of ownership of a licensed provider are impending or occur so that a new license may be issued.

G. Conditions which have not been covered in these regulations shall be handled in accordance with the standard practices as interpreted by the Department.

Section 402. Medical Control Physician. (I)

Each licensed provider that provides patient care shall retain a Medical Control Physician to maintain quality control of the care provided, whose functions include the following:

A. Quality assurance (QA) of patient care including development of protocols, standing orders, training, policies, and procedures; and approval of medications and techniques permitted for field use by direct observation, field instruction, in-service training (IST) or other means including, but not limited to:

1. Patient care report review;
2. Review of field communications recordings;
3. Post-run interviews and case conferences; and
4. Investigation of complaints or incident reports.

B. The Medical Control Physician shall serve as medical authority for the licensed provider, to perform in liaison with the medical community, medical facilities, and governmental entities.

C. The Medical Control Physician shall have independent authority sufficient to oversee the quality of patient care for the agency.

D. Providers shall register their Medical Control Physician with the Department and provide a copy of their current standing orders and authorized medication list signed and dated by Medical Control Physician.

E. The Department must be notified of any change in Medical Control Physician, drug list, or standing orders within ten (10) days of the change.

F. The Medical Control Physician may withdraw at his or her discretion, the authorization for personnel to perform any or all patient care procedure(s) or responsibilities.

G. All initial Medical Control Physicians must attend a Medical Control Physician Workshop conducted by the Department within twelve (12) months of being designated Medical Control Physician. Failure to attend the above mentioned workshop will result in immediate dismissal from that position.

H. Medical Control Physicians shall complete Department mandated continuing education updates to maintain their status.

I. Medical Control Physicians may respond to scene calls to render care, function as medical providers, provide medical direction, and/or exercise their medical oversight authority.

J. Providers may have multiple Medical Control Physicians especially if they have multiple regional locations.

Section 403. Non-Credentialed Ambulance Operator or Driver. (II)

A. An ambulance driver shall:

1. Be at least eighteen (18) years old;
2. Be physically able to drive;
3. Possess a valid (non-disqualified) driver’s license from South Carolina or home state of provider. In the event of suspension or revocation of the driver’s license, the individual shall notify their agency and the agency must notify the Department;
4. Have a criminal background check required on initial hire and thereafter every four (4) years which meets the same requirements as certified EMS personnel as noted in Section 902.B; and
5. Display a picture ID in a manner visible to the public all times while on duty.

B. An ambulance driver shall complete a nationally accredited safety driving course, such as Certified Emergency Vehicle Operator (CEVO), specific to emergency vehicles within the first six (6) months of hire.

C. In emergencies that may require a third crew member, such as multiple casualty incidents (MCIs), disasters, or where immediate local EMS resources are taxed, an ambulance may, out of necessity, be driven to the hospital by a member of a fire department, law enforcement agency, or rescue squad. These out-of-necessity drivers are exempt from Section 403.A and B in this limited context.

D. Each EMS agency shall maintain its EMS drivers’ records and submit those credentials upon its initial agency license application and bi-annual agency license renewal.

Section 404. Criteria for License Category Basic Life Support (Ambulance). (II)
(Minimum Standard):

A. Shall have ambulances that are permitted pursuant to these regulations.

B. Shall have no less than five (5) currently credentialed South Carolina EMTs associated with the provider.

C. Shall have staffing patterns, policy and procedure, and if necessary, mutual aid agreements to ensure that an ambulance is en route with at least one (1) EMT and one (1) driver onboard to all emergent responses within five (5) minutes or the next closest staffed ambulance must be dispatched, excluding prearranged transports. Volunteer Services (services not utilizing paid personnel) without onsite personnel must have staffing patterns, policy and procedures, and if necessary, mutual aid agreements to ensure that an ambulance is en route with at

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least one (1) EMT and one (1) driver onboard to all emergent calls within ten (10) minutes or have the closest staffed ambulance dispatched.

D. Vehicle operators or attendants shall not utilize emergency lights and sirens unless the service is responding to a patient with a condition requiring emergency response, as defined in Section 200.G. Vehicle operators or attendants shall not utilize emergency lights and sirens from a call unless the service is conducting an emergency transport, as defined in Section 200.L.

E. The provider must demonstrate sufficient equipping and staffing capability to ensure that basic life support consisting of at least automatic defibrillation (AED), basic airway management, obstetrical care, and basic trauma care are onboard the ambulance.

F. The Department will, upon request, be furnished with staffing patterns, policy and procedure, and mutual aid agreements that ensures compliance with the en route times noted in Section 404.C.

G. Industries that provide ambulance service or rapid medical response for their employees may exempt the minimum number of EMTs noted in Section 404.B, as long as they meet en route times and staffing requirements of the regulations.

H. The provider maintains accurate records that include, but are not limited to, approved patient care reports, employee / member rosters, time sheets, CIS rosters, call rosters, training records and dispatch logs that show at least the time call was received, the type of call, and the time the unit was en route. Such records shall be available for inspection by the Department with copies furnished upon request.

Section 405. Criteria for License Category – Intermediate Life Support: (Ambulance). (II)

A. To be categorized as an intermediate life support (ILS) provider, the provider must meet all criteria established for basic life support (BLS), minimum standard. Additionally, the provider must demonstrate sufficient equipping to ensure that life support consisting of at least IV therapy, blind insertion airway devices (BIADs), and defibrillation capability (either manual or by AED) are onboard the ambulance. The minimum staffing of an ILS ambulance shall consist of two (2) EMTs, one (1) of which must be an EMT-I, AEMT or Paramedic, at least ninety-five percent (95%) of the time. B. An ILS licensed provider may elect to participate in a tiered response system. The provider must have a process in place to identify the acuity of the incoming EMS request in order to properly triage the response and dispatch the appropriate level unit(s). Triage calls may take place with assets such as Emergency Medical Dispatching (EMD) or other means that identifies whether the request is classified as an “ILS” or “BLS” level of response. BLS personnel may operate on an ILS equipped ambulance in the case where an ILS credentialed responder may intercept the unit. In the case where an ILS responder intercepts a BLS unit with a Quick Response Vehicle (QRV), all equipment needed to raise the level of permitting to ILS must be transferred to the BLS unit prior to commencing patient transport.

Section 406. Criteria for License Category - Advanced Life Support: (Ambulance). (II)

A. To be categorized as an advanced life support (ALS) provider, the provider must meet all criteria established for basic life support, minimum standard. Additionally, the provider must demonstrate sufficient equipping to ensure that life support consisting of IV therapy, advanced airway care, cardiac monitoring, defibrillation capability and drug therapy, approved by the Department and the unit Medical Control Physician, are onboard the ambulance. The minimum staffing of an ALS ambulance shall consist of a minimum of two (2) EMTs, one (1) of which must be a Paramedic at least ninety-five percent (95%) of the time. B. An ALS licensed provider may elect to participate in a tiered response system. The provider must have a process in place to identify the acuity of the incoming EMS request in order to properly triage the response and dispatch the appropriate level unit(s). Triage calls may take place with assets such as Emergency Medical Dispatching (EMD) or other means that identifies whether the request is classified as an “ALS” or “BLS” level of response. BLS personnel may operate on an ALS equipped ambulance in the case where an ALS credentialed responder

may intercept the unit. In the case where an ALS responder intercepts a BLS unit with a QRV, all equipment needed to raise the level of permitting to ALS must be transferred to the BLS unit prior to commencing patient transport.

Section 407. Criteria for License Category - Special Purpose Ambulance Provider: (Ambulance). (II)

A. Have an approved vehicle that is in compliance with Section 200.R.1 and meets minimum equipment requirements, as delineated in Section 704.

B. Have a Medical Control Physician as delineated in Section 402.

C. Provide the Department with copies of policy and procedures for the operation of the special purpose ambulance.

D. Provide a list, approved by the Medical Control Physician, of special purpose equipment carried on the special purpose ambulance for review and approval by the Department.

E. Provide other license information delineated in Section 401.

F. Except during extenuating circumstances, special purpose ambulances shall be used for interfacility transports only.

Section 408. Advanced Life Support Information. (II)

A. Ambulance service providers professing to provide ALS level of care, whether licensed at the ALS level or not, must at all times transport an ALS patient in an ambulance which is fully equipped as an ALS unit, per these regulations, with a Paramedic, physician or RN, as delineated in these regulations, in the patient compartment.

B. The minimum staffing for any transport above the BLS level (for BLS licensed providers), shall be two (2) certified EMTs, one (1) of which must be an EMT-I, an AEMT, or a Paramedic one hundred percent (100%) of the time. A BLS licensed agency may only deviate from this staffing pattern when responding to a mutual aid call for service. At that time, the units must be staffed with two (2) EMTs, one (1) of which must be a Paramedic ninety-five percent (95%) of the time for ALS responses.

Section 409. Advertising Level of Care. (II)

Ambulance service providers may not advertise that they provide a level of life support above the category for which they are licensed.

Section 410. Criteria for License Category - EMT Rapid Responder. (II)

A. Personnel assigned to Rapid Responder duty must be currently certified EMTs with no less than five (5) EMTs associated with the provider. The certification level of the responder must coincide with the agency's level of licensure. If the Rapid Responder agency is requested to respond, an EMT must respond on calls for an EMT licensed agency and a Paramedic must respond on calls for a Paramedic licensed agency eighty percent (80%) of the time.

B. Must have staffing patterns, policy and procedures, to ensure that a Rapid Responder unit is en route with at least one (1) EMT to all emergent calls within five (5) minutes. Volunteer units (services not utilizing paid personnel) without onsite personnel must have staffing patterns, policy and procedures to ensure that a Rapid Responder unit is en route with at least one (1) EMT to all emergent calls within ten (10) minutes.

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C. The Department will, upon request, be furnished with staffing patterns, policy and procedures to ensure compliance with the en route times noted in Section 410.B.

D. The provider maintains records that include, but are not limited to, approved patient care report forms, employee/member rosters, time sheets, call rosters, training records and dispatch logs that show at least time call received, type call and time unit is en route. Such records are to be available for inspection by the Department with copies furnished upon request.

Section 411. Special Exemptions for Volunteer EMS Providers Squads.

A. A volunteer EMS provider must have an EMT or higher, attending to the patient at the scene and in the ambulance while transporting the patient to the hospital.

B. If a volunteer EMS provider has a written response policy in place in which an EMT is allowed to respond directly to the scene from home or work, the ambulance may respond to the scene of the emergency even if an EMT is not on board. If the EMT does not arrive at the scene and another service is immediately available with appropriate staffing, the patient shall be transported by that service. If no other service is immediately available, the patient shall not be transported without at least one (1) EMT on board. Continual and repeated failure of a service to ensure an EMT arrives at the scene to provide care and transport may result in the Department taking disciplinary action against the agency.

C. If only one (1) EMT is available to staff the ambulance crew, that EMT must be the patient care provider and/or supervise the patient care being provided. The EMT may not be the driver of the ambulance when a patient is being transported.

D. An ambulance shall not respond to the scene of an emergency if it is known in advance that an EMT is not available. All ambulance services shall preplan for the lack of staffing by written mutual aid agreements with neighboring agencies and by alerting the local Public Safety Answering Point (PSAP) as early as possible when you know that EMT level staffing is not available. Careful preplanning, mutual aid agreements, and continual recruitment programs are necessary to ensure sufficient EMT staffing.

E. In all cases where the level of care is either EMT-I, AEMT, or Paramedic, the transporting unit shall be fully equipped to perform at that level of care.

SECTION 500.

PERMITS, AMBULANCE (I)

Section 501. Vehicle and Equipment.

A. Before a permit may be issued for a vehicle to be operated as an ambulance, its registered owner must apply to the Department for an ambulance permit. Prior to issuing an original or renewal permit for an ambulance, the Department shall determine that the vehicle for which the permit is issued meets all requirements as to design, medical equipment, supplies and sanitation as set forth in these regulations of the Department. Prior to issuance of the original permit, if the ambulance does not meet all minimum requirements and loses points during the inspection, no permit will be issued.

B. Permits will be issued for specific ambulances and will be displayed on the upper left-hand interior corner of the windshield of the ambulance or in the aircraft portfolio, whichever is applicable.

C. No official entry made upon a permit may be defaced, altered, removed or obliterated.

D. Permits may be issued or suspended by the Department.

E. Permits must be returned to the Department within ten (10) business days when the ambulance or chassis is sold, removed from service, or when the windshield is replaced due to damage.

F. The Department must be notified within seventy-two (72) hours of any collision (including pedestrians) involving any licensed provider’s vehicle or aircraft used to provide emergency medical services including rapid response, that results in any degree of injury to personnel, patients, passengers, observers, students, or other persons. The licensed agency must submit to the Department the vehicle’s issued permit (if applicable) if the damage renders the permitted vehicle out of service for more than two (2) weeks. The investigating law enforcement agency’s accident report shall also be forwarded to the Department when received by the agency when the above situations occur and the incident is reportable to the Department.

G. Licensed transport agencies may utilize Quick Response Vehicles (QRVs) which are non-permitted, first-response type vehicles. A QRV will be staffed with a minimum of one (1) provider that is credentialed at a level determined by the local Medical Control Physician (BLS, ILS, ALS) and equipped with locally adopted and Medical Control Physician authorized equipment, also in accordance with the level of credentialing as determined by the Medical Control Physician. For the purpose of this regulation, associated special event vehicles such as motorcycles, watercraft, all-terrain vehicles (ATVs), and bicycles fall under the QRV umbrella.

H. The Department shall not issue a vehicle or aircraft permit to an EMS provider that is unlicensed in South Carolina.

Section 502. Temporary Assets.

A. In cases where a short-term solution to an ambulance resource is needed (temporary rentals or loaner ground or air transport units), the Department may issue a temporary permit to a short-term asset. These temporary assets shall meet all initial equipment requirements for classification as specified in this regulation for the level of intended service.

B. Temporary permits shall be issued for a period not to exceed ninety (90) days and may only be renewed for extraordinary circumstances on a case-by-case basis.

C. Minimum exterior markings.

1. Illumination devices shall meet Section 601.F.1 and F.2.
2. Emblems and markings shall meet or exceed Section 601.B.1 and B.2 and may be affixed on vehicle with temporary markings.
3. The name of the service as stated in the provider’s license shall be of lettering not less than three (3) inches in height and may be affixed with temporary markings.
4. Temporary permitted air transport units are exempt from the minimal exterior markings requirements.

SECTION 600.

STANDARDS FOR AMBULANCE PERMIT

Section 601. Ambulance Design and Equipment.

The following designs are hereby established as the minimum criteria for ambulances utilized in South Carolina and are effective with the publication of these regulations. Any ambulance purchased after publication of these requirements must meet the following minimum criteria.

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A. Based Unit: Chassis shall not be less than three quarter ton. In the case of modular or other type body units, the chassis shall be proportionate to the body unit, weight and size; power train shall be compatible and matched to meet the performance criteria listed in the Federal KKK-A-1822 Specification, NFPA 1917, or similar specification standards accepted by the Department; maximum effective sized tires; power steering; power brakes; heavy duty cooling system; heavy duty brakes; mirrors; heavy duty front and rear shock absorbers; seventy (70) amp battery; one hundred (100) amp alternator; front end stabilizer; driver and passenger seat belts; padded dash; collapsible steering wheel; door locks for all doors; inside mirror; inside control handles on rear and side doors; all applicable safety-related upgrades on timetables to be determined by the Department after release by the appropriate federal authority.

B. Emblems and Markings: All items in this section shall be of reflective quality and in contrasting color to the exterior painted surface of the ambulance.

1. There shall be a continuous stripe, of not less than three (3) inches on cab and six (6) inches on patient compartment, to encircle the entire ambulance with the exclusion of the hood panel.

2. Emblems and markings shall be of the type, size and location as follows:

a. Side: Each side of the patient compartment shall have the "Star of Life" not less than twelve (12) inches in height. The word "AMBULANCE", not less than six (6) inches in height, shall be under or beside each star. The name of the licensee as stated on their provider's license shall be of lettering not less than three (3) inches in height.

b. Rear: The word "AMBULANCE", not less than six (6) inches in height, and two (2) "Star of Life" emblems of not less than twelve (12) inches in height.

c. Out-of-state licensed ground transport units shall meet the same markings and standards as in-state licensed units, unless specifically forbidden by the unit's home state of licensure.

3. Prior to private sale of ambulance vehicles to the public, all emblems and markings in Section 601.B must be removed.

C. Interior Patient Compartment Dimensions:

1. Length: The compartment length shall provide a minimum of twenty-five (25) inches clear space at the head and fifteen (15) inches at the foot of a seventy-six (76) inch cot. Minimum inside length will be one hundred sixteen (116) inches.

2. Width: Minimum inside width is sixty-nine (69) inches.

3. Height: Inside height of patient compartment shall be a minimum dimension of sixty (60) inches from floor to ceiling.

D. Access to Vehicle:

1. Driver Compartment.

a. Driver's seat will have an adjustment to accommodate the 5th percentile to 95th percentile adult male.*

*Note: This means that the driver's area will accommodate the male drivers who are ninety percent (90%) of the smallest and largest in stature, which includes weight and size.

b. There shall be a door on each side of the vehicle in the driver's compartment.

c. Separation from the patient area is essential to afford privacy for radio communication and to protect the driver from an unruly patient. Provision for both verbal and visual communication between driver and attendant will be provided by a sliding shatterproof material partition or door. The bulkhead must be strong enough to support an attendant's seat in the patient area at the top of the patient's head and to withstand deceleration forces of the attendant in case of accident.

2. Patient Compartment:

a. There shall be a door on the right side of the patient compartment near the patient's head area of the compartment. The side door must permit a technician to position himself at the patient's head and quickly remove him from the side of the vehicle should the rear door become jammed.

b. Rear doors shall swing clear of the opening to permit full access to the patient's compartment.

c. All patient compartment doors shall incorporate a holding device to prevent the door closing unintentionally from wind or vibration. When doors are open the holding device shall not protrude into the access area. Special purpose ambulances are exempt as long as access/egress is not obstructed due to wheelchair ramps or other specialized equipment.

d. Spare tire, if carried, shall be positioned such that the tire can be removed without disturbing the patient.

E. Interior Lighting:

1. Driver Compartment: Lighting must be available for both the driver and an attendant, if riding in the driving compartment, to read maps, records, or other. There must be shielding of the driver's area from the lights in the patient compartment.

2. Patient Compartment: Illumination must be adequate throughout the compartment and provide an intensity of forty-foot (40-foot) candles at the level of the patient for adequate observation of vital signs, such as skin color and pupillary reflex, and for care in transit. Lights shall be controllable from the entrance door, the head of the patient, and the driver's compartment. Reduced lighting level may be provided by rheostat control of the compartment lighting or by a second system of low intensity lights.

F. Illumination Devices:

1. Illumination Devices: Flood and load lights. There shall be at least one (1) flood light mounted not less than seventy-five (75) inches above the ground and unobstructed by open doors located on each side of the vehicle. A minimum of one (1) flood light, with a minimum of fifteen (15) foot candles, shall be mounted above the rear doors of the vehicle.

2. Warning lights. At a minimum alternating flashing red lights must be on the corners of the ambulance so as to provide three hundred sixty (360) degrees conspicuity.

G. Seats:

1. A seat for both driver and attendant will be provided in the driver's compartment. Each seat shall have armrests on each side of driver's compartment.

2. Technician (Patient Compartment): Two (2) fixed seats, padded, eighteen (18) inches wide by eighteen (18) inches high; to head of patient behind the driver, the other one may be square bench type located on curb (right) side of the vehicle. Space under the seats may be designed as storage compartments.

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H. Safety Factors for Patient Compartment:

1. Cot Fasteners: Crash-stable fasteners must be provided to secure a primary cot and secondary stretcher.

2. Cot Restraint: If the cot is floor supported on its own support wheels, a means shall be provided to secure it in position under all conditions. These restraints shall permit quick attachment and detachment for quick transfer of patient. All newly-manufactured ambulances purchased for use in South Carolina after July 1, 2017, shall meet all seating and cot restraint mandates outlined in the Federal KKK-A-1822F, all change notices included.

3. Patient Restraint: A restraining device shall be provided to prevent longitudinal or transverse dislodgement of the patient during transit, or to restrain an unruly patient to prevent further injury or aggravation to the existing injury.

4. Safety Belts for Drivers and Attendants:

a. Quick-release safety belts will be provided for the driver, the attendants, and all seated patients (squad bench). These safety belts will be retractable and self-adjustable.

5. Mirrors:

a. There shall be two (2) exterior rear view mirrors, one mounted on the left side of the vehicle and one (1) mounted on the right side. Location of mounting must be such as to provide maximum rear vision from the driver's seated position.

b. There shall be an interior rear view mirror or rear view camera to provide the driver with a view of occurrences in the patient compartment.

6. Windshield Wipers and Washers:

a. Vehicle is to be equipped with two (2) electrical windshield wipers and washers in addition to defrosting and defogging systems.

7. Sun Visors:

a. There shall be a sun visor for both driver and attendant.

I. Environmental Equipment: Driver/Patient Compartment.

1. Heating: Shall be capable of heating the compartment to a temperature of seventy-five (75) degrees Fahrenheit within a reasonable period while driving in an ambient temperature of zero degrees Fahrenheit. It must be designed to recirculate inside air, also be capable of introducing twenty percent (20%) of outside air with minimum effect on inside temperature. Fresh air intake shall be located in the most practical contaminant-free air space on the vehicle.

2. Heating Control: Heating shall be thermostatically or manually controlled. The heater blower motors must be at least a three (3) speed design. Separate switches will be installed in patient compartment.

3. Air Conditioning: Air Conditioning shall have a capacity sufficient to lower the temperature in the driver's and patient's compartment to seventy-five (75) degrees Fahrenheit within a reasonable period and maintain that temperature while operating in an ambient temperature of ninety-five (95) degrees Fahrenheit. The unit must be designed to deliver twenty percent (20%) of fresh outside air of ninety-five (95) degrees Fahrenheit

ambient temperature while holding the inside temperature specified. All parts, equipment, workmanship, shall be in keeping with accepted air conditioning practices.

4. Air Conditioning Controls: The unit air delivery control may be manual or thermostatic. The reheat type system is not required in the driver's compartment unit. Switches or other controls must be within easy reach of the driver in his normal driving position. Air delivery fan motor shall be at least a three (3) speed design. Switches and other control components must exceed in capacity the amperage and resistance requirements of the motors.

5. Environmental Control and Medications: The temperature in the patient compartment or anywhere medications are stored (QRVs, fire apparatus, rapid response vehicles, carry-in bags, and other) shall be monitored for temperature extremes to prevent drug adulteration. Medications (excluding oxygen) and IV fluids will be removed and discarded if the temperatures reach or exceed one hundred (100) degrees Fahrenheit (thirty-eight (38) degrees Celsius). Medications and IV fluids shall also be removed and discarded if temperatures in the drug storage area drop below twenty (20) degrees Fahrenheit (negative seven (-7) degrees Celsius).

6. Insulation: The entire body, side, ends, roof, floor, and patient compartment doors shall be insulated to minimize conduction of heat, cold, or external noise entering the vehicle interior. The insulation shall be vermin and mildew-proof, fireproof, non-hygroscopic, non-setting type. Plywood floor when undercoated will be considered sufficient insulation for the floor area.

J. Storage Cabinets: All cabinets must meet the criteria as stated in the most current edition of the Federal KKK-A-1822 Specification, NFPA 1917, or similar specification standards accepted by the Department as to types of surfaces, design and storage. Cabinets must be of sufficient size and configuration to store all necessary equipment. All equipment in interior cabinets must be accessible to attendant at all times.

K. Two-Way Radio Mobile: Two-way radio mobile equipment shall be included which will provide a reliable system operating range of at least a twenty (20) mile radius from the base station antenna. The mobile installation shall provide microphones for transmitting to at least medical control and receiving agencies, at both the driver's position and in the patient's compartment. Selectable speaker outputs, singly and in combination, shall be provided at the driver's position, in the patient's compartment, and through the PA system.

1. All radio frequencies utilized by a licensed service will be provided to the Department.

2. In the event technological advancements render the above components obsolete, the Department shall make determinations as to the efficacy of proposed technology on an individual basis prior to allowing their use.

L. Siren-Public Address: Siren and public address systems shall be provided. If a combined electronic siren and public address system is provided, in siren operation, the power output shall be minimum one hundred (100) watts. In voice operation the power output shall be at least forty-five (45) watts through two (2) exterior mounted speakers. The public address amplifier shall be independent of the mobile radio unit.

M. Antenna: Mounted with coaxial or other appropriate cable.

N. Glass Windows: All windows, windshield and door glass must be shatterproof.

O. Smoking Policy: Use of tobacco products or tobacco-like products (such as electronic cigarettes) is prohibited in the patient compartment and in the operator compartment of ambulances by all occupants.

P. The EMS provider shall establish a means to immediately identify that a vehicle is out of service for any operator who might have reason to use the vehicle. Any vehicle that is "out of service" whether for mechanical or staffing issues must be readily identifiable to the public and the Department. Out of service apparatus shall be identified by one (1) of the following means:

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1. Sign on outside of the driver's door near the door handle, minimum eight and one half inches by eleven inches (8.5" x 11") and red in color;
2. Special bag that covers the steering wheel, red in color, and labeled "Out of Service;"
3. Large sign on the driver's window, red in color, reading "Out of Service," laminated, or a permanent, commercially manufactured type, minimum eight and one half inches by eleven inches (8.5" x 11"). If the unit is being driven and is out of service, the sign may be placed in the far right hand corner of the front window so as to not obstruct the driver's vision but so as to be visible from the exterior of the vehicle; or
4. Highly visible mechanism at the driver's position on the vehicle that all members of the EMS provider recognize as an out of service indicator and is identified by a provider policy or standard operating procedure.

SECTION 700.

EQUIPMENT (II)

Section 701. Minimum Ambulance Medical Equipment.

The Joint Policy Statement on Equipment for Ground Ambulances (JPS) provides a recommended core list of supplies and equipment that shall be stocked on all ambulances to provide the accepted standards of patient care. For the purposes of this regulation, the following definitions from the JPS have been used:

Neonate: zero to twenty-eight (0-28) days of age;
Infant: twenty-nine (29) days to one (1) year; and
Child one (1) year old to eighteen (18), with delineations as follows:
Toddlers: one to two (1-2) years old;
Preschoolers: three to five (3-5) years old;
Middle childhood: six to eleven (6-11) years old; and
Adolescents: twelve to eighteen (12-18) years old.

Starting July 1, 2016, all ambulances shall be equipped with, but not limited to, all of the following:

A. Minimum of two (2) stretchers;

1. One (1) multilevel, elevating, wheeled cot with elevating back. Two (2) patient restraining straps (chest and thigh) minimum, at least two (2) inches wide shall be provided.

2. One (1) secondary patient transport stretcher, with a minimum of two (2) patient restraining straps. Minimum acceptable stretcher is vinyl covered, aluminum frame, folding stretcher.

B. Suction Devices;

1. An engine vacuum operated or electrically powered, complete suction aspiration system, shall be installed permanently on board to provide for the primary patient. It shall have wide bore tubing.

2. Portable suction device with regulator with at least a six (6) ounce reservoir.

3. Wide-bore tubing, rigid pharyngeal curved suction tip; tonsil and flexible suction catheters, 6 Fr–16 Fr, are commercially available must have two (2) between 6F and 10F and two (2) between 12 Fr and 16 Fr.

C. Oxygen Equipment;

1. Portable Oxygen Equipment: Minimum “D” size (360 Liter) cylinder, two (2) required (one (1) in service and one (1) full and sealed). Liter flow gauges shall be non-gravity, dependent type. Additionally, when the vehicle is in motion, all oxygen cylinders shall be readily accessible and securely stored.

2. Permanent On-Board Oxygen Equipment: The ambulance shall have a hospital grade piped oxygen system, capable of storing and supplying a minimum of 2400 liters of humidified medical oxygen.

3. Single-use, individually wrapped, non-rebreather masks and cannulas in adult and pediatric sizes shall be provided (three (3) each).

4. A “No Smoking” sign shall be prominently displayed in the patient compartment.

5. Pulse oximeter with adult and pediatric capabilities. Special Purpose Ambulances shall also maintain infant pulse oximetry capabilities.

D. Bag Mask Ventilation (BVM) Units;

1. One (1) adult, one (1) pediatric, one (1) infant: hand-operated. Valves must operate in all weather, and unit must be equipped to be capable of delivering ninety to one hundred percent (90-100%) oxygen to the patient. BVMs must include safety pop-off mechanism with override capability. Three (3) additional masks sizes small adult, toddler, and neonate shall be carried.

E. Nonmetallic Oropharyngeal (OPA) (Berman type) and Nasopharyngeal Airways (NPA);

1. All airways shall be clean and individually wrapped.

2. “S” tube-type airways may not be substituted for Berman type airways.

3. One each of the following sizes: NPA: 14 Fr-34 Fr and OPA sizes to accommodate neonate through large adult.

F. Bite sticks commercially made (clean and individually wrapped);

G. Eight (8) sterile dressings (minimum size five (5) inches by nine (9) inches);

H. Twenty-four (24) sterile gauze pads four (4) inches by four (4) inches;

I. Ten (10) bandages, self-adhering type, minimum three (3) inches by five (5) yards. Bandages must be individually wrapped or in clean containers;

J. A minimum of two (2) commercial sterile occlusive dressings, four (4) inches by four (4) inches;

K. Adhesive Tape, hypoallergenic, one (1) inch, two (2) inch, and three (3) inches wide;

L. Burn sheets, two (2), sterile;

M. Splints;

1. Traction type, lower extremity, overall length of splint minimum of forty-three (43) inches, with limb support slings, padded ankle hitch, traction device and heel stand. Either the Bi-polar or Uni-polar type is acceptable.

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2. Padded type, two (2) each, three (3) feet long, of material comparable to four-ply wood for coadaptation splinting of the lower extremities.

3. Padded wooden type, two (2) each, fifteen (15) inches by three (3) inches, for fractures of the upper extremity. Commercially available arm or leg splints may be substituted for items in Section 701.M.2 above, such as cardboard, metal, pneumatic, vacuum, or plastic.

N. Spinal immobilization devices;

1. Commercially available vest type KED, XP1 or other equivalent is acceptable.

2. Child backboard or pediatric board or any type commercially available spinal immobilization device sized for the pediatric patient.

3. Long spine board, at least sixteen (16) inches by seventy-two (72) inches constructed of three-quarter (3/4) inch impervious material and having at least three-quarter (3/4) inch runners on each side for lifting with appropriate straps. If not equipped with runners, board must be designed so handholds are accessible with work gloves.

4. Cervical collars to accommodate the infant, child, adolescent, and adult sizes. Collars must be manufactured of semi-rigid or rigid material. Commercially available adjustable collars may be substituted, must carry two (2) of each child adjustable and adult adjustable.

5. Six (6) patient restraint straps or commercially available disposable straps to accommodate patients from large adult to child sizes.

6. Head immobilization device, commercially available or towel or blanket rolls.

O. Three (3) each triangular bandages;

P. Two (2) blankets;

Q. Bandage shears, large size or trauma shears;

R. Obstetrical kit, sterile. The kit shall contain gloves, scissors or surgical blades, umbilical cord clamps or tapes, dressings, towels, perinatal pad, bulb syringe and a receiving blanket for delivery of infant;

S. Blood pressure manometer, cuff and stethoscope;

1. Blood pressure set, portable, both pediatric and adult.

2. Stethoscopes (adult and pediatric capable).

T. Emesis basin or commercially available emesis container;

U. Bedpan and urinal;

V. Two (2) functional battery operated, hand-carried flashlights or electric lanterns, suitable for illuminating both a localized work area or a walkway. Penlights do not meet this requirement;

W. Minimum of one (1) fire extinguisher, CO2 or dry chemical, five (5) pound capacity, type ABC;

X. Working gloves, two (2) pair with leather palms and reflective vests that meet American National Standard (ANSI 201) for High Visibility Public Safety Vests for each crew member;

Y. Minimum of 1000 cc of sterile water or normal saline solution for irrigation;

Z. Protective head gear and eye protection devices (minimum two (2) each) must be carried on each ambulance. Standard fire helmet face shield is not acceptable;

AA. Latex-free personal protective equipment including gloves, masks, gowns and eye shields;

BB. Automated External Defibrillator (AED) unless staffed by ALS personnel who are utilizing a manual monitor or defibrillator. Monitor may be utilized by BLS personnel if “AED Mode” is an available setting. The AED shall have pediatric capabilities, including child sized pads or a dose attenuator with adult pads;

CC. Flameless Flares: Three (3) red reflectorized (such as reflective triangles) or chemically induced illumination devices may be substituted for flares. Combustible type flares are not acceptable;

DD. One (1) set battery jumper cables, minimum 04 gauge copper, 600 amp rating;

EE. Glucometer with a minimum of five (5) test strips (Medical Control Option);

FF. One (1) commercially available arterial tourniquet device; and

GG. Five (5) adhesive bandages.

Section 702. Intermediate and Advanced Equipment.

Ambulances providing intermediate and advanced life support must, in addition to meeting all other requirements of Section 701 must have the following equipment:

A. Butterfly or scalp vein needles between nineteen (19) and twenty-five (25) gauge, a total of four (4) (Medical Control Option);

B. Four (4) each fourteen (14), sixteen (16), eighteen (18), twenty (20), twenty-two (22), and twenty-four (24) gauge IV cannulae;

C. Two (2) macro drip sets;

D. Two (2) micro drip sets;

E. Three (3) twenty-one (21) or twenty-three (23) and three (3) twenty-five (25) gauge needles, total six (6) as an MCO;

F. Three (3) intravenous (IV) tourniquets;

G. Laryngoscope handle with batteries;

H. Laryngoscope blades, adult, child, and infant sizes;

1. 0-4 Miller.

2. 1-4 Macintosh.

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I. One (1) each disposable endotracheal tubes sizes as well as intubation stylettes sized for each tube;

1. 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm cuffed or uncuffed.

2. 6.0, 6.5, 7.0, 7.5, 8.0 mm.

J. Equipment for drawing blood samples as an MCO;

K. Syringes, two (2) each 1 ml, 3 ml, 10 ml, 20 ml, and one (1) greater than or equal to 50 ml;

L. Twelve (12) alcohol and iodine preps for preparing IV injection sites;

M. A minimum of four (4) liters of normal saline or other appropriate IV solution;

N. Intraosseous devices;

1. Pediatric – minimum of two (2) sizes.

2. Adult – Minimum of one (1) size as an MCO.

O. Ambulances providing advanced cardiac life support must be equipped with a battery powered (DC) portable monitor-defibrillator unit, appropriate for both adult and pediatric patients with ECG printout and capable of transcutaneous pacing. The monitor-defibrillator equipment utilized by the service must have the capability of producing hard copy of patient's ECG, a 12-lead ECG, and performing continuous monitoring of end tidal carbon dioxide (EtCO₂) output. Portable EtCO₂ devices that meet the same criteria as above may be substituted;

P. Such medications or fluids as may be approved by the Department for possession and administration by EMTs trained and certified in their use and authorized by the provider's Medical Control Physician, as documented to the Department;

Q. Magill Forceps;

1. Adult.

2. Pediatric.

R. Blind Insertion Airway Devices (BIADs) such as dual lumen or LMA airways, age and weight appropriate;

S. Portable sharps container; and

T. Pediatric length-based, weight-based, or age-based medication dose chart or tape.

Section 703. EMT Rapid Responder Equipment.

A. All licensed Rapid Responder agencies operating within the state shall carry equipment required in the following sections. Protocols submitted must indicate areas where Medical Control Option (MCO) equipment is being authorized.

B. The Rapid Responder agency's vehicle must be properly marked as to identify the vehicle as an emergency vehicle.

C. The Rapid Responder agency shall follow the exact equipment cleanliness guidelines as outlined for transporting providers in Section 800.

D. All Rapid Responder vehicles will be equipped with at least the following items from Section 701: B.2, B.3, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, V, W, X, Y, Z, AA, BB.

E. Age and weight appropriate BIADs (Section 702.R) are an MCO for all Rapid Responder licenses.

F. Equipment in addition to Section 703.E to be carried by EMT-I or AEMT Rapid Responders:

1. Four (4) each, fourteen (14), sixteen (16), eighteen (18), twenty (20), and twenty-two (22) gauge IV cannulae;

2. Two (2) macro drip sets;

3. Two (2) micro drip sets;

4. One (1) sharps container;

5. A minimum of four (4) liters of normal saline or other appropriate IV solution;

6. Three (3) IV tourniquets;

7. Twelve (12) each, alcohol and iodine preps for preparing IV injection sites;

8. Five (5) adhesive bandages; and

9. Such medications or fluids as may be approved by the Department for possession and administration by EMTs trained and certified in their use and authorized by the provider's Medical Control Physician, as documented to the Department.

G. Equipment in addition to Section 703.F to be carried by Paramedic Rapid Responders:

1. Rapid Responders providing ALS must be equipped with a battery powered (DC) portable monitor-defibrillator unit, appropriate for both adult and pediatric patients with ECG printout and capable of transcutaneous pacing. The monitor-defibrillator equipment utilized by the service must have the capability of producing a hard copy of the patient's ECG and performing continuous monitoring of end tidal carbon dioxide (EtCO₂) output;

2. Such medications or fluids as may be approved by the Department for possession and administration by EMTs trained and certified in their use and authorized by the provider's Medical Control Physician, as documented to the Department;

3. As an MCO, ALS Rapid Responders may carry the following equipment from Section 702: G, H, I, P, S; and

4. ALS Rapid Responder agencies not providing laryngoscopic intubation must carry age and weight appropriate BIADs for airway management.

H. Any ALS agency not performing laryngoscopic intubations, and only providing BIADs for airway management, is not required to provide continuous monitoring of end tidal carbon dioxide (EtCO₂) output.

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Section 704. Special Purpose Ambulance Equipment.

A. All special purpose ambulances shall be equipped with at least the following items from Section 701: A.1, B, C, D (appropriate size), E, F, T, U, V, W, X, AA, BB, CC in addition to the special purpose equipment that is documented to the Department as enumerated in Section 407. Section 407.A.1 can be replaced by a specialized patient transfer device so long as there is a provision to safely secure the device in the special purpose ambulance.

B. Special purpose equipment as documented to the Department as enumerated in Section 407 must be on the special purpose ambulance when it is in use and is subject to inventory and inspection by the Department as provided for in Section 407.

SECTION 800.

SANITATION STANDARDS FOR LICENSED PROVIDERS

Section 801. Exterior Surfaces.

A. The exterior of the vehicle shall have a reasonably clean appearance.

B. All exterior lighting shall be kept clear of foreign matter (insects, road grime, or other) to ensure adequate visibility.

Section 802. Interior Surfaces Patient Compartment-Ambulance.

A. Interior surfaces shall be of a nonporous material to allow ease of cleaning. Carpet-type materials shall not be used on any surface of the patient compartment.

B. Floors shall be free from sand, dirt and other residue that may have been tracked into the compartment.

C. Wall, cabinet, and bench surfaces shall be kept free of dust, sand, grease, or any other accumulated surface matter.

D. Interiors of cabinets and compartments shall be kept free from dust, moisture or other accumulated foreign matter.

E. Bloodstains, vomitus, feces, urine and other similar matter must be cleaned from the unit and all equipment after each call, using an agent or sodium hypochlorite solution described in Section 802.H.

F. Window glass and cabinet doors shall be clean and free from foreign matter.

G. A receptacle shall be provided for the deposit of trash, litter, and all used items.

H. An EPA recommended germicidal/virucidal agent or a hypochlorite solution of ninety-nine (99) parts water and one (1) part bleach must be used to clean patient contact areas. For surfaces where such an EPA solution is not recommended, alcohol or sodium hypochlorite solution can be used.

I. A container specifically for the deposit of contaminated needles or syringes and a second container for contaminated or infectious waste shall be provided and will be easily accessible from the patient compartment.

J. All licensed providers must carry sufficient, appropriate cleaning supplies in their vehicles so that the crews are able to clean their unit between calls and be in compliance with Sections 802.A through G.

Section 803. Linen.

A. Storage area for clean linens shall be provided in such configuration so that linens remain dry and clean. (Ambulance)

B. Freshly laundered or disposable linens (minimum of six (6) sets) shall be used on cots and pillows, and shall be changed after each patient is transported. (Ambulance)

C. Soiled linen is to be transported in a closed plastic bag or container and removed from the ambulance as soon as possible.

D. Blankets and towels shall be clean and stored in such a manner to ensure cleanliness.

1. Towels and sheets shall not be used more than once between laundering.

2. Blankets shall be laundered or cleaned as they become soiled. Blankets shall preferably be of a hypoallergenic material designed for easy maintenance.

Section 804. Oxygen Administration Apparatus. (II)

A. Oxygen administration devices such as masks, cannulas, and delivery tubing shall be disposable and once used shall be disposed of and not reused.

B. All masks and cannulas and tubing shall be individually wrapped and not opened until used on a patient.

C. Oxygen humidifiers shall be filled with distilled or sterile water upon use only. Reusable humidifiers must be cleaned after each use. Disposable, single-use humidifiers are acceptable in lieu of multiuse types.

D. All units that carry portable oxygen must have a non-sparking oxygen wrench for use with the oxygen tanks on that unit.

Section 805. Resuscitation Equipment. (II)

A. Bag mask assemblies and masks shall be free from dust, moisture, and other foreign matter and stored in the original container, jump kit, or a closed compartment to promote sanitation of the unit. Additional equipment needed to facilitate the use of a bag valve mask, such as a syringe, shall be stored with the bag mask assembly. Masks, valves, reservoirs, and other items or attachments for bag mask assemblies shall be clean. Manufacturer's recommendations on single-use equipment shall be followed where indicated.

B. An EPA recommended germicidal/virucidal agent or a sodium hypochlorite solution of ninety-nine (99) parts water and one (1) part bleach must be used to clean equipment not specifically addressed as single-use. For surfaces where such an EPA solution is not recommended, alcohol or sodium hypochlorite solution shall be used.

Section 806. Suction Unit.

A. Suction hoses shall be clean and free from foreign matter. Manufacturer's recommendations on single-use equipment must be followed where indicated.

B. Suction reservoir shall be clean and dry.

C. Suction units shall be clean and free from dust, dirt or other foreign matter.

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D. Tonsil tips and suction catheters shall be of the single-use, disposable type, stored in sealed, sterile packaging until used.

E. Suction units with attachments shall be cleaned and sanitized after each use. (See Section 805.B).

Section 807. Splints.

A. Padded splints shall be neatly covered with a non-permeable material and clean. When the outside cover of the splint becomes soiled, they shall be thoroughly cleaned or replaced.

B. Pneumatic trousers, if used, shall be clean and free from dust, dirt or other foreign matter.

C. Commercial splints shall be free of dust, dirt or other foreign matter.

D. Traction splints with commercial supports shall be clean and free from accumulated material.

E. All splinting materials must be stored in such a manner as to promote and maintain cleanliness.

F. All splints must be in functional working order with the recommended manufacturer's attachments.

G. Manufacturer's recommendations on single-use equipment must be followed where indicated.

Section 808. Stretchers and Spine Boards.

A. Pillows, mattresses and head immobilization devices (HIDs) shall be covered with a non-permeable material and in good repair. (Single-use items are exempt.)

B. Stretchers, cots, pillows, HIDs and spine boards shall be clean and free from foreign material.

C. Canvas or neoprene covers on portable type stretchers shall be in good repair.

D. All restraint straps and/or devices shall be kept clean and shall be washed immediately if soiled.

E. Spinal immobilization boards shall be manufactured from an appropriate material to facilitate cleaning.

F. All spinal immobilization boards shall be free from rough edges or areas that may cause injury.

Section 809. Bandages and Dressings. (II)

A. Bandages need not be sterile, but they must be clean. They shall be individually wrapped or stored in a closed container or cabinet to ensure cleanliness.

B. Dressings must be sterile, individually packaged and sealed, and stored in a closed container or compartment. If the seal is broken or wrap is torn, the dressing is to be discarded.

C. Dressings or burn sheets must be sterile and single-use only.

D. Triangular bandages must be single-use disposable type.

E. All bandages or dressings that have been exposed to moisture or otherwise have become soiled must be replaced.

Section 810. Obstetrical (OB) Kits. (II)

A. All OB kits must be sterile and wrapped with cellophane or plastic. If the wrapper is torn or the kit is opened but not used, the items in the kit that are not individually wrapped must be resterilized or discarded and replaced.

B. OB kits must be single-use only.

C. Items that have an expiration date in OB kits may be replaced individually if other items are individually sealed and sterile.

Section 811. Oropharyngeal Appliances. (II)

Instruments inserted into a patient's mouth or nose that are single-use only shall be individually wrapped and stored properly. All instruments inserted into a patient's mouth (such as laryngoscope blades) that are not intended for single-use only must be cleaned and decontaminated following manufacturer's guidelines.

Section 812. Communicable Diseases. (II)

A. When an ambulance or transport vehicle has been contaminated in the transport of a patient known to have a blood-borne or respiratory droplet-borne pathogen, the vehicle must be taken out of service until cleaning and decontamination is completed.

B. Linen must be removed from the cot and properly disposed of, or immediately placed in a plastic bag or container and sealed until properly cleaned.

C. Patient contact areas, equipment and any surface soiled during the call, must be cleaned in accordance with Section 802.H of these guidelines.

Section 813. Miscellaneous Equipment.

Miscellaneous equipment such as scissors, stethoscopes, blood pressure cuffs and/or other items used for direct patient care shall be cleansed as they become soiled. Items shall be kept clean and free from foreign matter.

Section 814. Equipment and Materials Storage Areas.

Equipment not used in direct patient care shall be in storage spaces that prevent contamination or damage to direct patient care equipment or materials.

Section 815. Personnel.

A. All personnel functioning on the vehicle shall present themselves in a clean appearance at all times. This includes both the certified EMS attendants and the non-certified drivers if applicable.

B. Hands and forearms shall be thoroughly washed according to Standard 1910.1030 set forth by the Occupational Safety and Health Administration (OSHA).

C. Uniforms and clothing shall be clean or changed if they become soiled, contaminated, or exposed to vomitus, blood or other potentially infectious material (OPIM).

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SECTION 900.

EMERGENCY MEDICAL TECHNICIANS

Section 901. General.

A. All ambulance attendants shall have a valid Emergency Medical Technician (EMT, EMT-I, AEMT, or Paramedic) certificate. No person shall provide patient care within the scope of an Emergency Medical Technician (EMT, EMT-I, AEMT, or Paramedic) without having proper South Carolina certification from the Department. (I)

B. EMTs (EMT, EMT-I, AEMT, or Paramedic) shall only engage in those practices for which they have been trained and are within the scope of their Department-issued certification. Students currently enrolled in a Department-approved EMT, AEMT, or Paramedic program under the supervision of an appropriately credentialed preceptor may practice advanced skills for which they have been authorized in their respective training program. (I)

C. EMTs (EMT, EMT-I, AEMT, or Paramedic) shall perform procedures under the supervision of a physician licensed in South Carolina. The means of supervision shall be direct, by standing orders or by electronic or voice communications. (I)

D. All Department-certified EMTs (EMT, EMT-I, Special Purpose EMT, AEMT, or Paramedic) shall maintain an up-to-date profile in the South Carolina Credentialing Information System (CIS). (III)

E. A pocket ID card shall be issued along with the South Carolina certificate. The original pocket card must be in the possession of the EMT (EMT, EMT-I, Special Purpose EMT, AEMT, or Paramedic) at all times that the EMT is on-duty or patient care is being rendered. (III)

F. Except in cases of a disaster or catastrophe, when licensed services in the locality are insufficient to render the required services and/or mutual aid is requested, a South Carolina EMT certification (all levels) is limited in its scope of practice to South Carolina. (III)

Section 902. Initial EMT, AEMT, and Paramedic Certification. (I)

A. Any person seeking certification as an EMT, AEMT, or Paramedic shall complete the appropriate Department-approved training program, pass the National Registry of Emergency Medical Technicians (NREMT) examination for the level of certification desired, possess a current NREMT credential, and meet the requirements established by the Department as provided by S.C. Code Section 44-61-80(C).

B. A person seeking certification as an EMT, AEMT, or Paramedic must undergo a state criminal history background check, supported by fingerprints by the South Carolina Law Enforcement Division (SLED), and a national criminal history background check, supported by fingerprints by the Federal Bureau of Investigation (FBI).

1. The results of these criminal history background checks are reported to the Department. SLED is authorized to retain the fingerprints for certification purposes and for notification to the Department regarding criminal charges.

2. The cost of the state criminal history background check is delineated in S.C. Code Section 44-61-80(D).

3. The state and national criminal history background checks are required for all EMTs when the EMT applies for certification or recertification. The results of these criminal history background checks are only valid for forty-five (45) days from the date the results are received by the Department from SLED and the FBI.

4. Applications for certification of individuals convicted of or under indictment for the following crimes shall be denied in all cases:

a. Felonies involving criminal sexual conduct;

b. Felonies involving the physical or sexual abuse of children, the elderly, or the infirm including, but not limited to, criminal sexual conduct with a minor, making or distributing child pornography or using a child in a sexual display, incest involving a child, or assault on a vulnerable adult; or

c. Crimes against vulnerable populations (such as, but not limited to, children, patients, or residents of a healthcare facility) including abuse, neglect, theft from, or financial exploitation of a person entrusted to the care or protection of the applicant.

C. Applications from individuals convicted of, or under indictment for, other offenses not listed above will be reviewed by the Department on a case by case basis.

D. All Certifications are valid for a period not exceeding four (4) years from the date of issuance as provided in S.C. Code Section 44-61-80(E).

Section 903. Recertification of EMT, AEMT, and Paramedic Certification.

A. EMTs, AEMTs, and Paramedics shall recertify their Department-issued certification by submitting the following to the Department a minimum of thirty (30) days prior to expiration of their certificate:

1. A properly completed and signed application for recertification;

2. Documentation of current NREMT credentials for the appropriate level of certification; and

3. Other credential(s) as required by the Department (state-approved CPR credential and/or Advanced Cardiac Life Support (ACLS) credential).

4. An individual who was certified in this state before October 1, 2006, and has continuously maintained a South Carolina state EMT certification at any level without lapse, may continue to renew that certification without a NREMT credential.

5. An individual who has gained a NREMT credential on or after October 1, 2006, must maintain their NREMT credential to be certified, recertified, and maintain their South Carolina certification.

B. EMTs, AEMTs, and Paramedics seeking recertification shall undergo a state and national criminal history background check as provided for in S.C. Code Section 44-61-80(D).

Section 904. Special Purpose EMT.

A. A person seeking a South Carolina Special Purpose EMT credential shall meet all requirements established by the Department.

B. All South Carolina certified individuals shall maintain an up-to-date profile in the South Carolina Credentialing Information System (CIS).

C. A person seeking a certification or recertification as a Special Purpose EMT must undergo a state criminal history background check as provided in S.C. Code Section 44-61-80(D).

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D. In order to be issued a valid Special Purpose EMT certificate, an individual must meet all of the following criteria:

1. The Special Purpose EMT must be a South Carolina licensed registered nurse (RN) or a Nurse Licensure Compact (NLC) State RN who works in a critical care hospital setting such as neonatology, pediatrics, or cardiac care;

2. The Special Purpose EMT must have completed an acceptable training program for delivery of the special area or possess experience in that special care area satisfactory to the Department;

3. The Special Purpose EMT must be employed by the medical service which utilizes the special purpose ambulance and recommended by the director of the medical service which utilizes the special purpose ambulance;

4. The medical service by which the Special Purpose EMT is employed must have operational procedures and medical protocols directing the daily operations of the Special Purpose EMT and special purpose ambulance. These medical protocols must be in written or electronic form, approved, and signed by the Medical Control Physician of the licensed EMS agency which operates the special purpose ambulance in order for the Special Purpose EMT to administer the special medical treatment required by these protocols;

5. A South Carolina Special Purpose EMT certificate shall be in force no more than four (4) years;

6. A pocket ID card shall be issued along with the South Carolina certificate. The original pocket card must be in the possession of that Special Purpose EMT individual all times that the person is on-duty or patient care is being rendered; and

7. Special Purpose EMTs shall only engage in those practices for which they have been trained and have been approved by the Department.

E. Special purpose EMTs may be assisted by other healthcare professionals who are determined qualified and approved by the Department to assist in attendance of the patient during transportation in a special purpose ambulance.

Section 905. Reciprocity.

A. Candidates seeking reciprocity in South Carolina must hold either a NREMT credential or a current certification from another state for the level for which they are applying.

B. Candidates seeking reciprocity as an EMT, AEMT, or Paramedic must undergo the required criminal history background check in accordance with S.C. Code Section 44-61-80(D). The results of these criminal history background checks are only valid for forty-five (45) days from the date the results are received by the Department from SLED and FBI.

C. Candidates not certified in South Carolina who hold a current and valid NREMT certification may apply for direct reciprocity at the level of the NREMT credential they hold by creating (and maintaining) an up-to-date profile in the South Carolina Credentialing Information System (CIS) and submitting the following:

1. A properly completed and signed reciprocity application;

2. A copy of their current NREMT certification for the level of reciprocity for which they are making application; and

3. All other requirements as established by the Department.

D. South Carolina EMT certificates for all levels of direct reciprocity shall expire four (4) years from the date the Department approves the candidate's application.

E. A pocket ID card shall be issued along with the South Carolina certificate. The original pocket card must be in the possession of that individual at all times that the EMT is on-duty or patient care is being rendered.

F. EMT certifications (EMT, AEMT, and Paramedic) must maintain a NREMT credential to be certified, recertified, and maintain their current South Carolina certification.

G. Candidates not certified in South Carolina who hold a current and valid EMT certification from other states may apply for a one (1) year provisional reciprocity at the level of the certification they hold by creating (and maintaining) an up-to-date profile in the South Carolina Credentialing Information System (CIS) and submitting the following:

1. A properly completed and signed reciprocity application;
2. A properly completed out-of-state certification verification form;

3. A copy of their current state certification pocket card for the level of provisional reciprocity for which they are making application. The pocket card must show their out-of-state certification expiration date. All provisional reciprocity candidates must have a minimum of six (6) months remaining on their out-of-state certification by the time the Department receives all required documentation necessary for certification. Exceptions will be granted on a case-by-case basis; and

4. All other requirements as established by the Department.

H. South Carolina EMT certificates for all levels of provisional reciprocity will expire on the fifteenth (15th) of the month one (1) year from the date of issue. Provisional certifications are non-renewable and extensions are not permitted.

I. A pocket ID card will be issued along with the South Carolina certificate. The original pocket card must be in the possession of that individual all times that patient care is being rendered.

J. To convert a provisional certification to a regular South Carolina certification a reciprocity candidate must complete all requirements necessary to obtain a NREMT certification. All recertification requirements must meet all conditions stated in Section 903.

K. EMT certifications (EMT, AEMT, and Paramedic) must maintain a current NREMT credential to be certified, recertified, and maintain their current South Carolina certification.

Section 906. Certification Examinations.

A. Any candidate desiring EMT certification in South Carolina must successfully pass the NREMT examinations and obtain a NREMT certification.

B. The Department is responsible for the approval and location of all EMT psychomotor examination sites in South Carolina.

C. In accordance with NREMT guidelines, the psychomotor portion of the NREMT examinations for the EMT may be delegated to the approved training institutions to be conducted as part of the EMT course or may be conducted as a separate psychomotor examination approved by the Department. This psychomotor examination must be monitored by either a NREMT testing representative or a Department representative. The

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ability of a training institution to conduct an NREMT psychomotor examination may be revoked at any time should the Department discover such examinations are not being held in accordance with NREMT guidelines.

D. The AEMT and Paramedic psychomotor portion of the NREMT examination shall be conducted in accordance to the NREMT guidelines.

Section 907. Emergency Medical Technician Training Programs. (II)

A. These programs, which include initial and refresher EMT, AEMT, and Paramedic, are established by the Department and offered in approved technical colleges, other colleges and universities, vocational schools, and State Regional EMS training offices. The curricula for these training programs are the most current National EMS Education Standards (“Standards”) or any other curricula approved by the Department. Paramedic programs must be CAAHEP accredited or hold a CoAEMSP Letter of Review.

1. An application must be filed with the Department for a training institution to receive approval. No EMT, AEMT, or Paramedic training program may be conducted without approval by the Department.

2. All approved training institutions must designate one (1) person as the EMT program coordinator. This person shall be responsible to the Department for compliance with all applicable requirements pertaining to the training program.

3. Upon recommendation of the South Carolina EMS Training Committee and approval of the South Carolina EMS Advisory Council, a list of required equipment for the training programs will be maintained by the Department and updated as necessary.

4. Training institutions will be granted approval for no more than four (4) years at which time a re-approval may be granted to training institutions which have been compliant with all requirements and have actively conducted initial EMT training programs. An institution shall not conduct courses with expired institution credentials.

5. Department-approved Training Centers in existence prior to the effective date of these regulations shall continue to provide EMT training in accordance with the provisions of this article.

6. All EMS training institutions must be granted approval by the Department prior to advertising or beginning any EMT course.

7. Any EMT course offered through an approved institution shall be an open course, with the exception of classes which are closed due to associated security concerns and/or requirements. Regardless of the location of the course, any candidate who satisfies the eligibility requirements shall be granted a seat in the course on a first-come, first-served basis until all seats have been filled.

8. EMT teaching institutions that instruct ALS shall retain a Medical Control Physician to provide medical oversight over their program.

B. Continuing Education Program or CE (formerly In-Service Training (IST) Program) – This program is established by the Department and is granted to approved South Carolina licensed EMS agencies for the sole purpose of recertification of South Carolina credentialed EMTs on their roster.

1. EMS agencies seeking approval for a CE program must file an application with the Department.

2. Upon recommendation of the South Carolina EMS Training Committee and approval of the South Carolina EMS Advisory Council, a list of required equipment for the CE programs will be maintained by the Department and updated as necessary.

3. CE programs will be granted approval for no more than four (4) years at which time reapproval may be granted to IST programs which have been compliant with all requirements.

4. All CE programs must meet or exceed all requirements established by the NREMT for recertification.

5. No South Carolina licensed EMS provider may begin a CE program prior to receiving approval by the Department.

6. CE programs may verify skills for currently credentialed state and NREMT personnel on their CIS roster. Provisional credentialed EMTs must have their NREMT skills verified at a Department approved NREMT testing site.

C. Continuing Education Units (CEUs) – The Department may approve additional CEUs on a case-by-case basis from medical schools, hospitals, simulation centers, Department credentialed teaching institutions, formal conventions, seminars, workshops, educational classes, and symposiums. All Continuing Education Coordinating Board for Emergency Medical Services (CECBEMS) approved courses are accepted by the Department for CE credit in accordance with NREMT standards.

1. Requests for state approved CEUs are made through the Department and must be received by the Department in writing at least thirty (30) days prior to the scheduled event.

2. Requests for state approved CEUs must include the following:

a. Date, times, and agenda of the event;

b. Topics covered;

c. List of speakers and their credentials; and

d. Any additional information which may be requested by the Department.

D. Pilot Programs – The Department may authorize providers to initiate pilot programs which provide training in new and innovative procedures that have potential for lifesaving care.

1. Under no circumstances shall pilot programs be initiated without prior approval by the Department.

2. Those who wish to initiate a pilot program must provide in writing to the Department a detailed proposal of the program and any supporting materials. Upon recommendation by the South Carolina Medical Control Committee and with approval by the South Carolina EMS Advisory Council, the Department may authorize the program.

3. The EMTs who participate in these programs are allowed to perform the pilot procedures, under Medical Control Physician oversight, during the period of the pilot program.

4. At the conclusion of the pilot program, a study must be submitted to the Department describing the outcome or results of the program. Research gained from the pilot programs may be used to revise and upgrade existing EMT programs and scope of practice.

E. All training programs shall be taught by Department-certified instructors. Instructors that meet all requirements and satisfactorily complete the Department's instructor orientation of the EMT Course Administration and Policy Guidelines shall be certified by the Department. Instructor certifications shall expire on the last day of the month in which their State EMT certification expires.

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F. To be certified as an EMT instructor, all new candidates must meet the following requirements:

1. Be twenty-one (21) years of age or older;
2. Possess high school diploma or GED;
3. Possess a current State and NREMT Paramedic credential;
4. Successfully completed a forty (40) hour state, National Association of EMS Educators (NAEMSE), International Fire Service Accreditation Congress (IFSAC), ProBoard or Department of Defense (DOD) fire instructor, or South Carolina Criminal Justice Academy instructor methodology course;
5. Possess a current and valid CPR instructor credential;
6. Must submit a properly completed and signed instructor application; and
7. Meet all other requirements for their level of instructor certification as required by the Department.

G. Instructor certificates may be renewed by submission of the following:

1. A properly completed and signed instructor recertification application;
2. A copy of a current South Carolina and NREMT Paramedic certification;
3. A copy of a current and valid CPR instructor credential;
4. Satisfaction of all teaching requirements as determined by the Department; and
5. Satisfaction of all other requirements as determined by the Department.

H. An EMT Instructor authorization may be suspended or revoked for any of the following reasons:

1. Any act of misconduct as outlined in Section 1100;
2. Suspension or revocation of the holder's South Carolina or NREMT certification;
3. Failure to maintain required credentials necessary for instructor designation;
4. Any act of proven sexual harassment toward another instructor or candidate;
5. Use of profane, obscene or vulgar language while in the presence of candidates or the EMT program coordinator during the context of class or related functions;
6. Conducting class without the minimum required equipment available and in working condition;
7. The use of any curricula not approved by the Department;
8. Gross or repeated violations of policy pertaining to the EMT training program;
9. Multiple instructor reprimands within a given period of time as established by the Department; or
10. Any other actions determined by the Department that compromises the integrity of the program. Those actions may include, but are not limited to the following:

- a. Unprofessional behavior in the classroom;
 - b. Failure to notify the EMT program coordinator when classes must be cancelled or rescheduled;
 - c. Consistently starting class late or dismissing class early;
 - d. Conducting classes while under the influence of alcohol;
 - e. Conducting classes while under the influence of drugs that negatively impair the ability to instruct (prescribed, non-prescribed, or illegal);
 - f. Falsification of any documents pertaining to the course (such as attendance logs, equipment checklist);
- or
- g. Repeated class results on the written and/or practical portion(s) of candidate examinations reflecting a class pass rate on the NREMT cognitive or psychomotor examinations of less than fifty percent (50%) (first-time pass rate) for two (2) consecutive same level classes or two (2) classes of the same level in three (3) years.

Section 908. Endorsement of Credentials.

A. The Department is tasked by S.C. Code Section 44-61-30(A) with developing standards and promulgating regulations for the improvement of emergency medical services.

B. There are areas of specialized practice in EMS which require further education, training, and clinical experience to receive credentials in those specialized areas of care and practice. The Department has an obligation to the public to recognize, endorse, and regulate these specialized practices to ensure a uniform scope of practice across the state.

C. The Department shall establish minimum educational and clinical guidelines for these endorsed credentials beyond a Paramedic certification.

D. The Department-endorsed credential shall include, but is not limited to, the following areas of specialized training:

- 1. Community Paramedic;
- 2. Critical Care Paramedic; and
- 3. Tactical Paramedic.

E. Endorsement of South Carolina credentials shall only be granted by the Department to Paramedics that are currently certified by the Department and hold an unencumbered current South Carolina certification. If a Paramedic's South Carolina certification is expired, suspended, or revoked by the Department, the endorsement follows the same status as their certification.

F. The specially endorsed South Carolina Paramedics shall only practice their skills within the scope of practice of their Department-approved agency, under a South Carolina licensed Medical Control Physician. Specially endorsed Paramedics are not independent healthcare practitioners.

G. The specially endorsed South Carolina Paramedics shall require additional specialty continuing education as determined by the Department.

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H. The types of care rendered by the specially endorsed Paramedics shall include, but are not limited to, critical care interfacility services, prehospital services, preventative care, social service referrals, chronic care support, follow-up care and maintenance, and tactical medical support of law enforcement.

I. Licensed agencies using these specialized services shall have specific protocols by their Medical Control Physician and approved by the Department.

Section 909. Certification Patches.

A. An individual initially certified in South Carolina at any level shall receive a complimentary patch for the level which he or she received his or her certification.

B. Additional patches may be purchased for individuals for services which meet the following criteria:

1. The individual holds a current South Carolina certification; or

2. The individual is an EMS agency director, logistics officer, or training officer and is purchasing patches in bulk for his or her service.

SECTION 1000.

PERSONNEL REQUIREMENTS (I)

A. During the transportation of patients, there shall be an EMT, EMT-I, AEMT or Paramedic in the patient compartment at all times. The crew member with the highest level of certification shall determine which crew member will attend the patient during transport. If advanced life support procedures are in use, the responsible EMT-I, AEMT or Paramedic shall attend the patient in the patient compartment during transport.

B. Exception: Transferring or receiving medical facilities' registered nurses and physicians are authorized as ground ambulance attendants when assisting EMTs in the performance of their duties when all of the following requirements are met:

1. The required medical care of the patient is beyond the scope of practice for the certification level of the EMT.

2. When the ambulance transport is between medical facilities or from medical facility to the patient's residence.

3. When the responsible physician, transferring or receiving, assumes responsibility of the patient and provides appropriate orders, written preferred, to the registered nurse for patient care.

4. The registered nurse is on duty with the appropriate medical facility during the ambulance transport.

C. No person under the age of eighteen (18) shall operate any emergency vehicle owned or operated by the licensed provider.

D. No person shall act or serve in the capacity of attending a patient while under felony indictment or with certain past felony convictions as listed in Section 902.B.4.

E. All licensed providers must notify the Department immediately should they become aware of a felony indictment or conviction of any person on their roster.

SECTION 1100.

REVOCATION OR SUSPENSION OF CERTIFICATES OF EMERGENCY
MEDICAL TECHNICIANS (I)

A. The Department shall, upon receiving a complaint of misconduct as herein defined, initiate an investigation to determine whether or not suitable cause exists to take action against the holder of an emergency medical technician certificate.

1. The initial complaint shall be in the form of a brief statement, dated and signed by the person making the complaint, which shall identify the person or service that is the subject of the complaint and contain a summary as to the nature of the complaint. The Department is also authorized to initiate an investigation based upon information acquired from other sources.

2. Information received by the Department through inspection, complaint or otherwise authorized under S.C. Code Sections 44-61-10 et seq. shall not be disclosed publicly except in a proceeding involving the question of licensing, certification or revocation of a license or certificate.

B. "Misconduct" constituting grounds for a revocation or suspension or other restriction of a certificate means while holding a certificate, the holder:

1. Used a false, fraudulent, or forged statement or document or practiced a fraudulent, deceitful, or dishonest act in connection with any of the certification requirements or official documents required by the Department;

2. Was convicted of a felony or another crime involving moral turpitude, drugs, or gross immorality;

3. Was addicted to alcohol or drugs to such a degree as to render the holder unfit to perform as an EMT;

4. Sustained a physical or mental disability that renders further practice by him dangerous to the public;

5. Obtained fees or assisted in the obtaining of such fees under dishonorable, false or fraudulent circumstances;

6. Disregarded an appropriate order by a physician concerning emergency treatment and transportation;

7. At the scene of an accident or illness, refused to administer emergency care on the grounds of age, sex, race, religion, creed or national origin of the patient;

8. After initiating care of a patient at the scene of an accident or illness, discontinued such care or abandoned the patient without the patient's consent or without providing for the further administration of care by an equal or higher medical authority;

9. Revealed confidences entrusted to him in the course of medical attendance, unless such revelation is required by law or is necessary in order to protect the welfare of the individual or the community;

10. By action or omission and without mitigating circumstance, contributed to or furthered the injury or illness of a patient under his care;

11. Was careless, or reckless, or irresponsible in the operation of an emergency vehicle;

12. Performed skills above the level for which he was certified or performed skills that he was not trained to do;

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13. Observed the administration of sub-standard care by another EMT or other medical provider without documenting the event and notifying a supervisor;

14. By his actions, or inactions created a substantial possibility that death or serious physical harm could result;

15. Did not take or complete remedial training or other courses of action as directed by the Department;

16. Was found guilty of the falsification of any documentation as required by the Department;

17. Breached a section of the Emergency Medical Services Act of South Carolina or a subsequent amendment of the Act or any rules or regulations published pursuant to the Act.

18. Failed to provide a patient emergency medical treatment of a quality deemed acceptable by the Department.

C. The Department may take enforcement action, including suspending or revoking certifications or assessing a monetary penalty against the holder of a certificate at any time it is determined that the holder no longer meets the prescribed qualifications for being a certified EMT as provided in this regulation and the EMS Act.

D. The suspension or revocation of the emergency medical technician certificate shall include all levels of certification.

E. Any adverse action or event related to credentialed personnel shall be reported as required to the National Practitioner Data Bank, in accordance with federal law.

SECTION 1200.

AIR AMBULANCES

Section 1201. Licensing. (I)

It shall be unlawful for any ambulance service provider, agent or broker to secure or arrange for air ambulance service originating in the State of South Carolina unless such ambulance service meets the provisions of South Carolina Emergency Medical Services Act and regulations.

A. Air Ambulance Licensing and Insurance Requirements:

1. Air ambulance licensing procedures must meet the requirements in Section 400. Air ambulance permit procedures are contained in Section 500. A Department issued permit is required for each aircraft;

2. As part of the licensing procedure, every air ambulance operator shall carry an air ambulance insurance policy. The coverage amounts shall ensure that;

a. Each aircraft shall be insured for the minimum amount of one million dollars (\$1,000,000) for injuries to, or death of, any one (1) person arising out of any one (1) incident or accident;

b. The minimum amount of three million dollars (\$3,000,000) for injuries to, or death of, more than one (1) person in any one (1) accident;

c. The minimum amount of five hundred thousand dollars (\$500,000) for damage to property from any one (1) accident;

d. Submit proof that the provider carries professional liability coverage in the minimum amount of five hundred thousand dollars (\$500,000) per occurrence, with a company license to do business in the aircraft's home assigned state; and

e. All listed insurance shall provide a thirty (30) day cancellation notice to the Department. In accordance with Section 303, an agency is subject to enforcement action including but not limited to revocation or fines for laps of coverage for any period of time. A schedule of fines is listed in Section 1501.

3. Submit a copy of current FAA operational certificate and include designation for air ambulance operations, Administration Air Taxi and Commercial Operator Certification, ACTO;

4. Submit a letter of agreement that all aircraft shall meet the specifications of all applicable subsections of Section 501, if the aircraft is leased from a pool;

5. Proof that the Medical Control Physician meets the qualifications of Section 402;

6. The operator or firm must conform to all Federal Aviation Regulations (FARs), which are rules prescribed by the Federal Aviation Administration (FAA) Part 135; and

7. Each aircraft must be inspected and issued a permit by the Department prior to use.

B. Out-of-State Air Ambulances.

1. Out-of-state air ambulances transporting patients from locations originating in South Carolina must obtain a license in South Carolina prior to engaging in operations and must have a current and valid license in their home state, if applicable, except where exempt pursuant S.C. Code Section 44-61-100(D).

2. Out-of-state air ambulances operating in a state where no license is available must obtain a license in South Carolina and meet all requirements in Section 1200.

3. Out-of-state air ambulances transporting patients initiating in South Carolina must have the patient care report submitted into the South Carolina PreMIS system within seventy-two (72) hours of completing the transport.

C. Air Ambulance Categories:

1. Prehospital Transport Air Ambulance. Air ambulance services that transport patients in the prehospital setting will be permitted as either an advanced or basic life support service. In addition each prehospital service shall be required to meet the requirements and be licensed accordingly. Each such service shall contract with a Medical Control Physician.

2. Special Purpose Air Ambulance. The interfacility transportation of a critically injured or ill patient by an air ambulance (fixed-wing or rotary-wing aircraft) that includes the provision of medically necessary supplies and services, at a level of service beyond the normal scope of practice of a Paramedic. The Special Purpose air unit is necessary when a patient's condition requires ongoing care that must be furnished by one (1) or more healthcare professionals in an appropriate specialty area (such as neonate, critical care nursing, respiratory care, cardiovascular care), or a Paramedic with additional training approved by the Department. It is the responsibility of the provider's Medical Control Physician to ensure that the level of patient care required in any given transport is adequate for that patient's medical needs.

D. Air Ambulance Aircraft Requirements. The aircraft operator shall, in all operations, comply with all federal aviation regulations which are adopted by reference, FAA Part 135. The aircraft shall meet the following specifications:

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1. Be configured in such a way that the medical attendants have adequate access for the provision of patient care within the cabin to give cardiopulmonary resuscitation and maintain patient's life support;

a. The aircraft or ambulance must have an entry that allows loading and unloading without excessive maneuvering (no more than forty-five (45) degrees about the lateral axis and thirty (30) degrees about the longitudinal axis) of the patient.

b. The configuration does not compromise functioning of monitoring systems, intravenous lines, and manual or mechanical ventilation.

2. A minimum of one (1) stretcher or cot must be provided that can be carried to the patient and allow loading of a supine patient by two (2) attendants;

a. The maximum gross weight allowed on the stretcher or cot (inclusive of patient and equipment) as consistent with manufacturer's guidelines.

b. Aircraft stretchers, cots, and the means of securing it in-flight must be consistent with national aviation regulations.

c. The stretcher or cot must be sturdy and rigid enough that it can support cardiopulmonary resuscitation.

d. The head of the cot is capable of being elevated at least thirty (30) degrees for patient care and comfort.

e. The patient placement must allow for safe medical personnel egress.

3. Have appropriate communication equipment to ensure both internal crew and air to ground exchange of information between individuals and agencies appropriate to the mission, including at least medical control, air traffic control, emergency services (EMS, law enforcement agencies, and fire), and navigational aids;

4. Be equipped with radio headsets that ensure internal crew communications and transmission to appropriate agencies;

5. Pilot is able to control and override radio transmissions from the cockpit in the event of an emergency situation;

6. Lighting. Supplemental lighting system shall be installed in the aircraft or ambulance in which standard lighting is insufficient for patient care;

a. A self-contained lighting system powered by a battery pack or a portable light with a battery source must be available.

b. There must be adequate lighting for patient care. Use of red lighting or low intensity lighting in the patient care area is acceptable if not able to isolate the patient care area from effects on the cockpit or on a pilot.

c. For those flights meeting the definition of "long range," additional policies must be in place to address how adequate cabin lighting will be provided during fueling and or technical stops to ensure proper patient assessment can be performed and adequate patient care provided.

7. Have hooks and/or appropriate devices for hanging intravenous fluid bags;

8. Helicopters must have an external landing light and tail-rotor position light;

9. Design must not compromise patient stability in loading, unloading, or in-flight operations;

10. Temperature; and

a. The interior of the aircraft must be climate controlled to avoid adverse effects on patients and personnel on board.

b. Thermometer is to be mounted inside the cabin.

c. Cabin temperatures must be measured and documented every fifteen (15) minutes during a patient transport until temperatures are maintained within the range of fifty to ninety-five (50 to 95) degrees Fahrenheit (ten to thirty-five (10 to 35) degrees Celsius) for aircraft.

11. Electric power outlet. Must be provided with an inverter or appropriate power source of sufficient output to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical aircraft or ambulance equipment. Extra batteries are required for critical patient care equipment.

E. Aircraft Flight Crew Manning Requirements. The aircraft operator shall, in all operations, comply with all federal aviation regulations which are adopted by reference, FAA Part 135.

1. Rotorcraft Pilot:

a. The pilot must possess at least a commercial rotorcraft-helicopter and instrument helicopter rating 05.07.02.

b. The pilot in command must possess two thousand (2000) total flight hours (or total flight hours of at least fifteen hundred (1500) hours and recent experience that exceeds the operator's pre-hire qualifications such as current air medical and/or search and rescue experience or Airline Transport Pilot, ATP, rated) prior to an assignment with a medical service with the following stipulations:

i. A minimum of twelve hundred (1200) helicopter flight hours;

ii. At least one thousand (1000) of those hours must be as Pilot-in-Charge (PIC) in rotorcraft;

iii. One hundred (100) hours unaided (if pilot is not assigned to a Night Vision Goggles (NVG) base or aircraft);

iv. One hundred (100) hours unaided or fifty (50) hours unaided as long as the pilot has one hundred (100) hours aided (if assigned to an NVG base or aircraft); and

v. A minimum of five hundred (500) hours of turbine time.

c. The pilot must be readily available within a defined call-up time to ensure an expeditious and timely response.

2. Rotorcraft mechanic:

a. The helicopter mechanic is vital to mission readiness and, as such, shall possess at least two (2) years of experience and must be a certified air frame and power plant mechanic.

b. The mechanic must be properly trained and FAA certified to maintain the aircraft designed by the flight service for its aeromedical program.

3. Fixed-Wing Pilot:

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a. A fixed-wing pilot must possess two thousand (2000) airplane flight hours prior to assignment with a medical service with the following stipulations:

- i. At least one thousand (1000) of those hours must be as Pilot-in-Charge (PIC) in an airplane;
- ii. At least five hundred (500) of those hours must be multi-engine airplane time as PIC. (Not required of single-engine turbine aircraft);
- iii. At least one hundred (100) of those hours must be night flight time as PIC; and
- iv. Both pilots in a two-pilot aircraft must be ATP rated.

b. In aircraft that require two (2) pilots, both pilots must be type rated for that make and model, and both pilots must hold first class medical certificates if the certificate holder operates internationally. Both pilots must have training on Crew Resource Management (CRM), or Multi-pilot Crew Coordination (MCC).

4. Fixed-Wing Mechanic:

- a. The mechanic is vital to mission readiness and must be a certified air frame and power plant mechanic.
- b. The mechanic must be properly trained and FAA certified to maintain the aircraft designated by the flight service for its aeromedical program.
- c. The mechanic must obtain and maintain a current Airframe and Powerplant (A&P) certificate.

F. Off-Line Medical Control Physician (Medical Director). The off-line Medical Control Physician of air ambulance services shall be responsible for:

1. Being knowledgeable of the capabilities and limitations of the aircraft used by his service;
2. Being knowledgeable of the medical staff's capability relative to the patient's needs;
3. Being knowledgeable of the routine and special medical equipment available to the service;
4. Ensuring that each patient is evaluated prior to a flight for the purpose of determining that appropriate aircraft, flight and medical crew and equipment are provided to meet the patient's needs;
5. Ensuring that all medical crew members are adequately trained to perform in-flight duties prior to functioning in an in-flight capacity; and
6. Must meet all requirements, duties and responsibilities listed in Section 402.

G. Aircraft Medical Crew Requirements:

1. Each basic life support air ambulance must be staffed with at least one (1) currently certified South Carolina EMT.
2. Each advanced life support air ambulance must be staffed with at least one (1) currently certified South Carolina Paramedic or South Carolina flight nurse as may be required by the patient's condition.
3. Each special purpose air ambulance must be staffed with at least one (1) Special Purpose EMT, Paramedic or RN with specialty training, as approved by the Department.

4. Each crew member must wear a flame retardant uniform with reflective striping.
5. Each crew member must display a legible photo identification with first name and certification level (for example, pilot, RN, or other) while patient care is anticipated to be rendered.

H. Orientation Program:

1. All medical flight crew members must complete a base level flight orientation program approved by the Department and supervised by the service's Medical Control Physician.
2. The flight orientation program shall be of sufficient duration and substance to cover all patient care procedures, including altitude physiology, and flight crew requirements.

Section 1202. Medical Supplies and Equipment. (II)

A. Local Medical Control Option (MCO) items are required equipment, unless the Medical Control Physician declines to carry suggested equipment. The MCO items must be stated in writing (such as incorporated into SOPs or Standing Orders) and submitted to the Department within ten (10) days of change.

B. Delivering Oxygen. Oxygen shall be installed according to national aviation regulations (FAA Part 135.91). Medical transport personnel can determine how oxygen is functioning by pressure gauges mounted in the patient care area.

1. Each gas outlet shall be clearly identified.
2. "No Smoking" sign shall be included.
3. Oxygen flow must be stoppable at or near the oxygen source from inside the aircraft or ambulance.
4. The following indicators shall be accessible to medical transport personnel while en route:
 - a. Quantity of oxygen remaining; and
 - b. Measurement of liter flow.
5. Adequate amounts of oxygen for anticipated liter flow and length of transport with an emergency reserve must be available for every mission.
6. When the vehicle is in motion, all oxygen cylinders shall be affixed to a wall or floor with crash stable, quick release fittings.

C. Sanitation. The floor, sides, ceiling and equipment in the patient cabin of the aircraft or ambulance must be a nonporous surface capable of being cleaned and disinfected by the standards listed in Section 800.

D. Basic Life Support (BLS) Equipment. BLS Air Ambulances shall have all the following equipment on board:

1. Automatic External Defibrillator (AED);
 - a. An AED shall be secured and positioned for easy access to the medical attendant(s).
 - b. Adult and Pediatric paddles, pads, and cables shall be available.

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2. Suction Device. A portable suction device, age and weight appropriate, with wide bore tubing and at least a six (6) ounce reservoir;

- a. Wide-bore, rigid pharyngeal curved suction tip: Minimum, two (2) each.
- b. Sterile, single-use, flexible suction catheter between 6 Fr – 16 Fr: Minimum, two (2):
 - i. One (1) must be between 6 Fr – 10 Fr.
 - ii. One (1) must be between 12 Fr – 16 Fr.

3. Airway Equipment;

- a. Nasal Cannulas (NC): Adult and pediatric with adequate length tubing, two (2) each.
- b. Non-Rebreather Mask (NRB): Adult and pediatric with adequate length tubing, two (2) each.
- c. Nasopharyngeal airways (NPAs): 16 Fr-34 Fr adult and child sizes, one (1) each. All airways shall be stored in a manner to maintain cleanliness.
- d. Nonmetallic oropharyngeal airways (OPAs): sizes 0-5, one (1) each. All airways shall be stored in a manner to maintain cleanliness.

e. Bag Valve Ventilation Units (BVMs):

i. One (1) adult, hand operated. Valves must operate in all weather, and unit must be equipped to be capable of delivering ninety to one hundred (90 to 100) percent oxygen to the patient.

ii. One (1) child, hand operated. Valves must operate in all weather and unit must be equipped to be capable of delivering ninety to one hundred (90 to 100) percent oxygen to the patient. The BVM must include safety pop-off mechanism with override capability.

iii. One (1) infant, hand operated. Valves must operate in all weather and unit must be equipped to be capable of delivering ninety to one hundred (90 to 100) percent oxygen to the patient. The BVM must include safety pop-off mechanism with override capability.

iv. In conjunction with the ventilation units above, 0, 1, 2, 3, 4, 5 masks will be carried (either the disposable or non-disposable types, local MCO).

f. Adult and Pediatric Magill forceps, one (1) each (local MCO).

g. Blind Insertion Airway Device (BIAD): meet all age and weight size categories as defined by Food and Drug Administration (FDA). Syringe(s) needed to inflate bulbs shall be included in packaging, if not appropriate size(s) must be carried by provider (local MCO).

4. Bandage Material;

a. ABD pad five (5) inches by nine (9) inches, or larger, two (2) minimum.

b. Individually wrapped, sterile four (4) inches by four (4) inches gauze pad, fifteen (15) minimum.

c. Gauze bandage rolls individually wrapped and sterile in three (3) varieties of sizes (for example, 4.5 inches x 4.1 yards, 3.4 inches x 3.6 yards), one (1) each.

- d. Commercial sterile occlusive dressing, minimum size four (4) inches by four (4) inches, two (2) each.
- e. Adhesive tape, hypoallergenic, one (1), two (2), and three (3) inches wide, one (1) each.
- f. Sterile burn sheet, one (1) each (local MCO).
- g. Triangular bandages, minimum two (2) each (local MCO).
- h. Large trauma bandage shears, one (1) each.
- i. Minimum of 250 mL of sterile water or normal saline for irrigation.

5. Splints;

- a. Traction-type, lower extremity splint. Uni-polar or bi-polar type is acceptable (local MCO).
- b. Padded, wooden-type splints, two (2) each, fifteen (15) inches by three (3) inches and thirty-six (36) inches by three (3) inches, or other approved commercially available splints for arm or leg fractures (local MCO).

6. Spine Boards;

- a. One (1) Long Spine Board (at least sixteen (16) inches by seventy-two (72) inches). The use of folding backboards is acceptable as a substitute for the long spine board (local MCO).
- b. Cervical collars for adult and pediatric adjustable or available in sizes of short, regular, or tall; minimum one (1) each. Each cervical collar shall be manufactured with rigid or semi-rigid material (local MCO).
- c. Adult and Pediatric head immobilization device, commercially or premade: One (1) each (local MCO).
- d. Nine (9) foot straps, minimum three (3) each, or one set of 10-point spider straps (local MCO).

7. Obstetrical kit: The kit shall be sterile, latex free and contain the following: gloves, scissors or surgical blades, umbilical cord clamps or tapes, dressing, towels, perinatal pad, bulb syringe and a receiving blanket for delivery of infant (local MCO);

8. Assessment tools; and

- a. Adult and Pediatric blood pressure sphygmomanometer, cuff, bladder, and tubing must be clean and in good repair.
- b. Stethoscope with membrane(s) and tubing in good repair.
- c. Adult and Pediatric pulse oximeter with numeric reading.
- d. Glucometer or blood glucose measuring device (local MCO).

9. Miscellaneous Equipment:

- a. Eye protection or face shield, one (1) for each medical crew member (local MCO).
- b. Non-sterile, latex free exam gloves in two (2) variations of size, labeled; minimum of five (5) pairs each.

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- c. Waterless hand cleanser, commercial antimicrobial.
- d. EPA recommended germicidal/viralcidal agent or a sodium hypochlorite solution of ninety-nine (99) parts water and one (1) part bleach used for cleaning equipment.
- e. A clearly marked sharps container (may be fixed or portable) with locking mechanism.
- f. Emesis basin, one (1) (local MCO).
- g. Bedpan and urinal, one (1) each (local MCO).
- h. Two (2) dependable flashlights or electric lanterns.
- i. One (1) fire extinguisher approved for aircraft use. Each shall be fully charged with valid inspection certification and capable of extinguishing type A, B, or C fires. At least one (1) hand fire extinguisher must be provided and conveniently located on the flight deck for use by the flight crew.
- j. Additional equipment. Equipment not found in this regulation is subject to inspection and must be stored and operate to the manufacturer's recommendations. If any fault is found, the equipment must be immediately removed for repair and/or replacement.

E. Advanced Life Support (ALS) Equipment. Air ambulances providing ALS in the Prehospital or Special Purpose category must have all the following equipment and supplies on board in addition to Section 1202.D:

- 1. Cardiac monitor;
 - a. Must be secured and positioned so that displays are visible to the medical attendant(s) and;
 - b. Must have printable four (4) lead waveform, twelve (12) lead/EKG, SpO₂ waveform with numeric reading, and invasive pressure monitor port(s) for adult and pediatric (including neonate, if applicable) and;
 - c. One (1) extra roll of printer paper;
 - d. Have an internal rechargeable battery pack(s);
 - e. Extra battery or AC adapter and cord available;
 - f. Defibrillator, which may be integrated into cardiac monitor modular to include:
 - i. Adult and Pediatric paddles and pads are available; and
 - ii. Appropriate size pads and settings must be available for neonatal transports (if neonatal transports are conducted); and
 - g. Adult and Pediatric capabilities to Transcutaneous Pace. Either stand-alone unit or integrated in to cardiac monitor modular.
- 2. Advanced airway and ventilatory support equipment;
 - a. One (1) laryngoscope handle with extra set of batteries and bulbs, if applicable.
 - b. Laryngoscope blades, adult, child, and infant sizes.

- i. 0-4 Miller.
- ii. 1-4 Macintosh.
- c. One (1) each disposable endotracheal tubes sizes as well as intubation stylettes sized for each tube.
 - i. 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm cuffed or uncuffed.
 - ii. 6.0, 6.5, 7.0, 7.5, 8.0 mm.
 - iii. Other sizes (local MCO).
- d. Water soluble lubricating jelly, four (4) each.
- e. Adult and Pediatric Magill forceps, one (1) each.
- f. Blind Insertion Airway Device (BIAD) that meet all age and weight size categories as defined by FDA. Syringe(s) needed to inflate bulbs shall be included in packaging, if not appropriate size(s) must be carried by provider.
- g. Age appropriate Positive End-Expiratory Pressure (PEEP) valve (may be incorporated into BVMs).
- h. A mechanical ventilator and circuit appropriate to age/weight, including neonate (if applicable) which must include measurement of:
 - i. Fraction of inspired oxygen (FiO₂);
 - ii. Tidal volume (V_t);
 - iii. Respiratory rate (RR) or frequency; and
 - iv. Positive End-Expiratory Pressure (PEEP).
- i. Continuous Positive Airway Pressure (CPAP), able to be incorporated within the mechanical ventilator; appropriate settings and attachments (such as face masks) for adults and pediatric patients, and neonate patients (if applicable).
- j. Bi-level Positive Airway Pressure (BiPAP), which may be incorporated within the mechanical ventilator; appropriate settings and attachments for adults and pediatric; neonate (if applicable).
- k. Printable waveform End-tidal CO₂ continuous monitoring capabilities, which may be incorporated within cardiac monitor modular.

3. Venous Access;

- a. Intravenous catheters 14g-20g, two (2) of each.
 - i. 22g-24g, two (2) each required if pediatric or neonate transports are conducted.
- b. Intraosseous needles.
 - i. Adult and Pediatric needles.

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ii. Neonate size required if applicable.

c. Minimum of two (2) macro drip sets, 10-20gtts/mL.

d. Minimum of two (2) independent multi-channel infusion pump that allows fluid and medications to be administered at different rates, sequentially. IV pump, at minimum, must:

i. Have an internal rechargeable battery pack;

ii. Have a AC adapter and cord; and

iii. Display the infusion rate, volume infused, and volume remaining.

e. Two (2) sets of IV pump tubing.

f. 18g-25g needles at least one and one-half inch length, minimum of four (4):

i. Two (2) must be 18g-20g.

ii. Two (2) must be 23g-25g.

g. Syringes.

i. 1mL, two (2) each.

ii. 3-5mL, two (2) each.

iii. 10-20mL, four (4) each.

h. Minimum of three (3) IV start kits containing:

i. Latex free tourniquet.

ii. Antiseptic solution.

iii. Latex free IV catheter dressing.

iv. Intravenous arm boards for pediatric patients, two (2) each (local MCO).

4. Intravenous Fluids;

a. A total of 2000mL of intravenous fluids onboard, may be a combination of:

i. Sizes (such as 100mL-1000mL).

ii. Variety (such as Lactated Ringers, Normal Saline, D5W).

iii. Must have the capability to administer warm fluids.

5. Miscellaneous Equipment; and

a. A current color-coded Pediatric weight and length-based drug dose chart.

b. Alcohol or iodine prep pads for preparing IM injections, minimum six (6).

6. Additional equipment: equipment not found in this regulation is subject to inspection and must be stored and operate to the manufacture recommendations. If any fault is found, the equipment must be immediately removed for repair and/or replacement.

Section 1203. Special Purpose Air Ambulances. (II)

All special purpose air ambulances must be equipped with at least the following items from Section 1202: A, B, C, D, and E.

Section 1204. Medication and Fluids for Advanced Life Support Air Ambulances. (II)

Such medications and fluids approved by the Board for possession and administration by EMTs, and specified by the Medical Control Physician, will be carried on the air ambulance. Medications not included on the approved medication list for Paramedics may be carried on board the air ambulance so long as there is a written protocol which is signed and dated by the Medical Control Physician, for the use of the medications, fluid, or blood product and delineates administration only by a registered nurse or physician.

A. Medications must be easily accessible.

B. Controlled substances are in a double locked system and kept in a manner consistent with state and federal Drug Enforcement Agency (DEA) regulations.

C. Storage of medications allows for protection from extreme temperature changes within the U.S. Pharmacopeia guidelines as listed in Section 601.I.5, if environment deems it necessary.

D. If there is a refrigerator on the vehicle for medications, a temperature monitoring and tracking policy is required, and the refrigerator is used and labeled “for medication use only.”

Section 1205. Rescue Exception. (II)

An aircraft without a permit may be used for occasional non routine missions, such as the rescue and transportation of victim/patients, who may or may not be ill or injured, from structures, depressions, water, cliffs, swamps or isolated scenes, when in the opinion of the rescuers or EMS provider present at the scene, such is the preferred method of rescue and transportation incident thereto due to the nature of the entrapment, condition of the victim, existence of an immediate life-threatening condition, roughness of terrain, time element and other pertinent factors:

A. Provided that after the initial rescue, an EMT or higher level EMS technician accompanies the victim-patient en-route with the necessary and appropriate EMS supplies needed for the en-route care of the specific injuries or illness involved.

B. Provided the aircraft is of adequate size and configuration to effectively make the rescue and to accommodate the victim-patient, attendant(s) and equipment.

C. Provided reasonable space is available inside the aircraft for continued victim-patient comfort and care.

D. Provided a permitted aircraft is not available within a reasonable distance response time; and

E. Provided the victim-patient is transferred to a higher level of EMS ground transportation for stabilization and transport if such ground unit is available at a reasonably safe landing area.

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SECTION 1300.

PATIENT CARE REPORTS (III)

Section 1301. Patient Care Reports.

A. Each licensed provider must create and submit an electronic patient care report (ePCR) for each patient contact regardless of patient transport decision.

B. The primary care attendant is responsible for documenting all patient contact, care, and transport decision within the ePCR. All required documentation must be completed within twenty-four (24) hours of the conclusion of call.

C. Each licensed provider must submit its ePCRs into PreMIS within seventy-two (72) hours of the conclusion of call.

D. When transporting to an emergency room (ER), patient ePCR shall be submitted to the ER within thirty (30) minutes of the completion of the call. In lieu of that, a paper pre-run information sheet may be substituted until the ePCR is sent. ePCR information shall be sent no later than twenty-four (24) hours from completion of the call.

Section 1302. Data Manager.

A. Each licensed provider that provides patient care shall appoint a Data Manager to ensure accuracy, HIPAA compliance, security, and provide timely submission of ePCRs into PreMIS.

B. The Department must be notified of any change in the Data Manager within ten (10) days.

C. The Data Manager shall ensure that each ePCR submitted reflects all the attendants on the incident including non-certified drivers (if applicable).

Section 1303. Content.

A. Patient care reports shall reflect services, treatment, and care provided directly to the patient by the provider including, but not limited to, information required to properly identify the patient, a narrative description of the call from time of first patient contact to final destination, all providers on the call, and other information as determined by the Department.

B. All patient care reports shall be coherently written, authenticated by the author, and time stamped.

C. Patient care reports involving refusals shall include, but not be limited to the following: details of any assessment performed; information regarding the patient's capacity to refuse; information regarding an informed refusal by the patient; information regarding provider's efforts to convince the patient to accept care; and any efforts by the provider to protect the patient after the refusal if the patient becomes incapacitated.

D. Data submissions from ePCR software shall maintain a quality score no higher than fifty percent (50%) of the average state data quality score, as provided by the Department's vendor. Licensed providers shall have ninety (90) calendar days from the Department's notification to successfully correct data quality. For example, if the average state data quality score is five (5), then the licensed providers must have a quality score of seven and one half (7.5) or lower to meet this requirement.

Section 1304. Report Maintenance.

A. South Carolina utilizes PreMIS, an electronic patient care reporting system that is compliant with the current version of the National EMS Information System (NEMSIS). Data submissions from ePCR software into the state system must meet the Department's requirements as outlined in the South Carolina EMS Data Manager's program manual.

B. The licensed provider shall provide accommodations and equipment adequate for the protection, security, and storage of patient care reports.

C. The Department maintains an electronic data stream of the ePCR with the state-required data elements from the original report. Licensed providers must maintain their copy of the original data, all attachments and appended versions of each ePCR for no less than ten (10) years on all adult patients and thirteen (13) years for minor patients as stated in S.C. Code Section 44-115-120. Attachments to ePCRs include, but are not limited to, EKGs, waveform capnography records, code summaries, short reports, and other forms of recorded media.

D. Prior to closure of business, the licensed provider must arrange for preservation of ePCRs to ensure compliance with these regulations. The provider must notify the Department, in writing, describing these arrangements within ten (10) days of closure.

E. In the event of a change of ownership, all patient care reports shall be transferred to the new owner(s).

F. The patient care report is confidential. Reports containing protected or confidential health information shall be made available only to authorized individuals in accordance with state and federal laws.

G. When patient care is transferred, the receiving agency shall receive the copy of the patient care report within a reasonable amount of time, preferably at the time of transfer, to ensure continuity in quality care.

H. Pursuant to S.C. Code Section 44-61-160, a person who intentionally fails to comply with reporting, confidentiality, or disclosure of requirements in this section is subject to a civil penalty of not more than one hundred dollars (\$100) for a violation of the first time a person fails to comply and not more than five thousand dollars (\$5000) for a subsequent violation.

SECTION 1400.

DO NOT RESUSCITATE ORDER

Section 1401. Purpose and Authority of Emergency Medical Services Do Not Resuscitate Order.

A. Title 44, Chapter 78 of the 1976 S.C. Code directs the Department to promulgate regulations necessary to provide directions to emergency medical personnel in identifying and honoring the wishes of patients who have executed a Do Not Resuscitate Order for Emergency Services. The Do Not Resuscitate Order for Emergency Services is commonly referred to as the EMS DNR law.

B. The EMS DNR law is applicable only to resuscitative attempts by EMS providers in the pre-hospital setting such as the declarant's home, a long-term care facility, during transport to or from a health care facility and in other locations outside of acute care hospitals.

C. Specific statutory authority is found in S.C. Code Section 44-78-65.

Section 1402. Definitions.

A. The definitions contained in S.C. Code Section 44-78-15 are hereby incorporated by reference.

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B. Agent or Surrogate means a person appointed by the declarant under a Health Care Power of Attorney, executed or made in accordance with the provisions of S.C. Code Sections 62-5-504 and/or 44-77-10.

C. Cardiac Arrest means the cessation of a functional heartbeat.

D. Cardiopulmonary Resuscitation or CPR means the use of artificial respirations to support restoration of functional breathing combined with closed chest massage to support restoration of a functional heart beat following cardiac arrest.

E. Department means the South Carolina Department of Health and Environmental Control.

F. Respiratory Arrest (Pulmonary Arrest) means cessation of functional breathing.

G. Do Not Resuscitate Order for Emergency Medical Services marker is a bracelet or necklace that is engraved with the patient's name, the health care provider's name and telephone number and the words "Do Not Resuscitate" or the letters DNR.

Section 1403. General Provisions.

A. The EMS DNR Form. The document which is to be a "Do Not Resuscitate Order" for EMS purposes must be in substantially the following form:

NOTICE TO EMS PERSONNEL

This notice is to inform all emergency medical personnel who may be called to render assistance to

(Name of patient)

that he/she has a terminal condition which has been diagnosed by me and has specifically requested that no resuscitative efforts including artificial stimulation of the cardiopulmonary system by electrical, mechanical, or manual means be made in the event of cardio-pulmonary arrest.

REVOCAION PROCEDURE

THIS FORM MAY BE REVOKED BY AN ORAL STATEMENT BY THE PATIENT TO EMS PERSONNEL, OR BY MUTILATING, OBLITERATING, OR DESTROYING THE DOCUMENT IN ANY MANNER.

Date: _____

Patient's Signature (or Surrogate or Agent)

Physician's Signature

Physician's Address

Physician's Telephone Number

B. Distribution of the EMS DNR Form. The EMS DNR form, along with instructions for execution and a patient information sheet shall be distributed by the Department to health care providers. Informational pamphlets shall be prepared by the Department and made available to other interested parties upon request.

C. Location of the Executed EMS DNR Form. The executed EMS DNR Form shall be placed in a location where the document is easily observed and recognized by EMS personnel. The form shall be displayed in such a manner that it will be visible and protected at all times.

D. EMS DNR Marker. The DNR marker shall be a bracelet or necklace as approved by the Department. The marker may be worn upon the execution of the EMS DNR Document. Wearing of the marker shall not be mandatory but is encouraged. The marker will alert EMS personnel of the probable existence of the EMS DNR document. The marker shall be of metallic construction and shall be unique and easily recognizable. The marker shall contain the patient's name, the health care provider's name and telephone number and the words "Do Not Resuscitate" or the letters DNR.

E. No person under the age of eighteen (18) may request or receive a "Do Not Resuscitate Order for Emergency Medical Services" as noted in S.C. Code Section 44-78-50(B).

Section 1404. Revocation of EMS DNR Order.

The EMS DNR Order may be revoked at any time by the oral expression of the patient to EMS personnel or by the mutilation, obliteration or destruction of the document in any manner. If the order is revoked, EMS personnel shall perform full resuscitation and treatment of the patient.

Section 1405. Patient's Assessment and Intervention. (II)

When EMS Personnel report to a scene, they shall do a patient assessment. If an EMS DNR bracelet or necklace is found during the assessment, EMS personnel shall make a reasonable effort to determine that an EMS DNR form exists and to ensure that the EMS DNR form applies to the person on which the assessment is being made. If no DNR form is found, resuscitative measure will be initiated. If after starting resuscitative measures an EMS DNR form is later found, resuscitative measure must be stopped.

Section 1406. Resuscitative Measures to be Withheld or Withdrawn. (II)

In the event that the patient has a valid EMS DNR order, the following procedures shall be withheld or withdrawn:

- A. CPR;
- B. Endotracheal intubation and other advanced airway management;
- C. Artificial ventilation;
- D. Defibrillation;
- E. Cardiac resuscitation medication; and
- F. Cardiac diagnostic monitoring (ONLY withheld in the face of cardiac arrest).

Section 1407. Procedures to Provide Palliative Treatment. (II)

The following treatment may be provided as appropriate to patients who have executed a valid EMS DNR order:

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- A. Suctioning;
- B. Oxygen;
- C. Pain medication;
- D. Non-cardiac resuscitation medications;
- E. Assistance in the maintenance of an open airway as long as such assistance does not include intubation or advanced airway management;
- F. Control of bleeding;
- G. Comfort care; and
- H. Support to patient and family.

Section 1408. DNR Information for the Patient, the Patient's Family, the Health Care Provider and EMS Personnel. (II)

- A. Responsibilities of the patient or his or her Surrogate or agent.

The patient and his or her surrogate or agent shall:

1. Make all care givers aware of the location of the EMS DNR Form and ensure that the form is displayed in such a manner that it will be visible and available to EMS personnel.
2. Be aware of the consequences of refusing resuscitative measures.
3. Be aware that if the form is altered in any manner resuscitative measures will be initiated.
4. Understand that in all cases, supportive care will be provided to the patient.

- B. Responsibilities of the Health Care Provider (Physician) The patient's physician:

1. Has determined that the patient has a terminal condition.
2. Has completed the patient's EMS DNR Form.
3. Has explained to the patient and family the consequences of withholding resuscitative care; the medical procedures that will be withheld and the palliative and supportive care that will be administered to the patient.

- C. Responsibilities of EMS Personnel.

EMS personnel:

1. Will confirm the presence of the EMS DNR Form and the identity of the patient.
2. Upon finding an unaltered EMS DNR Form, will withhold or withdraw resuscitative measures such as CPR, endotracheal intubation or other advanced airway management, artificial ventilation, defibrillation, cardiac resuscitation medication and related procedures.

3. Will provide palliative and supportive treatment such as suctioning the airway, administration of oxygen, control of bleeding, provision of pain and non-cardiac medications, provide comfort care and provide emotional support for the patient and the patient's family.

4. Must have in his possession either the original or a copy of the DNR Order during transport of the patient.

SECTION 1500.

FINES AND MONETARY PENALTIES

Section 1501. Fines and Monetary Penalties.

A. When a decision is made to impose monetary penalties, the following schedule shall be used as a guide to determine the dollar amount:

MONETARY PENALTY RANGES

FREQUENCY	CLASS I	CLASS II	CLASS III
1 st	\$300 - 500	\$100 - 300	\$50 - 100
2 nd	\$500 - 1,500	\$300 - 500	\$100 - 300
3 rd	\$1,000 - 3,000	\$500 - 1,500	\$300 - 800
4 th	\$2,000 - 5,000	\$1,000 - 3,000	\$500 - 1,500
5 th	\$5,000 - 7,500	\$2,000 - 5,000	\$1,000 - 3,000
6 th or more	\$10,000	\$7,500	\$2,000 - 5,000

B. When a licensed agency fails a vehicle reinspection, a Class IV penalty may be levied upon the agency. Pursuant to S.C. Code Section 44-61-70, the following Class IV fine schedule shall be used when a permitted ambulance or licensed rapid responder service loses points upon reinspection:

Frequency of violation of standard within a thirty-six (36) month period:

MONETARY PENALTY RANGES

FREQUENCY	CLASS IV Points/Penalty	
1 st	0-24	\$25-50
2 nd	25-50	\$50-100
3 rd	51-100	\$100-300
4 th	101-500	\$300-500
5 th	501-1000	\$500-1500
6 th or more	Over 1000	\$1000-3000

C. There may be multiple occurrences of a violation (Class I, II, and III) within a one (1) day period that would constitute multiple fineable occurrences. (For example, in allowing uncertified personnel to render patient care, each patient treated is an "occurrence" and thus a separate fineable offense.)

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

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regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

SECTION 1700.

GENERAL

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

Fiscal Impact Statement:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any inherent requirements of this regulation. There are no external costs anticipated.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness is based on an analysis of the factors listed in S.C. Code Sections 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: R.61-7, Emergency Medical Services.

Purpose: The purpose of these amendments to R.61-7 is to clarify standards pertaining to Emergency Medical Services in South Carolina. These amendments incorporate changes in the statutory authority of the regulation, incorporate statutory requirements for EMT certification and training, update the vehicle equipment list to current accepted industry standards, modify the ground ambulance requirements to reflect the most current standards, change the air ambulance requirements to reflect the latest statutory amendments, incorporate requirements for ambulance drivers, modify the name of first responder agencies to rapid response vehicles, add and amend definitions, and rewrite the certification and training requirements. In addition, provisions have been amended for general clarity, readability, grammar, references, codification, and overall improvement to the text of the regulation.

Legal Authority: 1976 Code Section 44-7-260.

Plan for Implementation: Upon approval by the General Assembly and publication in the *State Register* as a final regulation, a copy of R.61-7, which includes these latest amendments, will be available electronically on the Department's Laws and Regulations website. Subsequently, this regulation will be published in the South Carolina Code of Regulations. Printed copies will be available for a fee from the Department's Freedom of Information Office. The Department will also send an email to stakeholders, affected services and facilities, and other interested parties.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Pursuant to S.C. Code Section 1-23-120(J), the Department is required to perform a formal review of its regulations every five (5) years and update them if necessary. Regulation 61-7 has not been substantively updated since 2006. These amendments are necessary to incorporate changes in the Emergency Medical Services Act. The amendments further clarify and improve EMT certification and training, vehicle equipment lists, ground and air ambulance standards, and incorporate requirements for ambulance drivers.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these amendments. Amendments to R.61-7 update standards of licensure, procedures, and requirements for EMS organizations and providers while maintaining the interests of patient health and safety and lessening provider burdens.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The amendments to R.61-7 seek to reasonably simplify the EMS regulations while providing standards in the interest of patient care and safety for the treatment and transport of the sick and injured in South Carolina. There is no anticipated effect on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the revision is not implemented, unnecessary burdens may be placed on EMS providers by not updating the regulations to current national standards.

Statement of Rationale:

The Department is amending R.61-7 to incorporate changes in the Emergency Medical Services Act of South Carolina. Specifically, the amendments incorporate updated statutory requirements for EMT certification and training, eliminate the vehicle equipment list, modify the ground ambulance requirements to reflect the latest standards, change the air ambulance requirements to reflect the latest statutory amendments, include additional certified personnel into the regulation, and modify names of certain response agencies.

Document No. 4611

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 61

Statutory Authority: 1976 Code Section 44-1-140

61-52. Psittacine Birds

Synopsis:

In the interest of good government and efficiency, the Department of Health and Environmental Control has repealed Regulation 61-52, Psittacine Birds. See detailed information for this repeal in the Statements of Need and Reasonableness and Rationale herein.

A Notice of Drafting for this repeal was published in the *State Register* on August 28, 2015.

Instructions: Repeal R.61-52, Psittacine Birds, in its entirety.

Text:

61-52. [Repealed]

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Fiscal Impact Statement:

The repeal of R.61-52 is anticipated to have no substantial fiscal or economic impact on the State and its political subdivisions.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness complies with Section 1-23-115(c)(1)-(3) and (9)-(11), S.C. Code of Laws, 1976, as amended.

DESCRIPTION OF REGULATION: R.61-52, Psittacine Birds.

Repeal of R-61-52, Psittacine Birds.

Purpose: This regulation describes psittacine birds and restricts individuals and businesses from selling birds known to be ill with Avian Chlamydiosis (also called Psittacosis, in humans) in South Carolina. The regulation requires documentation of any purchase, sale, trade, or exchange of psittacine birds in this State; such documentation is required to be presented for inspection by the Board of Health.

Regulation 61-52 has been repealed because it places an unnecessary financial burden on individuals and business owners in this State to have every psittacine bird sold, traded, or exchanged tested for Avian Chlamydiosis, as well as documentation retained. Also, fewer than 50 human Psittacosis cases have been reported annually to the CDC in the USA in recent years; and, most Psittacosis cases are effectively treated with antibiotics.

Legal Authority: 1976 Code Section 44-1-140.

Plan for Implementation: The repeal will take effect upon approval by the S.C. General Assembly and publication in the State Register. Subsequently the R.61-52 will appear as repealed in the S.C. Code of Regulations.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION REPEALS BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Regulation 61-52 puts an inordinate financial burden on the private sector to fund laboratory testing for every psittacine bird that is either purchased, sold, traded, or exchanged, as laboratory testing is required to determine *Chlamydophila psittaci* status of birds. It would also present an inordinate burden on individuals and businesses in the private sector to keep transaction records for every purchase, sale, trade, and exchange of psittacine birds in this State. Regulation 61-52 requires these transaction records to be kept and available for inspection by the Board of Health; while, no Bureau of the Department is currently charged with performing this task.

DETERMINATION OF COSTS AND BENEFITS:

The repeal of R.61-52 will have no substantial fiscal or economic impact on the State and its political subdivisions; however, it could produce economic savings to the private sector.

UNCERTAINTIES OF ESTIMATES:

No known uncertainties.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

There are no known anticipated detrimental effects to either the environment or public health posed by the repeal of 61-52. The incidence of known severe disease in humans due to *C.psittaci* infection is very low; since 1996, the CDC has received reports of fewer than 50 cases of Psittacosis in the United States each year. In South Carolina, only 2 cases have been reported in the previous 5 year period. Psittacosis symptoms may be mild, consisting of only influenza-like illness; therefore, actual Psittacosis disease burden is unknown, as most people are unlikely to pursue testing for milder illness. Also, routine antibiotic therapy is available to effectively treat most cases of Psittacosis, which was not the case in earlier eras.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect to either the environment or public health posed by the repeal of R. 61-52, as individuals and businesses currently do not adhere to the requirements of the regulation.

Statement of Rationale:

The Department has repealed R.61-52 for a number of substantive reasons. Modern scientific research has shown that most psittacine birds are asymptomatic carriers of *C.psittaci*; therefore, laboratory testing is required to demonstrate infection in these birds. Testing of all psittacine birds that are purchased, sold, traded, or exchanged in the State would pose an inordinate burden on individuals and business owners in the private sector. Also, retention of documentation of said testing, as well as purchases, sales, trades, and exchanges of all psittacine birds would posed a large burden for the private sector. Finally, in the current era of medicine, Psittacosis is effectively treated with antibiotics; and, fewer than 50 human cases are reported annually in the USA to the CDC.

Document No. 4596

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**CHAPTER 61**

Statutory Authority: 1976 Code Section 44-7-260

61-103. Residential Treatment Facilities for Children and Adolescents.

Synopsis:

Regulation 61-103 has not been substantively updated since 1991. The amendments herein include the Department's effort to incorporate updates and clarification relating to licensing requirements, accident and incident reporting, admission and intake requirements, resident rights, program activities, inservice training, infection control and sanitation, record maintenance and retention practices, personnel requirements, medication management, fire and life safety requirements, and construction and design requirements. In addition, current provider-wide exceptions and memoranda applicable to residential treatment facilities for children and adolescents have been incorporated.

A Notice of Drafting was published in the *State Register* on May 22, 2015.

**Changes described below are made pursuant to letter dated April 27, 2016
of the Health Subcommittee of the House of Representatives' Regulations
and Administrative Procedures Committee**

Section-by-Section Discussion of Health Subcommittee Changes:

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Section 101.A.2. The definition for psychological abuse was amended for consistency with S.C. Code Section 43-35-10(10).

Section 101.DD. The definition for local transportation was amended to remove references of costs to residents.

Section 400.A.6. Requirements for policies and procedures have been amended to clarify the required plan for cooperation with other public and private entities to ensure comprehensive treatment for all residents.

Section 701.B.17. Requirements for educational testing and prior educational records have been amended to require records “when available upon request.”

Section 901.A.3. Resident care and services language has been amended to require that the facility “ensure that each resident has a primary physician and psychiatrist who maintain familiarity with the resident’s physical and mental health status.”

Section 901.A.6. Requirements for the written agreement between residents and facilities have been amended to include the amount a resident receives for his or her personal needs allowance, “if applicable.”

Section 901.F (former). The requirement for opportunities for participation in religious services have been removed from this section.

Section 902.C. The program activities requirements have been amended to require that the facility “develop the recreational program, and provide and coordinate recreational activities for the residents, including maintaining recreational supplies.

Section 903. Transportation requirements have been amended to remove references of costs to residents.

Section 1001.C (former). Rights and assurances requirements have been amended to remove references to the prohibition on discrimination against residents.

Section 1001.D (now 1001.C). Language referencing payment offered and service cost has been removed.

Section 1001.F (former). Requirements for telephone use by residents have been removed.

Section 1002.A.10. Language was amended to require “[t]he 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 and explained to the resident and family.

Section 1302. The requirement of maintaining a supply of food on the premises has been amended to apply only to facilities preparing food onsite.

Section 1303.B (former). Language requiring a congenial and relaxed environment in the dining area has been removed.

Section 1303.G. (now 1303.F). Requirements for snacks have been amended to require that suitable food and snacks be available between meals.

Section 1305.A. Language requiring a dietitian to sign off on each resident’s special diet menu has been removed.

Section 2602.B.2. Resident room floor area requirements for rooms for more than one (1) resident have been amended to require at least eighty (80) square feet per licensed bed.

Section-by-Section Discussion below of Amendments submitted by the Department of Health and Environmental Control on January 12, 2016, for legislative review:

TABLE OF CONTENTS

The table of contents was added.

61-103.100. Definitions (formerly 61-103.A(1))

The definitions of 101.A Abuse, 101.B Administrator, 101.C Airborne Infection Isolation, 101.D Annual, 101.E Assessment, 101.F Authorize Healthcare Provider, 101.G Blood Assay for *Mycobacterium tuberculosis*, 101.I Consultation, 101.J Contact Investigation, 101.K Controlled Substance, 101.M Designee, 101.O Direct Care Staff Member, 101.P Discharge, 101.Q Dispensing Medication, 101.R Exploitation, 101.S Facility, 101.T Health Assessment, 101.U Incident, 101.V Individual Treatment Plan, 101.W Inspection, 101.X Investigation, 101.Y Latent TB Infection, 101.Z Legend Drug, 101.AA License, 101.BB Licensed Nurse, 101.DD Local Transportation, 101.EE Medication, 101.FF Neglect, 101.GG Nonlegend Drug, 101.HH Physical Examination, 101.II Physician, 101.JJ Physician Assistant, 101.KK Quarterly, 101.LL Repeat Violation, 101.NN Resident

Room, 101.PP Responsible Party, 101.QQ Restraint, 101.RR Revocation of License, 101.SS Risk Assessment, 101.TT Sponsor, 101.UU Staff Member, 101.VV Suspension of License, and 101.WW Volunteer were added. The definitions of 101.H (formerly A(1)(d)) Child/Adolescent, 101.L (formerly A(1)(e)) Department, 101.N (formerly A(1)(f)) Dietitian, 101.CC (formerly A(1)(k)) Licensee, 101.MM (formerly A(1)(n)) Resident, and 101.OO (formerly A(1)(o)) Residential Treatment Facility for Children and Adolescents have been amended. The definitions of A(1)(A) Attic, A(1)(b) Automatic Sprinkler System, A(1)(c) Basement, A(1)(g) Existing Facilities, A(1)(h) Exit, A(1)(i) Fire-Resistance Rating, A(1)(j) First Floor, A(1)(l) Multi-Story, A(1)(m) New Facilities, and A(1)(p) Story have been deleted. The remaining definitions were renumbered to adjust the codification.

61-103.A(2). Interpretations

This section has been deleted.

61-103.102. LICENSE REQUIREMENTS (formerly 61-103.B)

Section B title was renamed License Requirements and renumbered to adjust the codification.

61-103.102.A. License

Section 102.A was added to delineate the scope of licensure and to require that the facility shall provide only the care and services it is licensed to provide pursuant to the defined facility requirements.

61-103.102.B. Compliance (formerly 61-103.A(2)(f))

Section 102.B was relocated from former Section A(2)(f) and clarifies the requirements for compliance with these regulations.

61-103.102.C. Compliance with Structural Standards

New Section 102.C was added to allow facilities licensed at the time of promulgation of these regulations to continue utilizing the previously-licensed structure without modification.

61-103.102.D. Licensed Bed Capacity

New Section 102.D was added to delineate the requirements of the licensed bed capacity for facilities.

61-103.102.E. Persons Received in Excess of Licensed Bed Capacity

New Section 102.E was added to require that facilities not exceed the licensed number of beds as stated on the face of the license. Section 102.E further adds an exception for persons received in cases of emergency.

61-103.102.F. Issuance and Terms of License (formerly 61-103.B(2))

Section 102.F (formerly B(2)) was relocated and amended to clarify the license terms and provisions relating to multiple facilities and license placement within the facility.

61-103.102.G. Facility Name (formerly 61-103.B(2)(d))

Section 102.G was relocated from former Section B(2)(d).

61-103.102.H. License Application (formerly 61-103.B(1))

Section 102.H was relocated from former Section B(1) and clarifies the requirements of the license application.

61-103.102.I. Licensing Fees

New Section 102.I was added to prescribe the fees required for licensure. Section 102.I adds that fees for additional beds shall be prorated based upon the remaining months of the licensure years.

61-103.102.J. Late Fee

New Section 102.J was added to require a late fee of seventy-five dollars (\$75.00) or twenty-five percent (25%) of the licensing fee amount for failure to submit a renewal application or fee by the license expiration date.

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Section 102.J further adds that continual failure to submit completed and accurate renewal applications and/or fees by the expiration date may result in an enforcement action.

61-103.102.K. License Renewal

New Section 102.K was added to delineate the requirements for license renewals. Section 102.K further adds that if a license renewal is delayed due to enforcement actions, the renewal license shall be issued only when the matter has been resolved.

61-103.102.L. Change of License (formerly 61-103.B(3))

Section 102.L was relocated from former Section B(3). Section 102.L.2 was added to require that changes in facility name or address, as notified by the post office, shall be accomplished by application or by letter from the licensee.

61-103.102.M. Exceptions to Licensing Standards (formerly 61-103.A(2)(h))

Section 102.M was relocated from former Section A(2)(h) and clarifies the exceptions to these standards.

61-103.200. ENFORCEMENT OF REGULATIONS

New Section 200 title was added for clarity and to update codification.

61-103.201. General

New Section 201 was added to delineate the means and methods by which the Department enforced these regulations

61-103.202. Inspections and Investigations (formerly 61-103.A(2)(e))

Section 202.A (formerly A(2)(e)) requires an inspection prior to initial licensing of a facility. Section 202.B was added to state that facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by state law. Section 202.C clarifies the use of photocopied records during an inspection or investigation. Section 202.D delineates the requirements for facilities found noncompliant with the standards of these regulations. Section 202.E delineates FOIA requirements for inspection and investigation reports. Section 202.F states that the Department may charge a fee for inspections and delineates the assessed fees for inspections.

61-103.203. Consultations

New Section 203 was added to allow consultations by the Department as requested by the facility or as deemed appropriate by the Department.

61-103.300. ENFORCEMENT ACTIONS (formerly 61-103.A(3))

The amendment revises the language in Section 300 (formerly A(3)) to clarify enforcement actions and adds the appropriate section title.

61-103.301. General (formerly 61-103.A(3))

Section 301 was relocated from former Section A(3) and adds language subjecting facilities to monetary penalties, or license revocation, suspension, or denial for statutory or regulatory violations.

61-103.302. Violation Classifications

Sections 302.A-D takes language from former Section A(3) and clarifies the different violation classifications. Section 302.E prescribes the factors considered in arriving at a decision to take enforcement action. Section 302.F delineates the monetary penalty ranges for violations within a thirty-six (36) month period.

61-103.400. POLICIES AND PROCEDURES (formerly 61-103.C(8))

Section 400 was relocated from former Section C(8) and clarifies the requirements of facility policies. Section 400.B was added to require facilities to establish a time period for review of all policies and procedures, at a minimum of every two (2) years, and requires that reviews be documented.

61-103.500. STAFF AND TRAINING

New Section 500 title was added for clarity.

61-103.501. Governing Authority (formerly 61-103.C(2))

Section 501 (formerly C(2)) was amended to clarify the requirements and duties of the governing authority of the facility.

61-103.502. Administrator (formerly 61-103.C(3))

Section 502 was relocated from former Section C(3) and delineates the requirements of the facility administrator. Section 502.B requires that 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. Section 502.D requires a staff member to be designated in writing to act in the absence of the administrator.

61-103.503. Personnel (formerly 61-103.C(5))

Sections 503.A and 503.B prescribe the criminal background check requirements for new personnel. Section 503.C requires that staff members and volunteers be provided the necessary training to perform their duties. Section 503.D delineates the minimum qualifications for personnel. Section 503.G requires written agreements between facilities and third parties when the facility utilizes an outside source to provide services at the facility.

61-103.504. Staff (formerly 61-103.F)

Section 504.A requires a direct care staff member actively on duty and present in the facility at all times the facility is occupied. Section 504.B states that the number and qualifications of staff members shall be determined by the number and condition of the residents. Section 504.C requires the facility to maintain documentation to ensure compliance with direct resident care staffing requirements.

61-103.505. Direct Resident Care Staffing (formerly 61-103.F(6))

Section 505.A was added to require a physician or authorized healthcare provider on-call twenty-four (24) hours a day and to require that his or her contact information be clearly posted in accessible places for all staff. Section 505.B was relocated from former Section F(6)(b). Section 505.C was relocated from former Section F(6)(a).

61-103.506. Inservice Training (formerly 61-103.C(5)(e))

Section 506 was relocated from former Section C(5)(e). Section 506.A requires documentation of all inservice training signed and dated by the individual receiving the training and the individual providing the training and delineates the required inservice training. Section 506.B (formerly C(5)(d)) requires that all new staff and volunteers have documented orientation to the facility and their required duties and responsibilities within twenty-four (24) hours of their first day on the job in the facility.

61-103.507. Health Status

New Section 507 was added to require all staff members who have contact with residents to have a health assessment, including tuberculin skin testing, within twelve (12) months prior to initial resident contact.

61-103.600. REPORTING

New Section 600 was added to delineate the facility's reporting requirements.

61-103.601. Accidents and/or Incidents

Section 601.A requires the facility to maintain a record of each accident and/or incident for six (6) years after the resident stops receiving services. Section 601.B requires the facility to report each accident and/or incident resulting in unexpected death or serious injury within twenty-four (24) hours to the next of kin and the Department. Section 601.B further provides a non-exhaustive list of accidents and/or incidents required to be reported. Section 601.C requires the facility to immediately report every serious accident and/or incident to the attending physician, next of kin or responsible party and local law enforcement when applicable. Section 601.D requires the facility to submit a written report of its investigation of the accident and/or incident to the

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Department, including specific items, within five (5) calendar days of the accident and/or incident. Section 601.E requires the facility to retain these reports. Section 601.F requires the administrator or his or her designee to report abuse and suspected abuse, neglect, or exploitation to the appropriate authorities.

61-103.602. Fire and Disasters

Section 602.A requires the facility to immediately notify the Department of any fire in the facility and submit to the Department a complete written report within seventy-two (72) hours of the fire. Section 602.B requires the facility to immediately report any fire or natural disaster that displaces residents or jeopardizes or potentially jeopardizes the safety of the residents.

61-103.603. Communicable Diseases and Animal Bites

Section 603 requires that all cases of diseases and animal bites that require reporting to be accomplished in accordance with Regulation 61-20, Communicable Diseases.

61-103.604. Administrator Change

Section 604 requires the facility to notify the Department in writing within seventy-two (72) hours of any change in administrator status and provide to the Department in writing within ten (10) days the name of the new administrator.

61-103.605. Accounting of Controlled Substances

Section 605 requires the facility to report any theft or loss of controlled substances to local law enforcement and the Department's Bureau of Drug Control upon discovery of the theft or loss.

61-103.606. Emergency Placement Notification

Section 606 requires the facility to notify the Department no later than the following workday of the names and location of individuals relocated to temporary sheltering facilities. Section 606 further requires approval from the Department when relocation to the receiving facility exceeds five (5) days.

61-103.607. Facility Closure

Section 607.A was added to require facilities to notify the Department in writing prior to the permanent closure of a facility and to require the facility to notify the Department within ten (10) days of closure of the provisions to maintenance of the facility records. Section 607.B was added to delineate the requirements of facilities temporarily closing.

61-103.608. Zero Census

Section 608 requires that when there have been no residents in the facility 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.

61-103.700. RESIDENT RECORDS (formerly 61-103.G)

Section 700 (formerly G) updates the requirements for resident records and adds a new section title for clarity.

61-103.701. Content (formerly 61-103.G(1)(e))

Section 701 was relocated from former Section G(1)(e) and clarifies and updates the requirements of resident records. Section 701.A (formerly G(1)(e)) was updated to allow for electronic records.

61-103.702. Initial Assessment and Treatment Planning

Section 702.A was added to require a written initial assessment, signed and dated by all participants, of the resident to ensure appropriateness of placement prior to admission, but no later than seventy-two (72) hours after admission. Section 702.B requires an initial treatment plan to be formulated, written, and interpreted to the staff and resident within seventy-two (72) hours of admission.

61-103.703. Comprehensive Assessment (formerly 61-103.D(2)(a))

Section 703 was relocated from former Section D(2)(a) and prescribes the requirements of the comprehensive assessment.

61-103.704. Individual Treatment Plan (formerly 61-103.D(2)(b))

Section 704.A requires the facility to develop an Individual Treatment Plan (ITP) within fourteen (14) days of admission. Section 704.A further states that the ITP shall be reviewed and/or revised as changes in resident needs occur, but not less than semi-annually. Section 704.B requires the comprehensive treatment plan to be reviewed at least every ninety (90) days or more frequently if the objectives of the program indicate. Section 704.C delineates the specific requirements of the ITP. Section 704.D requires the ITP to delineate the responsibilities of the sponsor and of the facility in meeting the needs of the resident.

61-103.705. Record Maintenance (formerly 61-103.G(3))

Section 705.A (formerly G(3)(a)) was amended to require the facility to provide accommodations, space, supplies, and equipment adequate for the protection and storage of resident records. Section 705.B was added to require that when a resident is transferred from one facility to another, a transfer summary, including physical examination, TB testing, the ITP, and the medication administration record, shall be forwarded to the receiving facility at the time of transfer or immediately thereafter. Section 705.C was added to ensure confidentiality of resident records. Section 705.D was added to require that records generated for residents from other entities be maintained by the facility. Section 705.E allows the facility to determine the medium in which information is stored. Section 705.F (formerly G(3)(d)) was relocated and updated to add that upon discharge of a resident, the record shall be completed within thirty (30) days. Section 705.G requires resident records to be maintained for at least six (6) years following the discharge of the resident and other regulation-required documentation to be retained at least twelve (12) months or since the most recent Department general inspection, whichever is the longer period. Former Section G(3)(c) was re-codified as an exception and allows for the original record to follow the resident when he or she moves from one licensed facility to another within the same provider network, meaning the same licensee.

61-103.800. ADMISSION AND RETENTION (formerly 61-103.D(1))

Section 800 was relocated from former Section D(1) and prescribes the requirements for admission and retention.

61-103.900. RESIDENT CARE AND SERVICES

New section title was added for clarity.

61-103.901. General

Section 901.A requires that 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, and delineates the required items in the written agreement. Section 901.B requires the facility to coordinate with residents to provide care and services and to detail the care and services in the ITP. Section 901.C requires the facility to render care and services in accordance with orders from physicians or other authorized healthcare providers and to take precautions for residents with special conditions. Section 901.D requires the facility to provide necessary items and assistance for residents to maintain their personal cleanliness. Section 901.E requires facilities to recognize, respect, and accommodate for cultural differences in residents. Section 901.F requires the facility to provide opportunities for religious services for residents. Section 901.G requires that in the event of closure of a facility, the facility shall ensure continuity of care and services by promptly notifying the resident's attending physician or other authorized healthcare provider.

61-103.902. Program Activities (formerly 61-103.H)

Section 902.A requires the facility to provide a variety of recreational programs to suit the interests and capabilities of the residents that choose to participate. Section 902.B requires at least one (1) different structured recreational activity provided daily each week. Section 902.C requires the facility to designate a staff member responsible for the development of the recreational program. Section 902.D requires the facility to maintain recreational supplies adequate and sufficient to accomplish the activities planned. Section 902.E requires the

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facility to provide a current month's schedule of activities offered. Section 902.F was relocated from former Section H(1) and clarifies the requirements of activities in conjunction with the requirements of the SCDE.

61-103.903. Transportation

Section 903 was added to require that the facility secure or provide transportation for residents when a physician's services are needed.

61-103.904. Restraints and Seclusion (formerly 61-103.E)

Section 904 was relocated from former Section E and clarifies the requirements for restraints and seclusion. Section 904.A was relocated from former Section E. Section 904.B prohibits the use of restraints or seclusion for staff convenience and adds that 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. Section 904.C requires facilities to use only those devices specifically designed as restraints and prohibits the use of makeshift restraints. Section 904.D requires that residents requiring restraint for more than twenty-four (24) hours be transferred to an appropriate facility. Section 904.E was relocated from former Section E(3)(c). Section 904.F was relocated from former Section E(3)(d). Section 904.G was relocated from former Section E(3)(e). Section 904.H was relocated from former Section E(4)(f). Section 904.I was relocated from former Section E(4)(g). Section 904.J was relocated from former Section E(4)(h).

61-103.905. Discharge and Transfer (formerly 61-103.E(5))

Section 905.A was relocated from former Section E(5)(a). Section 905.B requires that prior to discharge, the resident, his or her appropriate family member and sponsor (if any) shall be consulted. Section 905.C was relocated from former Section E(5)(b). Section 905.D was relocated from former Section E(5)(c). Section 905.E requires that upon transfer or discharge, resident information shall be released in a manner that promotes continuity of care. Section 905.F requires that upon transfer or discharge the facility shall ensure that all medications, personal possessions, and funds are released to the responsible party and/or receiving facility.

61-103.1000. RIGHTS AND ASSURANCES

New section title was added for clarity to clearly delineate the requirements of residents' rights and assurances.

61-103.1001. General

Section 1001.A was added to require that the grievance and complaint procedure be placed in a conspicuous place in a public area of the facility and include the address and phone number of the Department. Section 1001.B requires the care, services, and items provided by the facility to be delineated in writing and verified by signature of the resident or responsible party. Section 1001.C prohibits discrimination of residents or potential residents. Section 1001.D requires that the facility comply with all relevant federal, state, and local laws and regulations concerning discrimination. Section 1001.E prohibits residents from performing duties of staff members. Section 1001.F requires that residents be permitted to use the telephone and allowed privacy on calls. Section 1001.G requires adequate safeguards for protection and storage of residents' personal belongings. Section 1001.H requires provisions to be made for safeguarding money and valuables for residents requesting this assistance.

61-103.1002. Statement of Rights of Residents

Section 1002.A was relocated from former Section C(7) and further delineates the rights that shall be afforded to residents. Section 1002.B requires that the Statement of Rights of Residents be posted in a conspicuous place in the facility.

61-103.1100. RESIDENT PHYSICAL EXAMINATION

New section title was added for clarity and codification. Section 1100.A was relocated from former Section D(2)(a)(1)(a) and requires a physical examination completed by a physician or other authorized healthcare provider within thirty (30) days prior to admission or within forty-eight (48) hours of admission and at least annually thereafter and delineates the required areas of the physical examination. Section 1100.B requires that

where there is a need for further testing or treatment, arrangements shall be made to carry out the further testing. Section 1100.C delineates the required actions when a resident or potential resident has a communicable disease.

61-103.1200. MEDICATION MANAGEMENT

New section title was added for clarity.

61-103.1201. General

Section 1201.A delineates the requirements of management and storage of medications and supplies in the facility. Section 1201.B prescribes the requirements for first aid kits within the facility. Section 1201.C requires the facility to maintain applicable reference materials published within the previous three (3) years available to staff members administering medications.

61-103.1202. Medication and Treatment Orders

Section 1202.A requires that medications and treatments be administered to residents only upon orders, including standing orders, of a physician or other authorized healthcare provider. Section 1202.B (formerly G(2)) requires that all orders, including verbal orders, be received only by legally authorized staff members and signed and dated by a physician or other authorized healthcare provider no later than seventy-two (72) hours after the order is given. Section 1202.C requires that medications and supplies ordered for a specific resident not be provided or administered to any other resident.

61-103.1203. Administering Medication and Treatments

Section 1203 was added to delineate the requirements of medication and treatment administration. Section 1203.D requires that a documented review of the MARs be performed by outgoing staff members at each shift change.

61-103.1204. Pharmacy Services (formerly 61-103.F(3))

Section 1204.A requires that any pharmacy within the facility be provided by or under the direction of a pharmacist. Section 1204.B requires facilities that maintain stocks of legend drugs and biologicals obtain and maintain a valid, current pharmacy permit from the S.C. Board of Pharmacy. Section 1204.C requires that labeling of medications be in compliance with all laws and regulations. Section 1204.D combines former Sections F(3)(a)(1) and F(3)(a)(3) and clarifies the requirements of the consulting pharmacist. Section 1204.E was relocated from former Section F(3)(c).

61-103.1205. Medication Containers

Section 1205.A delineates the requirements of medication containers. Section 1205.B requires an updated label on medications when a physician or authorized healthcare provider changes the dosage of a medication.

61-103.1206. Medication Storage

Section 1206.A requires that medications be properly stored and safeguarded in a locked medicine preparation room or locked in a cabinet at or near the staff work area to prevent access by unauthorized individuals. Section 1206.B prescribes the requirements for medications requiring refrigeration. Section 1206.C delineates the requirements of medication storage. Section 1206.D requires that the facility maintain records of receipt, administration, and disposition of all controlled substances. Section 1206.E delineates the storage and maintenance requirements for legend and nonlegend medications.

61-103.1207. Disposition of Medications

Section 1207 prescribes the requirements of medication disposition, including requirements for release to the resident and destruction of controlled substances.

61-103.1300. MEAL SERVICE (formerly 61-103.I)

Section 1300 was relocated from former Section I and the title was amended.

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61-103.1301. General

Section 1301.A requires that all facilities preparing food onsite shall be approved by the Department, and regulation, inspected, and permitted pursuant to Regulation 61-25. Section 1301.B requires that when meals are catered to a facility, such meals shall be obtained from an establishment permitted by the Department, pursuant to R.61-25. Section 1301.C require that liquid or powder soap dispensers and sanitary paper towels be available at each food service handwash lavatory.

61-103.1302. Food and Food Storage (formerly 61-103.I(1)(c)(2))

Section 1302 (formerly I(1)(c)(2)) requires at least a one (1) week supply of staple foods and a two (2) day supply of perishable foods to be maintained on the premises.

61-103.1303. Meals and Services (formerly 61-103.I(1)(a))

Section 1303.A requires facilities to provide dietary services to meet the daily nutritional needs of the residents. Section 1303.B prescribes the requirements of the dining area. Section 1303.C requires a minimum of three (3) nutritionally-adequate meals in each twenty-four (24) hour period. Section 1303.D requires that correct food temperatures be maintained. Section 1303.E prohibits the same foods from being repetitively served during each seven (7) day period. Section 1303.F requires specific times for meal service to be established and documented on a posted menu. Section 1303.G requires food and snacks to be offered between meals. Section 1303.H delineates the requirements pertaining to tray service.

61-103.1304. Meal Service Personnel (formerly 61-103.I(2))

Section 1304.A requires sufficient staff members to serve food and provide individual attention and assistance if needed. Section 1304.B requires that dietary services be organized with established lines of accountability and clearly defined job assignments for those engaged in food preparation and serving.

61-103.1305. Diets

Sections 1305.A and 1305.B delineate the requirements for facilities with residents in need of medically-prescribed special diets. Section 1305.C was relocated from former Section I(1)(2) and delineates the requirements of the facility dietitian. Section 1305.D requires the facility to maintain a diet manual published within the previous five (5) years.

61-103.1306. Menus

Section 1306.A requires that menus be planned and written a minimum of one (1) week in advance and be posted in one or more conspicuous places in a public area. Section 1306.B requires records of menus to be maintained at least thirty (30) days.

61-103.1307. Ice and Drinking Water (formerly 61-103.I(3)(a))

Section 1307.A requires that ice be from a water system in compliance with Regulation 61-58. Section 1307.B requires that potable drinking water be available and accessible to residents at all times. Section 1307.C (formerly I(3)(a)(3)) prohibits the usage of common cups. Section 1307.D (formerly I(3)(a)(2)) requires that ice delivered to resident areas in bulk be in nonporous, covered containers and cleaned after each use.

61-103.1400. EMERGENCY PROCEDURES AND DISASTER PREPAREDNESS

Section 1400 title was added for codification.

61-103.1401. Disaster Preparedness

Section 1401.A was added to require the facility to develop a written plan to be initiated in the event of a disaster and/or emergency evacuation and further requires that this plan shall be rehearsed annually. Section 1401.B delineates the requirements of the emergency and disaster evacuation plan.

61-103.1402. Emergency Call Numbers

Section 1402 was added to require that the facility post emergency call data in a conspicuous place and include at least the telephone numbers of fire and police departments, ambulance service, and poison control.

61-103.1403. Continuity of Essential Services

Section 1403 was added to require the facility to develop a written plan to be implemented to ensure continuation of essential patient support services in the event of inclement weather or other causes.

61-103.1500. FIRE PREVENTION AND PROTECTION (formerly 61-103.J)

Section 1500 was relocated from former Section J and the section title was amended for clarity.

61-103.1501. Arrangements for Fire Department Response and Protection (formerly 61-103.J(1))

Section 1501.A was added to require facilities to develop a suitable written plan for actions to be taken in the event of fire and other emergencies. Section 1501.B requires the facility to meet all requirements prescribed by the S.C. State Fire Marshal. Section 1501.C was relocated from former Section J(1).

61-103.1502. Fire Response Training (formerly 61-103.J(6)(b))

Section 1502 was relocated from former Section J(6)(b) and requires fire response training for each employee of the facility within twenty-four (24) hours of initial resident contact and annually thereafter.

61-103.1503. Fire Drills (formerly 61-103.J(6)(c))

Section 1503.A was relocated from former Section J(6)(c)(1). Section 1503.B was relocated from former Section J(6)(c)(2). Section 1503.C was added to prescribe the objectives of fire drills.

61-103.1600. PREVENTATIVE MAINTENANCE (formerly 61-103.K)

Section 1600 (formerly K(1)) was amended to require that the facility keep the structure and all associated components and equipment in good repair and operating condition. Section 1600 further requires code compliance and documentation of preventative maintenance.

61-103.1700. INFECTION CONTROL AND ENVIRONMENT

Section 1700 title was added for clarity.

61-103.1701. Staff Practices

Section 1701 was added to delineate the requirements of staff practices in order to prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances.

61-103.1702. Tuberculin Skin Testing

Section 1702.A was added to require facilities to conduct an annual tuberculosis risk assessment in accordance with CDC guidelines. Section 1702.B was added to require that a risk classification be part of the risk assessment in determining the need for an ongoing TB screening program for staff and the frequency of screening. Section 1702.C takes language from former Section C(5)(a) and amends the requirements of tuberculosis screening for staff to comply with current CDC guidelines. Section 1702.D delineates the requirements for resident tuberculosis screening procedures.

61-103.1703. Housekeeping (formerly 61-103.K(2))

Section 1703.A was relocated from former Section K(2)(a). Section 1703.B delineates the specific requirements of interior housekeeping. Section 1703.C delineates the specific requirements of exterior housekeeping.

61-103.1704. Infectious Waste

Section 1704 was added to require that all accumulated waste, including all contaminated sharps, dressings, and/or similar infectious waste, be disposed of in a manner compliant with OSHA and Regulation 61-105.

61-103.1705. Clean and Soiled Linen and Clothing

Section 1705.A takes language from former Section K(2)(c) and amends the requirements of clean linen and clothing relating to storage, supply, and transporting linens. Section 1705.B takes language from former Section K(2)(d) and delineates the requirements for storage, transport, and handling of soiled linen and clothing.

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61-103.1800. QUALITY IMPROVEMENT PROGRAM

Section 1800.A was added to require facilities to have a written, implemented quality improvement program that provides effective self-assessment and implementation of changes designed to improve the care and services provided. Section 1800.B delineates the specific requirements of the quality improvement program.

61-103.1900. DESIGN AND CONSTRUCTION (formerly 61-103.L)

Section 1900 (formerly L) was amended to adjust codification.

61-103.1901. General (formerly 61-103.L(1))

Section 1901.A (formerly L(1)(a)) was amended for grammar and to require that facilities be planned, designed, and equipped to provide for and promote the health, safety, and well-being of each resident, and to require compliance with the SCDE Office of School Facilities. Section 1901.A further requires that facilities shall meet the requirements of an institutional healthcare facility and shall not be considered dormitory use. Section 1901.B requires a facility to have a fire protection sprinkler system.

61-103.1902. Codes and Standards (formerly 61-103.L(2))

Section 1902.A (formerly L(2)(a)) was amended to require that facility and construction comply with applicable provisions of the regulation and the codes officially adopted by the South Carolina Building Codes Council, the South Carolina State Fire Marshal, and the SCDE Office of School Facilities and to require assurance that state and local officials have approved the facility for code compliance prior to licensure. Section 1902.B was added to require that all facilities shall comply with the construction codes and regulations applicable at the time a facility's license was issued, unless required otherwise by the Department.

61-103.1903. Submission of Plans (formerly 61-103.L(3))

Section 1903.A (formerly L(3)(a)) was amended to delineate specific requirements of plans and specifications. Section 1903.B (formerly L(3)(b)) prescribes the requirements of plans and specifications to be submitted to the Department for new construction or projects. Section 1903.C requires that all projects obtain all required permits from the locality having jurisdiction and construction without proper permitting shall not be inspected by the Department. Section 1903.D (formerly L(3)(e)(3)) requires the facility to maintain documentation and certification for all cosmetic changes utilizing paint, wall covering, floor covering, or otherwise. Section 1903.E requires any construction work which violates codes or standards to be brought into compliance. Section 1903.F was relocated from former Section L(3)(d)(2). Section 1903.G was relocated from former Section L(3)(e)(4). Section 1903.H was added to require that if the facility will provide space for the educational program, plans and specifications shall be submitted to the SCDE Office of School Facilities.

61-103.2000. FIRE PROTECTION EQUIPMENT AND SYSTEMS (formerly 61-103.O)

Section 2000 (formerly O) was amended to adjust codification.

61-103.2001. Fire Alarms and Sprinklers (formerly 61-103.O(1))

Section 2001.A was relocated from former Section O(1)(a). Section 2001.B (formerly O(1)(b)) was amended to require that the facility include a partial, manual, automatic, and supervised fire alarm system which transmits to a third party, notifies all areas and floors of the building by audible and visual alarm, and shuts down central recirculating systems. Section 2001.B requires that all fire, smoke, heat, sprinkler flow, and manual fire alarming devices be connected to and activate the main fire alarm system when activated.

61-103.2002. Smoke Detection System (formerly 61-103.O(2))

Section 2002 was relocated from former Section O(2)(a) and amended to require that when a smoke detection system is required it shall be installed in accordance with the applicable adopted codes and standards.

61-103.2100. EQUIPMENT AND SYSTEMS

New Section 2100 consolidates various sections of the regulation into one concise section.

61-103.2101. Gases (formerly 61-103.N(4))

Section 2101.A (formerly N(4)) was amended to reference the applicable code for handling and storing gases. Section 2101.B was added to delineate the requirements of “No Smoking” signs in the facility. Section 2101.C was added to require that smoking be allowed only in designated areas in accordance with the facility smoking policy and to prohibit smoking in resident rooms and staff bedrooms or bathrooms.

61-103.2102. Furnishings and Equipment

Section 2102.A requires that the facility maintain the physical plant free of fire hazards or impediments to fire prevention. Section 2102.B prohibits portable electric or unvented fuel heaters. Section 2102.C delineates the requirements of fireplaces and fossil-fuel or wood-burning stoves. Section 2102.D requires that all wastebaskets, window dressings, portable partitions, cubicle curtains, mattresses, and pillows be noncombustible, inherently flame-resistant, or treated or maintained flame-resistant.

61-103.2200. EXITS (formerly 61-103.P)

Section 2200 was relocated from former Section P(1) and renumbered to adjust the codification.

61-103.2300. WATER SUPPLY, HYGIENE, AND TEMPERATURE CONTROL (formerly 61-103.Q(1))

Section 2300 was relocated from former Section Q(1).

61-103.2301. General

Section 2301.A (formerly Q(1)(c)(1)) was amended to require water temperature of at least one hundred (100) degrees Fahrenheit and not to exceed one hundred twenty-five (125) degrees Fahrenheit. Section 2301.B was relocated from former Section Q(1)(c)(2). Section 2301.C (formerly Q(1)(c)(3)) was amended to require hot water supplied to the kitchen equipment and utensil washing sink to be supplied as required by R.61-25. Section 2301.D was added to delineate the requirements of hot water for washing linen and clothing.

61-103.2302. Cross-Connections (formerly 61-103.Q(1)(e))

Section 2302 was relocated from former Section Q(1)(e) and further defines the prohibition on cross-connections.

61-103.2400. ELECTRICAL (formerly 61-103.R)

Section 2400 was relocated from former Section R.

61-103.2401. General (formerly 61-103.R(1)(b))

Section 2401 (formerly R(1)(b)) was amended to require that all electrical installations be maintained in a safe, operable condition in accordance with applicable codes and inspected at least annually by a licensed electrician, registered engineer, or certified electrical inspector.

61-103.2402. Panelboards (formerly 61-103.R(3))

Section 2402 (formerly R(3)) was amended to require the facility to label the panelboard directory to conform to the room numbers and/or designations.

61-103.2403. Ground Fault Interrupting Receptacles (formerly 61-103.R(6))

Section 2403 was relocated from former Section R(6).

61-103.2404. Emergency Generator Service (formerly 61-103.R(7))

Section 2404 was relocated from former Section R(7) and amended to require an emergency generator complying with the applicable adopted codes.

61-103.2500. HEATING, VENTILATION, AND AIR CONDITIONING (HVAC)

Section 2500.A was added to require that the HVAC system be inspected at least once every year by a certified and/or licensed technician. Section 2500.B (formerly S(3)) was amended to require the facility to maintain a temperature of between seventy-two (72) and seventy-eight (78) degrees Fahrenheit in resident areas. Section

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2500.C was added to prohibit a facility from installing a supply or return grille within three (3) feet of a smoke detector. Section 2500.D was added to prohibit the installation of HVAC grilles in floors. Section 2500.E (formerly S(4)) was amended to require that return air ducts be filtered and discharged in a manner that would not be an irritant to residents, staff, or visitors. Section 2500.F was added to require that each shower, bath, and restroom be equipped with either operable windows or approved mechanical ventilation. Section 2500.G (formerly N(6)(a)) was amended to require an exhaust fan and Type I hood of proper size installed over cook stoves and ranges vented to the outside. Section 2500.H was relocated from former Section N(6)(b).

61-103.2600. PHYSICAL PLANT (formerly 61-103.T)

Section 2600 (formerly T) title was amended for clarity.

61-103.2601. Facility Accommodations

Section 2601.A was added to require sufficient living arrangements for residents. Section 2601.B delineates the minimum facility square footage requirements. Section 2601.C requires methods for ensuring privacy between residents and staff and visitors.

61-103.2602. Resident Rooms (formerly 61-103.T(2))

Section 2602.A prescribes the required furnishings for resident rooms. Section 2602.B was relocated from former Section T(2)(b) and delineates the required square footage for resident rooms. Section 2602.C was relocated from former Section T(2)(d)(1). Section 2602.D requires that when a hospital-type bed is used, the bed shall have at least two (2) lockable casters. Section 2602.E was relocated from former Section T(2)(d)(7). Section 2602.F was relocated from former Section T(2)(d)(3). Section 2602.G was relocated from former Section T(2)(d)(2). Section 2602.H prohibits resident rooms from being located in a basement. Section 2602.I prohibits residents of the same sex from occupying the same resident room. Section 2602.J (formerly T(2)(b)(2)) was amended to require that access to a resident room shall not be by way of another resident room, toilet, bathroom, or kitchen. Section 2602.K requires privacy when personal care is being provided in semi-private rooms. Section 2602.L requires that consideration be given to resident compatibility in room assignments. Section 2602.M requires at least one (1) private room for assistance in addressing resident compatibility issues.

61-103.2603. Work Stations (formerly 61-103.T(3))

Section 2603.A was relocated from former Section T(3)(a). Section 2603.B was relocated from former Section T(3)(b) and amended for clarity. Section 2603.C was relocated from former Section T(3)(c). Section 2603.D was relocated from former Section T(3)(d). Section 2603.E requires that each work station contain separate spaces for the storage of clean linen, wheelchairs, and general supplies and equipment.

61-103.2604. Bathrooms and Restrooms

Section 2604.A (formerly Q(2)(b)(2)(b)) was amended to require separate bathroom facilities for staff members, general public, and/or family. Section 2604.B (formerly Q(2)(b)(1)) was amended to require a minimum of one (1) toilet for each six (6) licensed beds or a fraction thereof. Section 2604.C requires at least one (1) handwash lavatory adjacent to each toilet and prescribes the requirements of soap in lavatories. Section 2604.D (formerly Q(2)(b)(2)(a)) was amended to require one (1) bathtub or shower for each eight (8) licensed beds or a fraction thereof. Section 2604.E was relocated from former Section Q(2)(b)(1)(a). Section 2604.F requires privacy at toilets, urinals, bathtubs, and showers. Section 2604.G requires toilet facilities at or adjacent to the kitchen for kitchen employees. Section 2604.H was relocated from former Section Q(2)(b)(2)(d). Section 2604.I (formerly Q(2)(b)(2)(e)) was amended to require bathroom walls to be nonabsorbent, washable surfaces to the highest level of splash. Section 2604.J was relocated from former Section Q(2)(b)(2)(f). Section 2604.K requires easily cleanable receptacles provided for waste materials, and requires that such receptacles in toilet rooms for women to be covered. Section 2604.L prescribes requirements for bath linens for residents.

61-103.2605. Doors (formerly 61-103.P(3))

Section 2605 (formerly P(3)) was amended to require that doors providing access into the facility and resident room(s) be in accordance with applicable codes.

61-103.2606. Ramps (formerly 61-103.P(4))

Section 2606.A was relocated from former Section P(4)(a). Section 2606.B requires the ramp to serve all portions of the facility where residents are located. Section 2606.C was relocated from former Section P(4)(e). Section 2606.D requires that ramps discharge onto a firm surface that is negotiable by a wheelchair in all weather conditions and to a location accessible for loading into a vehicle.

61-103.2607. Handrails and Guardrails

Section 2607.A requires handrails on at least one (1) side of each corridor or hallway. Section 2607.B requires guardrails on all porches, walkways, and recreational areas in accordance with the applicable adopted codes and standards.

61-103.2608. Janitor's Closet (formerly 61-103.T(6))

Section 2608.A requires a lockable janitor's closet in all facilities equipped with a mop sink or receptor and space for the storage of supplies and equipment. Section 2608.B requires daily cleaning of all janitor's closets and equipment and further requires frequent inspections by a responsible person for compliance.

61-103.2609. Storage Areas (formerly 61-103.T(4))

Section 2609.A requires that the facility provide adequate general storage areas for resident and staff belongings, equipment, and supplies. Section 2609.B prohibits the storage of supplies and equipment directly on the floor and prohibits the storage of supplies and equipment susceptible to water damage or contamination under sinks or in areas where water leakage is likely.

61-103.2610. Living, Recreation, and Dining Areas (formerly 61-103.T(8))

Section 2610 was relocated from former Section T(8) and renumbered to adjust the codification.

61-103.2611. Facility Grounds (formerly 61-103.T(7))

Section 2611 was relocated from former Section T(7) and renumbered to adjust the codification.

61-103.2612. Location (formerly 61-103.L(4))

Section 2612.A was relocated from former Section L(4)(b). Section 2612.B was relocated from former Section L(4)(c) and amended to clarify parking requirements. Section 2612.C was relocated from former Section L(4)(d).

61-103.2700. SEVERABILITY

Section 2700 was added to allow the regulation to remain valid should it be determined that a portion of the regulation be invalid or unenforceable.

61-103.2800. GENERAL (formerly 61-103.U)

Section 2800 (formerly U) was renumbered to adjust the codification.

Instructions: Replace Regulation 61-103, Residential Treatment Facilities for Children and Adolescents, in its entirety.

Text:

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- γ 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.

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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.

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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 101.00 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 cases 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.

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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.

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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;

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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

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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;

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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

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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.

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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;

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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

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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)

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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.

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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

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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)

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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

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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:

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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.

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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.

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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.

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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.

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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.

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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.

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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.

Fiscal Impact Statement:

Implementation of this regulation will not require additional resources. There is no anticipated additional cost by the Department or state government due to any inherent requirements of this regulation. There are no external costs anticipated.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness is based on an analysis of the factors listed in S.C. Code Sections 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: R.61-103, Residential Treatment Facilities for Children and Adolescents.

Purpose: The purpose of these amendments to R.61-103 is to clarify standards pertaining to Residential Treatment Facilities for Children and Adolescents. These amendments provide updates to definitions, licensure

requirements, accident and/or incident reporting requirements, residents' rights, record maintenance and retention, services and treatment, personnel requirements, infection control and sanitation, medication management, design and construction, and fire and life safety. In addition, provisions have been amended for general clarity, readability, grammar, references, codification, and overall improvement to the text of the regulation.

Legal Authority: 1976 Code Section 44-7-260

Plan for Implementation: Upon approval by the General Assembly and publication in the State Register as a final regulation, a copy of R.61-103, which includes these latest amendments, will be available electronically on the Department's Laws and Regulations website under the Health Regulations category at: <http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/>. Subsequently, this regulation will be published in the South Carolina Code of Regulations. Printed copies will be available for a fee from the Department's Freedom of Information Office. The Department will also send an email to stakeholders, affected services and facilities, and other interested parties.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

Pursuant to S.C. Code Section 1-23-120(J), the Department is required to perform a formal review of its regulations every five (5) years and update them if necessary. Regulation 61-103 has not been substantively updated since 1991. Therefore, many of the procedures, practices, and terms are outdated and/or no longer applicable. The amendments further clarify and improve licensure requirements, personnel requirements, services and treatment, record maintenance and retention, infection control and sanitation, emergency procedures and disaster preparedness, and medication management. Amendments to design and construction and fire and life safety are needed to comply with current codes and procedures.

DETERMINATION OF COSTS AND BENEFITS:

Implementation of these amendments will not require additional resources. There is no anticipated additional cost to the Department or state government due to any inherent requirements of these amendments. Amendments to R.61-103 improve residents' rights and assurances, resident care, services and treatment, accident and/or incident reporting requirements, update emergency procedures and disaster preparedness planning, and update design, construction, fire, and life safety measures to comply with current procedures and codes.

UNCERTAINTIES OF ESTIMATES:

None.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The amendments to R.61-103 seek to support the Department's goals relating to the protection of public health through the anticipated benefits highlighted above. There is no anticipated effect on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment. If the revision is not implemented, the regulation will be maintained in its current form without realizing the benefits of the amendments herein.

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Statement of Rationale:

The Department is amending R.61-103, *Residential Treatment Facilities for Children and Adolescents*. The amendments update R.61-103 to align with current practices, procedures, and nomenclature. The amendments address issues regarding licensure requirements, personnel requirements, emergency procedures and disaster preparedness planning, accident and/or incident reporting ambiguities, treatment and services, lessen the burden regarding design and construction requirements, and update the design, construction, fire, and life safety to current code.

Document No. 4612

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: 1976 Code Sections 44-1-110, 44-1-140 and 44-29-10 et seq.

61-21. Sexually Transmitted Diseases

Synopsis:

The Department of Health and Environmental Control (Department) amends Regulation 61-21, Sexually Transmitted Diseases. In the interest of supporting the Department's goal of promoting and protecting the health of the public in a more efficient and effective manner, these amendments will update the language to be consistent with medically accurate terms and disease prevention methods.

A Notice of Drafting for these amendments was published in the *State Register* on April 24, 2015.

Section-by-Section Discussion of Amendments:

Statutory Authority for the regulation is added under the title of the regulation.

61-21.B.

Revised to delete venereal in reference to sexually transmitted diseases and to define them as spread through person-to-person sexual contact and as identified annually in the DHEC List of Reportable Diseases.

61-21.H.

Revised to specify the public school notification requirement as kindergarten through fifth grade.

61-21.K(4)(c)

Revised to remove "nonoxynol-9 and other chemical agents" as this is no longer recommended.

61-21.L(3)

Revised to remove "nonoxynol-9 or other chemical agents" as this is no longer recommended. Revised to move "condoms" within the text for clarity and readability.

Instructions: Amend R.61-21 pursuant to each individual instruction provided with the text of the amendments below.

Text:**61-21. Sexually Transmitted Diseases.****Add statutory under title of the regulation to read:**

(Statutory Authority: 1976 Code Sections 44-1-110, 44-1-140 and 44-29-10 et seq.)

Amend Section B to read:

B. Sexually transmitted diseases declared dangerous to the public health. Sexually transmitted diseases are declared to be contagious, infectious, communicable, and dangerous to the public health. Sexually transmitted diseases include all diseases or infections spread through person-to-person sexual contact which are included in the annual Department of Health and Environmental Control List of Reportable Diseases.

Amend Section H(2) only; subitems H(1) and (3) remain the same, to read:

H. School Attendance Considerations and Notification Requirements.

(2) Requirement to notify public schools. In accordance with Section 44-29-135 S.C. Code of Laws, as amended, if a minor has AIDS or is infected with HIV and is attending a public school in kindergarten through fifth grade, the superintendent of the school district and the school nurse or other health professional assigned to the school the minor attends must be notified. The information given to the district superintendent and/or the school nurse or other health professional must be kept strictly confidential and should only be revealed to school personnel who have a bona fide need to know. All persons receiving this information must keep the information strictly confidential. Violation of this regulation may result in imposition of penalties as set forth in Sections 44-1-150 and 44-29-140 South Carolina Code of Laws and other applicable penalties.

Amend Section K(4)(c) only; subitems K(4)(a), (b), (d), (e), (f), (g), (h) and (i) remain the same, to read:

K. Recalcitrant HIV infected persons.

(4) In cases of recalcitrant persons who have HIV infection, modification of behavior must include cessation of behaviors that expose other persons to HIV. The Department may issue a public health order requiring the recalcitrant person to comply with appropriate directives to protect the public health. These directives may include, but are not limited to, any or all of the following:

(c) Always use condoms as recommended by public authorities during anal, vaginal or oral intercourse and exercise caution when using condoms due to possible condom failure or improper use;

Amend Section L(3); subitems L(1) and (2) remain the same, to read:

L. Prisons and STD/HIV infected prisoners.

(3) In order to protect the public health, all prisons and jails should allow during visits of prisoners and their sexual partners to possess and use condoms recommended by public health authorities. The prison or jail is not required by these regulations to expend public monies to purchase condoms, for either prisoners or visitors.

Fiscal Impact Statement:

The regulations will have no substantial fiscal or economic impact on the State or its political subdivisions. Implementation of this regulation will not require additional resources beyond those allowed. There is no

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anticipated additional cost by the Department or State Government due to any inherent requirements of this regulation.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness and Rationale was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11.)

DESCRIPTION OF REGULATION: Amendment of Regulation 61-21, Sexually Transmitted Diseases.

Purpose: The amendments to Regulation 61-21 update the language to be consistent with medically accurate terms and disease prevention methods. The Regulation gives the Department of Health and Environmental Control the responsibility and authority for specifying and directing the methods of control of communicable and other publicly preventable diseases.

Legal Authority: The legal authority for Regulation 61-21 is derived from 1976 S.C. Code Section 44-1-110, 44-1-140 and 44-29-10 et seq.

Plan for Implementation: Upon approval by the General Assembly and publication in the State Register as a final regulation, a copy of Regulation 61-21, including these amendments, will be available electronically on the Department's Laws and Regulation website. Subsequently, this regulation will be published in the S.C. Code of Regulations. Printed copies will be made available for a fee from the DHEC Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments to Regulation 61-21 are needed to update the medical terms and conditions to reflect current terminology, specify the school notification requirement as kindergarten through fifth grade, and to remove "nonoxynol-9 or other chemical agents" as this is no longer recommended.

The amendments are reasonable because they provide an efficient procedure without any anticipated cost increase, provide clear standards and criteria for the regulated community, and support Department goals.

DETERMINATION OF COSTS AND BENEFITS:

There are no anticipated cost increases to the State or its political subdivisions in complying with these amendments. There are no anticipated costs to the regulated community as a result of the amendments.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the State or its political subdivisions.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The amendments to Regulation 61-21 seek to support the Department's goals relating to the protection of public health through the anticipated benefits stated above. There is no anticipated effect on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment associated with these amendments. Possible detrimental effect on public health includes failure to realize the anticipated benefits highlighted above.

Statement of Rationale:

The Department is amending Regulation 61-21, Sexually Transmitted Diseases, in the interest of overall quality improvement and updates for consistency with current terminology and public health recommendations.

Document No. 4614

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: 1976 Code Sections 44-96-10 et seq.

61-107.12. Solid Waste Management: Solid Waste Incineration and Solid Waste Pyrolysis Facilities

Synopsis:

The South Carolina Solid Waste Policy and Management Act (Act), Section 44-96-10 et seq., S.C. Code of Laws, 1976, as amended, requires the South Carolina Department of Health and Environmental Control (Department or DHEC) to promulgate regulations establishing standards for the management of facilities that incinerate solid waste. In 1993, to satisfy the requirements of the Act, the Department promulgated R.61-107.12 Solid Waste Management (SWM): Solid Waste Incineration and Solid Waste Pyrolysis Facilities. The regulation was last amended May 28, 1999.

This amendment provides exemptions from R.61-107.12 for law enforcement, customs and agricultural import inspection agencies that use incinerators for the destruction of prohibited and illegal contraband; and conditional exemptions for small air curtain incinerators that store less than 400 cubic yards of land-clearing debris or yard trimmings. The amendment also makes the requirements for air curtain incineration facilities easier to understand by creating a new section in the regulation specifically for air curtain incineration facilities. Some of the requirements for air curtain incineration facilities have also been reduced. This amendment adds the procedures for notifying the public about new permit applications and Department decisions concerning permits. It also clarifies the financial assurance requirements for these facilities and updates the mechanisms available to use for financial assurance. The amendment updates the regulation with the correct statutory reference for the issuance of a Department order, a civil enforcement action, or a criminal enforcement action for violations of this regulation.

Section-by-Section Discussion:**Regulation 61-107.12, SWM: Solid Waste Incineration and Solid Waste Pyrolysis Facilities**

Insert new bold title text **“Part I. Applicability, Definitions, and General Provisions.”**

The regulation is revised into four parts. Part I will contain Sections A., B., and C. of the regulation.

A. Applicability.

A.2. is amended to strike “Mobile air” and replace with the “Air” for clarification; strike the text “trash” and replace with “trimmings” for clarification and consistency with other regulations; and strike the text “temporarily used in clean-up after a natural disaster” and replace with the text “used for emergency storm debris management at sites designated by state, county and municipal government” and for clarification and consistency with other regulations.

A.6. is added as a new sub-item to exempt government owned and operated incineration facilities from the requirements of R.61-107.12 when the incineration is performed by law enforcement agencies to destroy illegal or prohibited goods.

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A.7. is added as a new sub-item to introduce conditional exemptions for facilities that store less than four hundred cubic yards of clean wood waste prior to incineration. When the facility maintains the conditions of Part II, Sections B.,C.,E. and F. of the regulation, the facility is exempt from solid waste permitting requirements. This change is made to be consistent with a similar exemption contained in R.61-107.4 Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals.

B. Definitions. This section defines terms used in the regulation.

B.8. text “financial responsibility mechanism” is replaced with “financial assurance mechanism” for consistency with R.61-107.19 SWM: Solid Waste Landfills and Structural Fill.

B.12.I. is revised to renumber sub-items i. through vi. as sub-items 1. through 7. for consistency with outlining style used in the regulation.

B.19. revises the definition for “recovered materials” for consistency with the Solid Waste Policy and Management Act.

B.20. the text “lowdensity” is replaced with “low-density”.

B.29. adds a new sub-item and definition for “Waters of the United States” as found in R.61-9. Water Pollution Control Permits.

C. General Provisions. This section contains general requirements that are applicable to all solid waste incineration facilities.

C.1. is revised to clarify requirements for determinations of consistency with local solid waste management plans. The text “Incineration facilities shall be consistent with the State and host Region/County Solid Waste Management Plans.” is stricken, and the subs-item now states that 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. The revised section clarifies that 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. The revision further clarifies that consistency does 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, but that the facilities shall be consistent with the applicable local zoning and land use ordinances.

C.1.(a) is renumbered as C.1.a for stylistic consistency with outlining used in the regulation, and text revised to eliminate a tonnage limit exemption that no longer has applicability to any permitted incinerator.

C.1.(b) is renumbered as C.1.b for stylistic consistency with outlining used in the regulation.

C.2. is revised to add a reference to R.61-107.17. SWM: Demonstration of Need for its relevancy to siting a solid waste incineration facility.

C.3. is revised to clarify that an exemption granted under this regulation does not exempt the facility from permitting requirements of other Department programs and regulations.

C.5. and C.6. are deleted to eliminate the previous timelines allowed for unpermitted facilities to achieve compliance with the regulation.

C.7. through C.11. are renumbered to account for the removal of C.5. and C.6.

C.8. is renumbered as C.6. and corrects the text “collocated” with “co-located”.

C.10. is renumbered as C.8. and adds requirements for submittal of a disclosure statement and proof of financial assurance before an existing permit for a facility can be transferred to a new owner or operator.

Insert new bold title text “**Part II. Requirements for Air Curtain Incineration Facilities**” after sub-item C.9.

Part II contains all new text for application requirements, facility design, operating criteria, and reporting requirements for air curtain incineration facilities. The requirements in this new section have been revised and streamlined to reduce the regulatory burden on small business.

Insert new title text “A. Permit Application Requirements.” followed by text of new sub-items A.1. through A.3. This new application section streamlines the permitting process and reduces the documentation required for the applicant to submit. One paper copy and one digital copy of the application is required instead of three paper copies. An engineering report is replaced with an operating report that describes facility structures on site, access roads, loading and unloading areas, storage areas, fences and gates, disposal locations and planned re-use for ash from the site. It also requires a map showing the site, land use and zoning within a quarter mile of the site and a site plan showing property boundaries, with existing and proposed structures. Detailed engineering plans and specifications for the incinerator and other related machinery are still required. There are some new requirements for air curtain facility applications. The distances to any required buffers must be shown on a map. An itemized closure cost estimate is required instead of a closure plan. There are also new requirements for notifying the county and property owners contiguous to the permit area. Some of the application documents proposed for elimination include; drawings of buildings and structures on a one foot per quarter inch scale, air quality monitoring plans, operation and maintenance manuals, and waste control plans.

Insert new title text “B. Design Requirements for Air Curtain Incineration Facilities.”

Insert new text of sub-items B.1. through B.11. This section contains all of the design requirements of the current regulation with the exception that water available at adequate volume and pressure to supply water hose streams, automatic sprinklers, or water spray systems will not be required.

B.2. is a new requirement. The active waste handling area and burn trench must have separation from groundwater at all times.

B.4. the text “surface water” is replaced with “waters of the U.S.”

Insert new title text “C. Operations Criteria for Air Curtain Incineration Facilities.” after sub-item B.11.

Insert new text for sub-items C.1. through C.5. The operations criteria have been substantially revised. Due to the restricted waste stream and quantity of material that air curtain incinerator facilities can have on hand, the vector control requirements are eliminated. The pre-startup inspection by Department personnel is deleted. A vague reference to “minimizing interference with other activities in the area” is deleted. Redundant references to management of unauthorized wastes are eliminated from the text of the regulation.

C.1. is a new sub-item for the regulation that explicitly restricts the waste streams for an air curtain incinerator facility to clean wood, yard and land-clearing debris consisting of only untreated natural wood debris, untreated or unfinished wood waste, or mixtures of these waste streams.

Insert new title text “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:” after sub-item C.5.

Insert new text for sub-items D.1. through D.4. The reporting requirements are the same as in the current regulation except that the type of solid waste (i.e., residential, medical, commercial, industrial, special, and other) is not required for reporting for air curtain incineration facilities.

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Insert new title text “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.”

Insert new title text “F. Training Requirements. All air curtain incineration facilities shall comply with personnel training requirements in Part IV.C of this regulation.”

Insert new bold title text “**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.”

Part III. contains Section D. Permit Application Requirements, Section E. Design Requirements, Section F. Operations Criteria, and Section G. Monitoring and Reporting Requirements of the current regulation although the section lettering will be revised for consistency with outlining used in the regulation.

D. Permit Application Requirements is changed to “A. Permit Application Requirements” and the discussion reflects the codification change of Section D. sub-items to Section A. sub-items.

A.2. is revised to require permit application submittal of one printed copy and a digital copy rather than three printed copies.

A.2.c. text referencing air curtain incinerators is deleted from Part III.

A.2.d. text “Section I” is revised to “Part IV.C” to accommodate for changes made to the outlining of the regulation.

A.2.f. sub-item is deleted to eliminate submittal of a description of the air quality monitoring plan in the permit application since the requirements for air quality monitoring are addressed in other Department regulations and permits, and would be redundant. Subsequent sub-items in Section A are re-lettered to account for removal of A.2.f.

A.2.k. is revised to add new details required for closure plans.

A.2.l. is substantially revised to delete text concerning financial responsibility (addressed in another section of the regulation) and to add text that requires and defines a “closure cost estimate” and to provide the proper citation in the regulation to find financial assurance requirements.

A.2.m. text referencing air curtain incinerators is deleted from Part III.

A.3. through A.3.d. new text is added detailing public noticing requirements for a permitted incineration facility. The applicant will notify the county and landowners within a mile of the proposed permit area. The sub-item also describes how the Department will notify interested parties of the permit decision.

E. Design Requirements is changed to “B. Design Requirements.” And the discussion reflects the codification change of Section E. sub-items to Section B. sub-items.

B. Design Requirements title text referencing air curtain incinerators is deleted from Part III.

B.1. contains a stylistic revision.

B.3. text “surface waters” is revised to “waters of the U.S.”

B.4. text “U. S.” is revised to “U.S.” to remove a space between the letters.

B.5. delete the unnecessary comma following the word “facility” and text referencing air curtain incinerators is deleted from Part III. Text is added requiring all active waste handling areas and all ash management areas to have separation from the groundwater table at all times.

B.8. delete the unnecessary comma following the word “facility” and text referencing air curtain incinerators is deleted from Part III.

B.14. text “Preparedness” is capitalized for stylistic consistency.

F. Operations Criteria is changed to “C. Operations Criteria.” and the discussion reflects the codification change of Section F. sub-items to Section C. sub-items.

C. Operations Criteria title text referencing air curtain incinerators is deleted from Part III.

C.5. text “incinerator” is changed to “incineration”.

C.7.a. text referencing a “quarterly” report is revised to “annual” report.

C.7.d. is revised to clarify “Wastes shall be stored so as to prevent a fire hazard.”

C.8. text “Changes” is revised to be capitalized.

C.9. text “Preparedness” is revised to be capitalized.

C.9.b. and C.9.c. are revised to remove an outdated emergency response telephone number and to clarify who to contact during an emergency or unscheduled shutdown.

G. Monitoring and Reporting Requirements is changed to “D. Monitoring and Reporting Requirements.” and the discussion reflects the codification change of Section G. sub-items to Section D. sub-items.

D. Monitoring and Reporting Requirements title text referencing air curtain incinerators is deleted from Part III.

D.1. text is revised to clarify when the Department may require environmental monitoring.

D.2.d. text “of the distribution and/or disposal” is deleted for clarification.

D.3. text “Section J” is revised to “Part IV.D” to provide proper citation due to changes to the outlining of the regulation.

D.4. is revised to remove an outdated emergency response telephone number.

D.5. is the last sub-item in Part III.

Insert bold title text “**Part IV. General Requirements.**”

Part IV. contains Section H. Closure and Post-Closure Procedures, Section I. Personnel Training Requirements, Section J. Ash Residue Requirements, Section K. Corrective Action Requirements, Section L. Violations and Penalties, Section M. Permit Review, and Section N. Severability that apply to all solid waste incineration and pyrolysis facilities. A new section, Financial Assurance Requirements, is also added to Part IV. The lettering for these sections is revised for consistency with outlining style used in the regulation.

H. Closure and Post-Closure Procedures. is changed to “A. Closure and Post-Closure Procedures.” and the discussion reflects the codification change of Section H. sub-items to Section A. sub-items.

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A.1. sub-item and text referencing “Financial Assurance” is deleted entirely.

A.2. sub-item and text “Closure and Post-Closure Care Procedures.” is deleted so that the remaining text “Closure and post-closure procedures addressed in this section apply to all solid waste incineration facilities.” becomes the title text immediately following “A. Closure and Post-Closure Procedures.” The remaining sub-items in the section are re-numbered for consistency with outlining style used in the regulation.

A.3. is revised with text added to clarify when conditionally exempt facilities and permitted facilities are required to remove all wastes, contaminated soils and equipment for proper closure of a facility.

A.5. is revised to re-number a reference within the sub-item that changed when the sub-items of this section were re-numbered for consistency with outlining style used in the regulation.

Insert title text “B. Financial Assurance Requirements” after sub-item A.5.

Insert the new text sub-item B.1. through sub-item B.9.b. that compose this new section. This new section of the regulation clarifies the requirements for financial assurance for all permitted solid waste incineration facilities. It references the allowable mechanisms contained in R.61-107.19, SWM: Solid Waste Landfills and Structural Fill Part I.E and procedures for adjusting the amount of financial assurance required during the life of the facility. While this section is a newly proposed section, the requirements for financial assurance are the same as in the current regulation.

I. Personnel Training Requirements. is changed to “C. Personnel Training Requirements.” and the discussion reflects the codification change of Section I. sub-items to Section C. sub-items.

C.5. text “(3)” is added after “three” for stylistic consistency in the regulation.

J. Ash Residue Requirements. is changed to “D. Ash Residue Requirements” and the discussion reflects the codification change of Section J. sub-items to Section D. sub-items.

D.1.h. text “60 (sixty)” is changed to “sixty (60)” for stylistic consistency within the regulation.

K. Corrective Action Requirements. title text is changed to “E. Corrective Action Requirements.”

L. Violations and Penalties. title text is changed to “F. Violations and Penalties.” This section is revised to reference the authority of the Department to issue orders and initiate enforcement actions as granted in the Solid Waste Policy and Management Act. An outdated reference to the Administrative Procedures Act is deleted.

M. Permit Review. title text is changed to “G. Permit Review”. and the discussion reflects the codification change of Section M. sub-items to Section G. sub-items.

G.1. text “tocomply” is revised to “to comply”.

N. Severability. title text is changed to “H. Severability”

Instructions: Replace R.61-107.12 in its entirety with this amendment.

Text:

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.

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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

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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

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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.

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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

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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 inquiries.

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.

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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.

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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.

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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.

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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,

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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.

Fiscal Impact Statement:

Additional costs to state government are not anticipated. There are no direct costs to local governments that can be attributed to this regulation.

Statement of Need and Reasonableness:

The statement of need and reasonableness of the regulation was determined based on staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11):

DESCRIPTION OF THE REGULATION: Amendment, R.61-107.12, Solid Waste Management: Solid Waste Incineration and Solid Waste Pyrolysis Facilities.

Purpose: The amendment of R.61-107.12 Solid Waste Management: Solid Waste Incineration and Solid Waste Pyrolysis Facilities will reorganize the regulation, update the rules for public noticing incineration facilities, update the financial assurance provisions of the regulation, and clarify the timing aspects for making evaluations of consistency with state and local government solid waste management plans. The primary purpose of this regulation amendment is to clarify the requirements for air curtain incinerators by creating a new section of the regulation explicitly for air curtain incineration facilities. This amendment seeks to provide exemptions from R.61-107.12 for law enforcement, customs and agricultural import inspection agencies that use incinerators for the destruction of prohibited and illegal contraband; and conditional exemptions for small air curtain incinerators that store less than 400 cubic yards of land-clearing debris or yard trimmings. The amendment also updates the regulation with the correct statutory reference for the issuance of a Department order, a civil enforcement action, or a criminal enforcement action.

Legal Authority: 1976 Code Section 44-96-10 *et seq.*

Plan for Implementation: Upon approval of the General Assembly and publication in the South Carolina *State Register*, a copy of the revised regulation will be available electronically on the Department's Laws and Regulations website under the Land and Waste Management category at:

<http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/>. Subsequently, a copy of the regulation will be published in the S.C. Code of Regulations on the S.C. Legislature Online website. Printed copies will be available for a fee from the Department's Freedom of Information Office. Staff will notify parties that have expressed interest in the regulation amendment process, and will communicate

with affected parties on the requirements of the amended regulation. No additional positions or personnel should be needed to enforce the regulation as proposed.

DETERMINATION OF NEED AND REASONABLENESS OF THE PROPOSED REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments are needed and reasonable because the current regulation was last amended in 1999, and updates are needed for clarity and for consistency with other regulations. This amendment would make the solid waste management requirements for air curtain incinerators easier to convey with the creation of a new section of the regulation that explicitly addresses requirements for air curtain incineration facilities.

The amendment is reasonable in the way the requirements are simplified for South Carolina small businesses to utilize air curtain incineration for disposal of clean wood waste. The amendment should not require additional staff to implement the provisions.

DETERMINATION OF COST AND BENEFITS:

Internal costs and benefits: Implementation of this regulation amendment is not expected to require additional Department resources.

External costs and benefits: This amendment benefits the public with the addition of noticing requirements for new facilities. The revision will benefit the regulated community by clarifying exemptions and permitting requirements for incinerators. The increased noticing requirements are expected to add some additional costs to persons seeking permits; however, these costs are expected to be very small relative to the costs for siting a new facility.

UNCERTAINTIES OF ESTIMATES:

There are no foreseeable uncertainties of estimates relative to the costs to the State or its political subdivisions.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

The amendment will protect the environment and promote public health by ensuring that solid waste is managed properly prior to being burned at an incineration facility. The ability to use air curtain incinerators on site for the destruction of clean wood waste and debris can reduce the costs and air emissions associated with hauling material to other sites for grinding or disposal. This revision clarifies requirements for obtaining a solid waste permit, but does not reduce any requirements to obtain appropriate permits from the Bureau of Air Quality, and therefore does not reduce air quality standards for incinerating solid waste. There is no anticipated detrimental effect on the environment or public health as a result of the revision.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

The regulation clarifies the financial assurance requirements for all incineration facilities in the state and will likely lessen the chances that state or local governments are burdened with the costs of demolition and remediation of sites formerly used for incineration. There are no anticipated detrimental impacts to the environment or public health as a result of this proposed revision.

Statement of Rationale:

The South Carolina Solid Waste Policy and Management Act of 1991 directs the Department to develop regulations to ensure solid waste is disposed and managed in such a way as to be protective of the environment and public health. This amendment provides additional clarity and specificity to the existing regulations to

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address permitting requirements for solid waste incinerators. The revision reorganizes the regulation for clarity, addresses exemptions from permit requirements, adds public noticing requirements, and clarifies financial assurance requirements. The revisions are based on recommendations solicited from a workgroup comprised of representatives of state and local government, the waste disposal industry, manufacturers of air curtain incinerators, the State Solid Waste Advisory Council, environmental groups, the Association of Counties, and the South Carolina Municipal Association.

Document No. 4613

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-96-10 et seq.

61-107.279. Solid Waste Management: Used Oil

Synopsis:

The South Carolina Solid Waste Policy and Management Act (Act), Section 44-96-10 et seq., S.C. Code of Laws, 1976, as amended, requires the Department to promulgate regulations establishing standards for the management of used oil. In 1995, to satisfy the requirements of the Act, the Department promulgated R.61-107.279, Solid Waste Management: Used Oil. The regulation has not been amended since it became effective in 1995.

Amendments to this regulation support the Department's goal of protecting the health of the public and environment. This amendment removes the requirement for used oil fuel marketers to obtain a permit; revises existing language for clarity; and clarifies when used oil contaminated with polychlorinated biphenyls (PCBs) is regulated under the RCRA used oil standards and when it is not to conform to federal regulations. The revision clarifies violations and penalties.

Section-by-Section Discussion:

Regulation 61-107.279. Solid Waste Management: Used Oil.

Subpart B: Applicability

Section 61-107.279.10.i is revised to address PCBs consistent with the federal regulation 40 CFR 279.

Section 61-107.279.10.j is added to address how existing fuel marketer permits will be administratively terminated.

In section 61-107.279.11, Table 1 is reformatted for clarity and for consistency with the table in 40 CFR 279.11.

Subpart C: Standards for Used Oil Generators

Section 61-107.279.22.b(3) is added to require used oil generator facilities to ensure containers are "closed to prevent spillage or contamination from precipitation."

Subpart E: Standards for Used Oil Transporter and Transfer Facilities

Section 61-107.279.42.a – Changed for clarity.

Section 61-107.279.45.c(3) is added to require used oil transporters and used oil transfer facilities to ensure containers are "closed to prevent spillage or contamination from precipitation."

Section 61-107.279.46.a is revised to add the words “Used oil” before “manifests” for clarity.

In sections 61-107.279.46.f(2) and 61-107.279.46.f(4) the word “materials” is replaced with the words “used oil” for clarity.

Subpart F: Standards for Used Oil Processors and Re-refiners

Section 61-107.279.54.b(3) is added to require used oil processors and re-refiners to ensure containers are “closed to prevent spillage or contamination from precipitation.”

In sections 61-107.279.54.h(1)(a) and 61-107.279.h(2)(b) a comma is changed to a semicolon.

Sections 61-107.279.56.a and 61.107.279.56.c are revised to add the words “used oil” before the word “manifest” to provide clarity.

Subpart G: Standards for Burners Who Burn Off-Specification Used Oil for Energy Recovery

Section 61-107.279.62.a is changed to clarify that the used oil burner must renotify the EPA.

Section 61-107.279.65.a and 61-107.279.65.b are changed to add the words “used oil” before the word “manifests” for clarity.

Subpart H: Standards for Used Oil Fuel Marketers

Section 61-107.279.70.b(1) corrects the spelling of the word “incidently” to “incidentally.”

Section 61-107.279.73.a is changed to remove the requirement for used oil fuel marketers to obtain a permit from the Department. Used oil fuel marketers will now only be required to have an EPA identification number.

Section 61-107.279.74.b. clarifies record keeping requirements for used oil shipments by generators, transporters, processor/re-refiners.

Subpart I: Disposal of Used Oil

Section 61-107.279.80: “Can not” was changed to “cannot” for consistency.

Section 61-107.279.81 regulation numbers were updated to the correct citations.

Subpart M: Penalties

Subpart M is revised for consistency with other solid waste management regulations. Title is changed to “Violations and Penalties.”

Instructions: Amend R.61-107.279 pursuant to each individual instruction provided with the text of the amendments below.

Text:

Revise 61-107.279.10.i to read:

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

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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.

Add new subitem 61-107.279.10.j to read:

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.

Revise 61-107.279.11 Table to read:

Table: USED OIL NOT EXCEEDING ANY ALLOWABLE LEVEL SHOWN BELOW IS NOT SUBJECT TO THIS PART WHEN BURNED FOR ENERGY RECOVERY¹

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)	

¹The 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))

²Used 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.

Add new subitem 61-107.279.22.b(3) to read:

- 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.

Revise 61-107.279.42a to read:

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.

Add new subitem 61-107.279.45.c(3) to read:

- 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.

Revise 61-107.279.46.a to read:

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. Used oil manifests for each shipment must include, at a minimum:

Revise 61-107.279.46.f to read:

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.

Add new subitem 61-107.279.54.b(3) to read:

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.

Revise 61-107.279.54.h(1)(a) to read:

(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.

Revise 61-107.279.54.h(2)(b) to read:

(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.

Revise 61-107.279.56.a introductory paragraph; subitems 56.a(1)-(6) remain the same to read:

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:

Revise 61-107.279.56.c to read:

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.

Revise 61-107.279.62.a to read:

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

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must renotify EPA to identify used oil burning activities. In addition, the burner must obtain a permit from the Department.

Revise 61-107.279.65.a introductory paragraph; subitems 65.a(1)-(6) remain the same, to read:

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:

Revise 61-107.279.65.b to read:

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.

Revise 61-107.279.70.b(1) to read:

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;

Revise 61-107.279.73.a to read:

a. Used oil fuel marketers must have an EPA identification number.

Revise 61-107.279.74.b introductory paragraph; subitems 74.b(1)-(4) remain the same, to read:

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:

Revise 61-107.279.80 to read:

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.

Revise 61-107.279.81.c to read:

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).

Revise 61-107.279.93 SUBPART M PENALTIES to read:

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.

Fiscal Impact Statement:

Additional costs to state government are not anticipated. There are no direct costs to local governments that can be attributed to this regulation.

Statement of Need and Reasonableness:

This Statement of Need and Reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION:

Purpose: The purpose of this regulation is to ensure that used motor oil is collected, stored, transported, processed and disposed in an environmentally protective manner and as required by federal regulation, 40 CFR Part 279. The regulation applies to, and establishes standards for used-oil generators, collectors, transporters, processors, re-refiners, burners, and marketers. The regulation establishes standards for burning used oil, including exemptions for on-site use in space heaters. Additionally, it establishes prohibitions on certain uses of used motor oil, standards for used oil collection centers and aggregation points, and manifesting requirements for transporters. It also addresses standards for used oil filter disposal. It addresses the use of the Petroleum Fund to recover costs for the proper disposal of contaminated oil accepted from the public at a registered used oil collection facility.

Legal Authority: 1976 Code Sections 44-96-10 et seq. Legislative review is required.

Plan for Implementation: Upon approval of the General Assembly and publication in the South Carolina *State Register*, a copy of the revised regulation will be available electronically on the Department's Laws and Regulations website. Subsequently, a copy of the regulation will be published in the S.C. Code of Regulations on the S.C. Legislature Online website. Printed copies will be available for a fee from the Department's Freedom of Information Office. Staff will notify parties that have expressed interest in the regulation amendment process, and will communicate with affected parties on the requirements of the amended regulation. No additional positions or personnel should be needed to enforce the regulation.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments are needed and reasonable because they will update the used oil regulation to conform to the federal used oil regulation and will relieve used oil fuel marketers from securing a nonessential permit. The amendment will support the Department's goal of promoting and protecting the health of the public and the environment, by ensuring used oil is managed properly. This amendment clarifies when used oil contaminated with PCBs is regulated under RCRA used oil management; removes the requirement for used oil fuel marketers to secure a permit; and provides corrections for consistency, clarity, and formatting.

DETERMINATION OF COSTS AND BENEFITS:

Internal costs and benefits: Implementation of these amendments will not require additional resources. There is no anticipated additional cost by the Department or State government due to any inherent requirements of these amendments.

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External costs and benefits: These amendments will benefit used oil fuel marketers by relieving them of the burden of securing a nonessential permit. The amended regulation seeks to benefit the regulated community by giving clarity to the amount of PCBs that are allowable in used oil for it to be regulated under this regulation.

UNCERTAINTIES OF ESTIMATES:

There are no foreseeable uncertainties of estimates relative to the cost to the State or its political subdivisions.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The regulations will protect the environment and promote public health by ensuring that used motor oil will be stored and managed in such a way as to prevent it from being released to the environment. The revision will help those who collect, store or transport used motor oil more clearly understand the requirements of the regulation with respect to PCB levels, increasing the likelihood that contaminated oil will be managed in a safe, environmentally sound manner.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATIONS ARE NOT IMPLEMENTED:

If the amendments are not implemented, there is potential for used motor oil to be stored in such a way as to allow it to spill from storage containers, resulting in contamination to the environment; or to be stored in such a way as to become contaminated by precipitation, increasing the difficulty of properly managing the material. Without the clarification regarding PCB levels, there is the increased potential that transporters of used motor oil would improperly manage oil, resulting in discharges to the environment. According to the U.S. EPA, PCBs that are released into the environment remain in the air, water, and soil for extended periods, with the potential for many negative health impacts, to include cancer, and adverse effects on the immune, reproductive, nervous, and endocrine system.

Statement of Rationale:

The South Carolina Solid Waste Policy and Management Act of 1991 directed the Department to develop regulations to promote the recycling and proper management of used oil. The resulting regulation was promulgated in 1995, but has been identified by the Department and by various members of the used oil management community as being in need of updating.

A stakeholder workgroup developed the criteria on which the regulation revision is based. The Department conducted a stakeholder meeting and circulated multiple versions of the drafted revisions for comment from the stakeholder members. Comments received during the stakeholder process were considered as revisions were developed, and contributed significantly to the development of the regulations proposed for public comment. Issues were brought forth for consideration and resolved during the meeting and by email. The workgroup included private sector representatives including used oil fuel marketers, used oil processors, used oil transporters, used oil burners, and representatives of the waste management industry. Input was solicited from representatives of environmental organizations and the South Carolina Retail Association. Opportunity for public sector representation was provided to federal, state, county and municipal government representatives, the South Carolina Association of Counties, the South Carolina Municipal Association, the South Carolina Department of Commerce, and Department staff. A representative of the United States Environmental Protection Agency (EPA) also provided comment on the drafting of these amendments.

The Department conducted a stakeholder meeting and circulated multiple versions of the drafted revisions for comment from the stakeholder members. Comments received during the stakeholder process were considered as revisions were developed.

Document No. 4616
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
 CHAPTER 61
 1976 Code Sections 44-29-150 through 170

61-22. The Evaluation of School Employees for Tuberculosis

Synopsis:

The Department of Health and Environmental Control (“Department”) amends Regulation 61-22, The Evaluation of School Employees for Tuberculosis. Regulation 61-22 was last amended in 1986. These amendments incorporate current tuberculosis evaluation and preventive treatment guidelines, update the screening and evaluation requirements for school employees, clarify language relating to the issuance of certificates, and provide for consistency with applicable state and federal laws. Stylistic changes are also included.

A Notice of Drafting for these proposed amendments was published in the *State Register* on May 22, 2015.

See Discussion below and Statements of Need and Reasonableness and Rationale herein for detailed information.

Section-by-Section Discussion of Amendments:

Grammatical, capitalization, punctuation, references, outlining/codification corrections, and language changes for consistency were made throughout the regulation to improve the overall quality of the regulation in meeting current drafting and codification standards. Due to numerous amendments, Regulation 61-22 will be replaced in its entirety.

Applicability language “(Public or Private School, Kindergarten, Nursery or Day Care Center)” was deleted under the statutory authority at the beginning of this regulation and has been moved to the new Purpose and Scope Section at 61-22, Section I.

TABLE OF CONTENTS:

The table of contents was added to make Regulation 61-22 more user friendly in locating subject matter consistent with the text of Regulation 61-22.

Regulation 61-22, Section I, INTRODUCTION:

Renamed title from Introduction to Purpose and Scope. Updated and clarified language pertaining to pre-employment testing and annual risk assessment screening requirements.

Regulation 61-22, Section II, RATIONALE:

Section II was deleted in its entirety. Explanation as to why skin test is preferred over X-ray is not necessary. Additional information regarding use of X-ray was included in other sections as appropriate.

Regulation 61-22, Section III, DEFINITIONS:

Section III was renumbered to Section II and revised: Updated and clarified current national standards and guidelines and the purpose of the annual tuberculosis risk assessment questionnaire. Removed tables and added new definitions for blood assay mycobacterium tuberculosis treatment of tuberculosis infection, authorized healthcare provider, and two-step tuberculin skin test.

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Regulation 61-22, Section IV, GUIDELINES FOR SCREENING/EVALUATION:

Section IV was renumbered to Section III and revised: Clarified a ninety (90) day window for pre-employment testing, issuance of the certificate, and described the use of the risk assessment questionnaire, the screening process and documentation of the results.

Regulation 61-22, Section V, ADDITIONAL INFORMATION AND FORMS:

Section V, Additional Information and Forms, was renumbered to Section IV and clarified where the certification form and risk assessment may be found and deleted the testing flow chart.

Regulation 61-22, APPENDIX:

The appendix is new and replaces the testing flow chart with interpretation of tuberculosis skin test results.

Instructions: Replace R.61-22, The Evaluation of School Employees for Tuberculosis, in its entirety.

Text:

61-22. The Evaluation of School Employees for Tuberculosis.

(Statutory Authority: 1976 Code Sections 44-29-150, 44-29-160, 44-29-170)

TABLE OF CONTENTS

- I. PURPOSE AND SCOPE.
- II. DEFINITIONS.
- III. GUIDELINES FOR SCREENING AND EVALUATION.
- IV. ADDITIONAL INFORMATION AND FORMS.

I. PURPOSE AND SCOPE.

Sections 44-29-150 through 44-29-170 of the 1976 South Carolina Code of Laws pertain to the evaluation of employees of a public or private school, kindergarten, nursery or day care center for infants and children for tuberculosis. Section 44-29-150 authorizes the Department of Health and Environmental Control to establish guidelines for the evaluation of school employees for tuberculosis. Under these guidelines, all employees of a public or private school, kindergarten, nursery or child care center shall be screened for tuberculosis within ninety (90) days prior to initial hire, and will not be required to be evaluated annually for risk of tuberculosis exposure or development of tuberculosis disease. These guidelines shall apply to any person applying for a position or currently employed, whether full time, temporarily or in any other capacity, in a public or private school, kindergarten, nursery or child care center. The Department will provide guidelines to emphasize risk assessment for tuberculosis and targeted testing of identified high risk employees affording children greater protection against exposure to tuberculosis in the school environment.

II. DEFINITIONS.

For the purpose of the evaluation of public or private school, kindergarten, nursery or day care center for infants and children employees for tuberculosis, the following definitions and clarifications shall apply:

A. Adequate treatment. Therapy with anti-tuberculosis drugs that is determined by the department's Tuberculosis Medical Consultant to be sufficient for the treatment of infection or disease.

B. Blood assay for mycobacterium tuberculosis (BAMT). A general term used to refer to in vitro diagnostic

tests that assess for the presence of infection with mycobacterium tuberculosis (MTB), such as an interferon gamma release assay (IGRA).

C. Legally authorized healthcare provider. An individual authorized by law and currently licensed in South Carolina to provide specific medical treatments, care, or services to staff members and/or patients, such as, physicians, advanced practice registered nurses, physician assistants.

D. New employee. An individual being initially hired.

E. Non-reactor. An individual with a negative skin test (see Appendix) or a negative BAMT.

F. Non-routine testing. Testing that may be required in special circumstances where there is epidemiologic evidence, such as when an employee is identified as a close contact of a person with infectious tuberculosis disease, that employees may have become infected or infectious, when tuberculosis is known to have occurred in the public or private school, kindergarten, nursery or child care center environment, or when an employee is observed to have signs or symptoms suggestive of tuberculosis.

G. Regular employee. An individual currently employed who has had a pre-employment TB evaluation.

H. School employees. All employees to include teachers, bus drivers, office staff, custodial and cafeteria staff, and any other persons employed, in any capacity, by a public or private school, kindergarten, nursery or day care center for infants and children.

I. Treatment for tuberculosis infection (TTBI). Treatment to prevent tuberculosis disease from developing in tuberculin or BAMT positive reactors.

J. Tuberculin/BAMT positive reactor. Any individual found to have a positive skin test reaction (see Appendix), or an individual who has a positive BAMT.

K. Tuberculin skin test (TST). Test done by intradermal injection (Mantoux or any tuberculosis infection test currently approved by the Federal Drug Administration) of five (5) tuberculin units of purified protein derivative.

L. Tuberculosis disease (TB). A disease often contagious, usually diagnosed by chest x-ray and culture of tubercle bacilli from sputum or direct DNA testing, such as nucleic acid amplification testing (NAAT).

M. Tuberculosis infection. Presence of living tubercle bacilli in the body of an asymptomatic, non-infectious individual in which active disease has been excluded, as diagnosed by the TST or BAMT and a negative chest x-ray.

N. Two-step tuberculin skin test. Refers to the “booster test” where a second TST is given one to three (1 to 3) weeks after an initial negative TST in order to “boost” the immune system to recognize tubercle protein in the TST in the event infection is actually present in the body but is suppressed due to age or illness.

III. GUIDELINES FOR SCREENING AND EVALUATION.

A. Required screening and evaluation of public and private school, kindergarten, nursery or child care center employees for tuberculosis:

1. Each employee of a public or private school, kindergarten, nursery or day care center for infants and children shall have a DHEC Form 1420 on file in their personnel record at their current place of employment.

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2. Unless directed otherwise under part 5 or 6 of this subsection, new employees shall have a two-step TST or single BAMT within ninety (90) days prior to the date of initial employment and tuberculosis annual risk assessment questionnaires thereafter administered by the school district.

3. Unless directed otherwise under part 5 or 6 of this subsection, regular employees, if they have not already done so, shall provide documentation of a two-step TST or BAMT (DHEC Form 1420) to be kept on file at their current place of employment.

4. New or regular employees documented to have been reactors to a prior TST or to have had a positive BAMT shall not be required to have a TST or BAMT. These employees shall have their records and health status reviewed by a legally authorized healthcare provider and obtain certification of being non-infectious via DHEC Form 1420 in order to begin or continue employment.

a. If a prescribed course of treatment for TB infection with anti-tubercular medications has been completed and documentation is provided, the employee may continue to work and annual risk assessments shall be required.

b. If the employee has not completed treatment for TB infection, or cannot provide documentation of completed treatment, the employee may continue to work provided there are no “yes” answers to the symptom sections on the risk assessment questionnaire.

c. The DHEC Form 1420 shall be completed by a legally authorized healthcare provider certifying that the individual is considered to be infected and remains at lifelong risk of developing tuberculosis disease.

5. New or regular employees who have had active tuberculosis in the past shall not be required to have a TST or BAMT. Instead, these employees shall comply with the following:

a. Employees with a history of active tuberculosis shall have their records and health status reviews annually by a legally authorized healthcare provider who shall, if appropriate and in consultation with the Department of Health and Environmental Control Tuberculosis Medical Consultant, certify the employee as non-infectious on DHEC Form 1420. All employees shall have a DHEC Form 1420 on file at their current place of employment.

b. If the employee has completed a prescribed course of therapy with anti-tubercular medications, and provides documentation indicating completion of such treatment, the employee may continue to work provided there are no “yes” answers on the risk assessment questionnaire.

c. If the employee has not completed a prescribed course of treatment, or cannot provide documentation of completed treatment, a legally authorized healthcare provider shall note on DHEC Form 1420 that the individual is considered to be infected and remains at lifelong risk of developing tuberculosis diseases.

B. Disposition following results of screening and evaluation:

1. All employees found to be new tuberculin reactors shall have a chest x-ray and subsequent medical evaluation to rule out active tuberculosis disease prior to start or return to work.

2. Any employee with symptoms of pulmonary tuberculosis shall be evaluated regardless of the BAMT or TST result. All symptomatic employees shall be excluded from work until disease is ruled out or the employee is no longer considered infectious, as certified on DHEC Form 1420 by a legally authorized healthcare provider in consultation with the Department of Health and Environmental Control Tuberculosis Medical Consultant.

a. If a chest x-ray (and sputum cultures, acid fast bacillus (AFB) staining or NAAT, if necessary) of a tuberculin reactor shows no evidence of current tuberculosis disease, the employee shall be evaluated for TTBI.

(i) If TTBI is medically indicated, and if the employee completes the treatment regimen as prescribed, only annual risk assessments shall be required.

(ii) If TTBI is not medically indicated, or if the employee for whom such therapy is indicated does not complete the prescribed course of treatment, annual risk assessments shall be required and a notation shall be made by a legally authorized healthcare provider on DHEC Form 1420, that the individual is considered to be infected and remains at lifelong risk of developing tuberculosis disease. The DHEC Form 1420 shall be maintained in the employee’s personnel file.

b. If a chest x-ray (and sputum cultures, AFB staining, or NAAT, if necessary) of a tuberculin reactor shows evidence of current tuberculosis disease, the employee shall not work in any public or private school, kindergarten, nursery or day care center, until a Department of Health and Environmental Control Tuberculosis Medical Consultant certifies on DHEC Form 1420 that the individual is non-infectious. Certification is subject to review by the Department of Health and Environmental Control or delegated representatives in county health departments. This provision applies to an employee found to have tuberculosis disease at the time of hiring or at any other time.

3. Disposition of results of the tuberculosis risk assessment questionnaire:

a. Employees who have negative responses to the symptom and to the exposure risk sections of the questionnaire will need no further testing.

b. Employees with any “yes” responses to the tuberculosis symptoms section of the questionnaire shall receive further medical evaluation by a legally authorized healthcare provider which may include imaging, TST or BAMT testing, sputum collection or other, and further medical follow up based on symptoms.

4. New employees who are found to be infected, such as those who are reactors to the TST or who have a positive BAMT, will require a chest x-ray and certification (DHEC Form 1420) by a legally authorized healthcare provider that they are free of tuberculosis disease.

C. Documentation of results of screening and evaluation:

1. Results of the required evaluation or certification and the subsequent disposition for each employee shall be recorded on DHEC Form 1420 as provided for in Section 44-29-170 of the S.C. Code of Laws.

2. The public or private school, kindergarten, nursery or day care center for infants and children shall be required to maintain a copy of the annual risk assessment questionnaire completed by employees. Each employee of a public or private school, kindergarten, nursery or day care center for infants and children must have a DHEC Form 1420 on file in their personnel record at their current place of employment.

D. Non-routine screening:

Any employee may be required to undergo non-routine screening, if there is epidemiologic evidence that such employee may have become infected or infectious. Epidemiologic evidence for contact investigation includes, but is not limited to:

1. Identification of employees as close contacts of tuberculosis cases;
2. Occurrence of tuberculosis in the public or private school, kindergarten, nursery or child care facility environment; or
3. Observation of signs or symptoms in employees suggestive of tuberculosis.

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IV. ADDITIONAL INFORMATION AND FORMS.

A. Questions regarding this regulation may be addressed to personnel of the county health departments or the regional offices of the Department of Health and Environmental Control. Questions which cannot be resolved at the local level may be referred to the Tuberculosis Control Division, Department of Health and Environmental Control, 2600 Bull Street, Columbia, S.C. 29201.

B. Examination and certification may be obtained by employees from private physicians. Certification forms (DHEC Form 1420) are also available, upon request, from the Department of Health and Environmental Control.

Appendix. Interpretation of the Tuberculin Skin Test (TST).

Reference:

Targeted Tuberculin Testing, MMWR, 2000, (49) No, RR-6

Induration of 5 mm or greater is considered positive in	Induration of 10 mm or greater is considered positive in	Induration of 15 mm or greater is considered positive in
<p>Human immunodeficiency virus (HIV)-positive persons</p> <p>Recent contacts of TB case patients</p> <p>Persons with fibrotic changes on chest radiograph consistent with prior TB</p> <p>Patients with organ transplants and other immunosuppressed patients (Receiving the equivalent of 15 mg/d of prednisone for 1 month or more. Risk of TB in patients with corticosteroids increases with higher dose and longer duration.)</p>	<p>Recent immigrants (i.e., within the last 5 years) from high-prevalence countries</p> <p>Injection drug users</p> <p>Residents and employees of the following high-risk congregate settings: prisons and jails, nursing homes and other long-term facilities for the elderly, hospitals and other health care facilities, residential facilities for patients with acquired immunodeficiency syndrome (AIDS), and homeless shelters</p> <p>Mycobacteriology laboratory personnel</p> <p>Persons with the following clinical conditions that place them at high risk: silicosis, diabetes mellitus, chronic renal failure, some hematologic disorders (such as leukemias and lymphomas), other specific malignancies (such as carcinoma of the head, neck, or lung), weight loss of 10 percent of ideal body weight, gastrectomy, and jejunioileal bypass</p> <p>Children less than 4 years of age, or infants, children and adolescents exposed to adults at high-risk</p> <p>Persons on TNF inhibitors</p>	<p>Persons with no known risk factors for TB</p>

Fiscal Impact Statement:

There are no anticipated additional costs to the state and its political subdivisions.

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Statement of Need and Reasonableness:

This Statement of Need and Reasonableness was based on an analysis of the factors listed in S.C. Code Sections 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: R.61-22, The Evaluation of School Employees for Tuberculosis

Purpose: The purpose of these amendments to Regulation 61-22 is to update and clarify the guidelines for tuberculosis screening and evaluation of employees in school and child care settings. These amendments further clarify the language relating to the issuance of certificates and incorporate current evaluation and preventive treatment guidelines.

Legal Authority: The legal authority for Regulation 61-22 is found at 1976 Code Sections 44-29-150 through 170.

Plan for Implementation: Upon approval by the General Assembly and publication in the State Register as a final regulation, a copy of Regulation 61-22, including these amendments, will be available electronically on the Department's Laws and Regulations website. Subsequently, this regulation will be published in the South Carolina Code of Regulations. Printed copies will be available for a fee from the Department's Freedom of Information Office.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The amendments to Regulation 61-22 are needed to update and clarify the guidelines for tuberculosis screening and evaluation of employees in school and child care settings. The amendments are reasonable as they accomplish their intended purpose of identifying high-risk school employees and will afford children greater protection against exposure to tuberculosis in school settings.

DETERMINATION OF COSTS AND BENEFITS:

There are no anticipated additional costs to the state or its political subdivisions. School employees are currently required by S.C. Code Section 44-29-160 to obtain certification from their physician prior to hire.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the State.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

Implementation of the amendments herein will not compromise the protection of the environment or public health. The effect should be beneficial because the amendments provide for more frequent screening of school employees and facilitate targeted testing of identified higher risk school employees.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment if the amendments are not implemented. Failure to amend the regulation would result in the lack of periodic evaluation of school employees who may have been exposed to tuberculosis following the start of their employment and may result in the delayed diagnosis of mycobacterium tuberculosis.

Statement of Rationale:

These amendments of R.61-22 are needed, to incorporate current tuberculosis evaluation and preventive treatment guidelines, update the screening and evaluation requirements for school employees, clarify language relating to the issuance of certificates, and provide for consistency with applicable state and federal laws. The amendments herein are needed to update and clarify the guidelines for tuberculosis screening and evaluation of employees in school and child care settings in South Carolina. The amendments will also include stylistic changes.

Document No. 4580
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
 CHAPTER 61

Statutory Authority: 1976 Code Sections 44-63-10 et seq.

61-19. Vital Statistics

Synopsis:

The Department has substantially amended Regulation 61-19, Vital Statistics. Sections 1-42 of Regulation 61-19 have been revised and replaced in its entirety. The Fees Section, Section 43, of this Regulation was not changed except for codification consistency. These amendments seek to improve the quality, security and fraud prevention, protection of confidential information and uniformity of state data by implementing standard reporting requirements, and definitions and procedures for registering vital events as described in the 2011 Model State Vital Statistics Act and Regulations issued by the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS). Also, other changes have been made to improve the overall quality of the regulation to meet Legislative Council guidelines for drafting the text of regulations.

A Notice of Drafting for these amendments was published in the *State Register* on May 22, 2015.

This Regulation was withdrawn and resubmitted at the request of the Business, Commerce, and Administrative Procedures Subcommittee of the House Regulations and Administrative Procedures Committee by letter dated March 17, 2016 to correct a scrivener’s error:

Section 801.A. The reference in the last sentence is corrected from section 900 to section 1000.

Below is the Section by Section Discussion of Amendments Submitted by DHEC January 12, 2016 to the General Assembly for review:

The statutory authority citation added 1976 and the section symbol was replaced in text form to meet Legislative Council guidelines for drafting text of regulations.

The existing Regulation 61-19 Sections 1 – 42 have been substantively changed and substantially reorganized. Therefore, the entire existing regulation has been replaced with the exception of Section 43 Fees. The Fees Section has remained the same except the outline/codification was changed.

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The table was extensively revised to reflect the amendments.

61-19.100 Definitions

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Numerous definitions were added to define terminology in the amendments. Remaining definitions were renumbered to adjust the codification.

61-19.201 General (System of Vital Statistics)

Section outlines the organization of the system of vital statistics and the authority of the State Registrar.

61-19.301 General (Security and Confidentiality of System of Vital Statistics)

Section requires all users of the system to follow security procedures and allow validation by the Department of information submitted.

61-19.302 Preservation of Vital Records and Vital Reports (formerly 61-19 Section 38)

Section language was amended to utilize current terminology with the addition of allowance for the disposal of records as provided by in established retention schedules.

61-19.303 Confidentiality

Section protects and restricts all documents and data in vital records and vital reports and related documents. This amendment specifically prohibits access or release for commercial purposes.

61-19.304 Disclosure of Information from Vital Records or Reports for Health Research

Section outlines requirements for and utilization of a data release protocol to be developed by the Department.

61-19.401 Forms, Records, Reports, Electronic Data Files

Section makes minor modifications from a similar section in former regulation and adds allowance for the transfer of information from electronic health records.

61-19.402 Requirements for Preparation of Records and Reports

Section requires training of individuals submitting or certifying a vital event. Also, section restricts use of ink for signatures and hand printed reports to black ink where as former regulations only specified dark ink.

61-19.403 Person Required to Retain Documentation

Section adds requirements for the retention of documentation of the information and the source used in the reporting of vital events. Also, section requires documentation be maintained about the disposition of human remains. Documentation must be maintained for not less than ten years.

61-19.404 Duties to Furnish Information

Persons with information about the facts required in the reporting of vital events must provide information upon request of the State Registrar or within five days of receiving the information. Section also requires findings from autopsy or other sources be submitted within five days of receipt of such information.

61-19.405 Content of Vital Records and Vital Reports

Section requires uniformity with the minimum items on reports of vital events as recommended by the National Center for Health Statistics. The requirement for approval by the Board to create or modify a form used in the reporting of a vital event was deleted from former regulations.

61-19.501 General (Live Birth Registration)

Section was substantively revised to provide a time frame for the transfer of prenatal care information to the institution reporting the live birth. Criteria for the determination of maternity for purposes of reports of live birth were added. The responsible party priority order for filing reports of live births that occur out of institutions was modified to remove the father and to add the Coroner for cases where investigation is required.

61-19.502 Out-of-Institution Live Birth

Section specifies the documentary evidence required for a mother to report an unattended out of institution home birth.

61-19.503 Infants of Unknown Parentage; Foundling Registration

Section limits the reporting of a birth by an institution for infants of unknown parentage to infants up to 30 days of age. Infants of unknown parentage over 30 days of age will require a court order to establish a report of live birth.

61-19.601 General (Delayed Registration of Births)

Section was revised to provide consistency in requirements and format for the filing of a delayed birth record.

61-19.602 Documentary Evidence Requirements

Section was revised to provide consistency in the documentary evidence requirements for filing a delayed birth record. Eliminates the difference in number of documents required based on the age of the person filing.

61-19.603 Documentary Evidence Acceptability

Section adds additional criteria in order for the documentary evidence to be acceptable for supporting the facts of birth to be established. Documentary evidence must be from independent sources and not contradictory.

61-19.604 Abstraction of Documentary Evidence

Section retains information to be abstracted from the documentary evidence submitted but adds the requirement that a copy of acceptable documentary evidence be retained by the Department.

61-19.605 Verification by the State Registrar

Section modifies some of the language in former regulation but does not alter the content meaning.

61-19.606 Dismissal after One Year

Section was renumbered with minimal changes to language but no substantive changes from former regulation.

61-19.607 Delayed Birth Records Amended by Court Order

Section adds requirement for a delayed birth record to remain in delayed format and for any legal amendment to be clearly indicated on the record and any certification issued.

61-19.701 General (Death Registration)

Section eliminates the filing of reports in the county of death so that all reports will be filed electronically to improve timeliness and data quality. The requirement for utilizing information gathering procedures provided and approved by the State Registrar has been added. The registration of deaths not filed in a timely manner has been modified to mandate a court order when the funeral director and medical certifier are unavailable or unwilling to complete a report of death.

61-19.702 Judicial Procedures to Register a Death

Section adds the procedures and information needed to register a death record by a court order.

61-19.801 General (Fetal Death Registration)

Section makes minor change to criteria for reporting a fetal death so as to be consistent with the National Center for Health Statistics criteria and reporting definition. The limitation for including the name of the father on the report of fetal death is removed from this section. The requirement for utilizing information gathering procedures provided and approved by the State Registrar has been added to be consistent with the report of live birth and report of death.

61-19.901 Permits Governing the Disposal or Transportation of Dead Human Bodies

Section incorporates electronic processes for issuance and filing of reports with the Department and clarifies the responsibilities of all involved parties.

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61-19.902 Removal of Body

Section requires the funeral director or person acting as such to assure death is from natural causes and to obtain authorization of the Coroner prior to removal of a body.

61-19.903 Authorization for Disinterment and Reinterment

Section requires a permit signed by the next of kin and authorization by the Department prior to the disinterment of any body except upon order of a court of competent jurisdiction. Content of section is consistent with former regulation.

61-19.904 Disposition of Body or Fetus by Hospital Officials Authorized by Next of Kin

Section mandates hospitals to obtain a burial removal transit permit and file the report of death or fetal death in all situations where they dispose of the body or fetus. Content of section is consistent with former regulation.

61-19.1001 General (Reports of Induced Termination of Pregnancy)

Section mandates reporting of induced terminations of pregnancy regardless of length of gestation and whether performed in or outside an institution. The reports are statistical reports and only to be used for public health purposes.

61-19.1101 General (Correction and Amendment of Vital Records)

Section clarifies the allowable reasons and processes for amendments to vital records.

61-19.1102 Correction of Birth and Death Records

Section specifies when corrections of data entry errors and minor mistakes made in the filing of birth and death records can be made by the Department without amendment having to be marked on the record.

61-19.1103 Administrative Amendment of Vital Records

Section provides procedures for amending records using documentary evidence and an affidavit of an entitled person. The specific types of amendments are included in the definitions and further specifications are included in this section.

61-19.1104 Documentary Evidence Required to Amend or Correct Vital Records

Section specifies the information that must be included, the sources, age and types of documents that are acceptable to support an amendment to a vital record.

61-19.1105 Addition of Registrant's First or Middle Names on Live Birth Records

Section provides procedure whereby parents can add a first or middle name prior to the first birthday. After the first birthday, a legal change of name would be required after first birthday. Administrative process for changing name up to seventh birthday has been deleted.

61-19.1106 Date of Birth Amendments to Live Birth Records

Section adds specific instructions and procedures for amending the date of birth on a birth record and provides limitations to when date of birth can be changed.

61-19.1107 Amendments to Death Records

Section provides specific criteria for when the marital status can be changed on a death record without a court order. Other changes to a death record must be supported with acceptable documentary evidence. Signatures cannot be amended.

61-19.1108 Amendment of the Same Item More than Once

Section allows an amendment to be completed administratively only one time for each item on a record except for the cause and manner of death or clerical error by the Department. Content is similar to former regulation.

61-19.1109 Sealed Amendments and Replacement Records of Live Birth

Section prescribes the preparation of sealed files pursuant to state law and restricts access to such files except upon order of the Family Court. Content of this section is consistent with former regulation.

61-19.1110 Amendments by Court Order

Section specifies requirements for amending a birth or death record upon receipt of a certified copy of a court order and requires amendment to be marked on record and any certified copies of the record issued.

61-19.1201 General (Certifications from the System of Vital Statistics)

Section defines the requirements for applications, proof of identity and evidence of entitlement before any certification of a vital event can be issued. Government agencies are allowed to request a verification of facts contained in a vital record including through an electronic system approved by the Department.

Instructions: Replace Regulation 61-19 in its entirety with this amendment.

Text:

61-19. VITAL STATISTICS.

(Statutory Authority: 1976 S.C. Code Section 44-63-10 et seq.)

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SECTION 100 - DEFINITIONS

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

A. Amendment. A change to a certification item.

(1) Administrative Amendment. A change to correct a mistake on a certification item on a vital record using documentary evidence and an affidavit of correction.

(2) Sealed Amendment. A change to a birth record after an adoption, statutory maternity or paternity process, or other amendment required by law to be placed in a sealed file. A replacement record is created and the original record is sealed.

(3) Amendment by Court Order. A change to a record based on a court order.

B. **Certification.** The document issued by the State Registrar and containing all or a part of the exact information contained on the original vital record, and which, when issued by the State Registrar, has the full force and effect of the original vital record.

C. **Certification Item.** Any item of information that appears on a certification.

D. **Certifier.** A person required to attest to the accuracy of the information submitted on a vital event report.

E. **Correction.** A change to rectify a mistake on a birth or death record or a report of fetal death record.

F. **Court of Competent Jurisdiction.** A court within the United States with jurisdiction over the subject matter and over the necessary parties.

G. **Date of Registration.** The month, day, and year a vital event is incorporated into the official records of the Bureau of Vital Statistics.

H. **Dead Body.** A human body or such parts of a human body from the condition of which it reasonably may be concluded that death has occurred.

I. **Disclosure.** Making available or making known personally identifiable information contained in a vital record or vital report, by any means of communication.

J. **Electronic Signature.** An electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to attest to the accuracy of the facts in the record.

K. **Facts of Live Birth.** The child's name, date of birth, place of birth and sex, and the name(s) of parent(s) appearing on the record of live birth.

L. **Fetal Death.** Death prior to the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy and which is not an induced termination of pregnancy. The death is indicated by the fact that after such expulsion or extraction, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

M. **Final Disposition.** The burial, interment, cremation, removal from the State, or other authorized disposition of a dead body or fetus.

N. **Government Agency.** A unit of local, state, federal, or tribal government.

O. **Health Research.** A systematic study to gain information and understanding about health with the goal of finding ways to improve human health, conducted in accordance with generally accepted scientific standards or principles and designed to develop or contribute to generalizable scientific knowledge.

P. **Human Remains.** A dead body, or any part of the body of a human being from the condition of which it reasonably can be concluded that death occurred, but does not include human ashes recovered after cremation.

Q. **Individual.** A natural person.

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R. Induced Termination of Pregnancy. The purposeful interruption of an intrauterine pregnancy with the intention other than to produce a live-born infant, and which does not result in a live birth. This definition excludes management of prolonged retention of products of conception following fetal death.

S. Informant. The person who provides demographic and personal information as required for the report of death.

T. Institution. Any establishment, public or private, which provides:

- (1) in-patient or out-patient medical, surgical, or diagnostic care or treatment, or
- (2) nursing, custodial, or domiciliary care, or
- (3) to which persons are committed by law.

U. Interment. The disposition of human remains by entombment or burial.

V. Legal Representative. A licensed attorney representing the registrant or other entitled applicant.

W. Live Birth. The complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes, or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.

X. Personally Identifiable Information. Information that can be used to distinguish or trace an individual's identity, such as, but not limited to, his or her name, Social Security number, biometric records or address, alone, or when combined with other personal or identifying information which is linked or linkable to a specific individual, such as, but not limited to, date and place of live birth or mother's name prior to first marriage.

Y. Person in Charge of an Institution. The officer or employee who is responsible for administration and includes but is not limited to a person holding the title of chief executive officer, administrator, superintendent, director or executive director.

Z. Physician. A person authorized or licensed to practice medicine or osteopathy pursuant to the laws of this State.

AA. Record. A report of a vital event that has been registered by the State Registrar.

BB. Registration. The process by which reports are accepted and incorporated into the official records of the Bureau of Vital Statistics.

CC. Report. A document, paper or electronic, containing information related to a vital event submitted by a person or entity required to submit the information in accordance with this regulation to the Bureau of Vital Statistics for the purpose of registering a vital event.

DD. Sealed File. The original record of a vital event that has been sealed after amendment and the evidence submitted to support the change. Sealed files shall not be subject to inspection, except upon order of the Family Court.

EE. State. A State of the United States, the District of Columbia, New York City, American Samoa, the Commonwealth of the Mariana Islands, the Commonwealth of Puerto Rico, Guam and the U.S. Virgin Islands.

FF. State Registrar. The State Registrar of Vital Statistics.

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

HH. System of Vital Statistics. The collection, registration, preservation, amendment, certification, verification, and the maintenance of the security and integrity of vital records; the collection of other reports required by this regulation; and activities related thereto including the tabulation, analysis, publication, and dissemination of vital statistics.

II. Verification. A confirmation of the information contained in a vital record.

JJ. Vital Event. A live birth, death, fetal death, marriage, divorce, annulment or induced termination of pregnancy.

KK. Vital Records. Reports of live birth, death, marriage, divorce, or annulment and data related thereto which have been accepted for registration and incorporated into the official records of the Bureau of Vital Statistics.

LL. Vital Reports. Reports of fetal death and induced terminations of pregnancy which have been accepted for registration and incorporated into the Department's vital statistics.

MM. Vital Statistics. The aggregated data derived from the records and reports of live birth, death, fetal death, induced termination of pregnancy, marriage, divorce, or annulment and supporting documentation and related reports.

SECTION 200 – SYSTEM OF VITAL STATISTICS

201. General

A. The System of Vital Statistics shall:

(1) be directed and supervised by the State Registrar who shall be custodian of its records.

(2) be uniform in policy and procedure throughout the State.

B. Public health programs within the Department may be provided copies of or data derived from vital records and vital reports required under these regulations, as the State Registrar determines are necessary for public health planning and program activities. The copies or data shall remain the property of the Bureau of Vital Statistics, and the uses shall be governed by the State Registrar.

C. The State Registrar may establish, designate or eliminate offices in the State to aid in the efficient administration of the system of vital statistics.

D. The State Registrar may delegate such functions and duties vested in him or her to employees of the Bureau of Vital Statistics and to employees of any office established or designated under Section 201C.

SECTION 300 - SECURITY AND CONFIDENTIALITY OF SYSTEM OF VITAL STATISTICS

301. General

All users of the system of vital statistics shall:

A. complete authentication procedures as required by the Bureau of Vital Statistics and only access the components of the system necessary for their official roles and duties;

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B. maintain specified levels of training related to security and acknowledge in writing security procedures and penalties;

C. allow validation of data provided in reports submitted for registration through site visits by Department staff at a frequency specified by the State Registrar to maximize the integrity of the data reported;

D. secure their workplace, storage and technology environments to protect all personally identifiable information;

E. acknowledge in writing the procedures to identify and report to the Department any breach of the system of vital statistics.

302. Preservation of Vital Records and Vital Reports

Records or reports registered with the Department shall be reproduced and preserved as determined appropriate by the State Registrar. Such reproductions when verified and approved by the State Registrar shall be accepted as the original vital record documents. The original vital record documents from which permanent reproductions have been made may be disposed of as provided by retention schedules.

303. Confidentiality

A. Vital records, vital reports, indices, related documents, and data or information contained therein shall be confidential. No person shall permit inspection of, or disclose data or information contained in vital records, vital records related documents or in vital reports or copy or issue a copy of all or part of any such record or report except as specifically allowed by state law.

B. To protect the confidentiality and security of vital records and vital reports, access to or disclosure of information contained in vital records for sale or release to the public, for direct or indirect marketing of goods or services, for other non-research solicitation of registrants or families of registrants, or for other commercial or speculative purposes shall not be deemed a proper purpose.

304. Disclosure of Information from Vital Records or Vital Reports for Health Research

A. Each request for vital records and reports data to be used for health research purposes shall be submitted in accordance with the data release protocol developed by the Department.

B. The Data Release Protocol shall:

(1) require the requestor to sign a data release agreement;

(2) prohibit the re-release of any information, unless specifically allowed in the data release agreement;

(3) restrict use of the data for the specified purpose; and

(4) specify that ownership of vital records and vital report data provided under the data release agreement remains with the Bureau of Vital Statistics.

C. To insure the confidentiality of registrants, health care facilities, and health care professionals, certain data elements shall be classified as Restricted, Confidential, or Never Releasable data elements.

(1) Restricted data are those data elements that require approval for release pursuant to the Data Release Protocol. Elements include, but are not limited to, health care facility identifiers, health care professional identifiers, patient medical record number or chart number, and state file number.

(2) Confidential data elements are those that shall be released only if authorized by law and include, but are not limited to, name and address.

(3) Never releasable data elements are those that may be used for statistical linking purposes only. Elements include, but are not limited to, social security number, and any other personal identifying information protected from release by law. All identifiers may be released back to the entity providing the data.

D. Other data elements not specified in Section 304C, shall be considered restricted data and shall be subject to the Data Release Protocol.

SECTION 400 - RECORDS AND REPORTS

401. Forms, Records, Reports, Electronic Data Files

All forms, records, electronic data files, reports, and supporting documentation used in the system of vital statistics are the property of the Department and shall be surrendered upon demand. The forms prescribed and distributed by the State Registrar for reporting vital events shall be used only for official purposes. Only those forms, including worksheets used in the preparation of records or reports, furnished or approved by the State Registrar shall be used for the submission of records and reports or in certifications thereof. Electronic data records will be accepted only when standards set by the State Registrar are met. Only computer programs specified and provided or otherwise authorized by the State Registrar shall be used for the submission of records and reports.

402. Requirements for Preparation of Records and Reports

A. All individuals preparing, submitting or certifying a vital event shall be trained or approved by the Bureau of Vital Statistics.

B. All forms, records, and reports relating to vital events must either be computer printed, typewritten or printed legibly in black, unfading ink, or generated using electronic media approved by the State Registrar.

C. All signatures required shall be either electronic or entered in black, unfading ink.

D. Unless otherwise directed by the State Registrar, a report shall only be acceptable for registration when it:

- (1) contains the certifier's name computer printed, typed, or printed legibly;
- (2) supplies all items of information or satisfactorily accounts for their omission;
- (3) does not contain alterations or erasures;
- (4) does not interfere with document imaging;
- (5) contains signatures as required;
- (6) has no marks or flags such as "copy" or "duplicate";
- (7) is an original;
- (8) is prepared on proper form;
- (9) does not contain improper or inconsistent data;

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(10) does not contain an indefinite cause of death which denotes only symptoms of disease or conditions resulting from disease;

(11) is prepared in conformity with regulations or instructions issued by the State Registrar;

(12) does not contain false information.

403. Persons Required to Retain Documentation

A. Every person in charge of an institution shall retain documentation of personal data as required for the reports of live birth, death, fetal death or induced termination of pregnancy required by this regulation. The documentation shall include information provided by the person being admitted or confined, but when it cannot be so obtained, the information shall be obtained from relatives or other persons acquainted with the facts. The name and address of the person providing the information shall be a part of the documentation.

B. Any licensed health care provider shall retain documentation of personal data concerning each person under the provider's care for a condition that results in a reportable vital event when such documentation is not maintained by an institution described in Section 403A. The documentation shall include such information as required for the provider to submit a report of live birth, death, fetal death or induced termination of pregnancy required by this regulation. The documentation shall include information provided by the person being treated. If the person being treated cannot provide the information, then the licensed health care provider shall obtain the information from relatives or other persons acquainted with the facts. The name and address of the person providing the information shall be a part of the documentation.

C. When a dead body or fetus is released or disposed of by an institution, the person in charge of the institution shall retain documentation showing the name of the decedent, date of death, name and address of the person to whom the body or fetus is released, and the date of removal from the institution. If final disposition is made by the institution, the date, place, and manner of disposition shall also be documented.

D. A funeral director, embalmer, or other person who removes from the place of death, transports, or makes final disposition of a dead body or fetus, in addition to filing any record or other report required by law or regulations, shall retain documentation which shall identify the body, and the following information pertaining to his or her receipt, removal, delivery, burial, or cremation of such body:

(1) The date, place, and time of receipt;

(2) The date, place, and manner of disposition;

(3) If the dead body or fetus is delivered to another funeral director, the date of such delivery and the name and address of the funeral director to whom delivered; and

(4) The demographic and personal data collected from the informant as required by the report of death for those deaths for which the funeral director was required to register the report.

E. Documentation maintained under this section shall be retained for a period of not less than 10 years and shall be made available for inspection by the State Registrar or his or her representative upon demand.

404. Duties to Furnish Information

A. Upon demand of the State Registrar, any person having knowledge of the facts shall furnish such information as he or she may possess regarding any live birth, death, fetal death, induced termination of pregnancy, marriage, or divorce or annulment. Any person required to report shall provide to the State Registrar

information that was required to be reported, but that was not so reported, within five calendar days of that person receiving that information.

B. Within five calendar days of receipt of any autopsy results or other information that would provide pending or missing information or correct errors in a reported cause of death, the physician, medical examiner, or coroner required to report the death shall register a supplemental report of the cause of death to amend the record.

405. Content of Vital Records and Vital Reports

A. In order to promote and maintain nationwide uniformity in the system of vital statistics, the forms of vital records and vital reports required by law, or by regulations, shall include as a minimum the items recommended by the National Center for Health Statistics or its successor agency.

B. Each vital record, vital report, and other document required by this regulation shall be prepared in the format approved by the State Registrar.

C. All vital records and vital reports shall contain the date of registration.

D. Information required in forms, vital records, or vital reports authorized by this regulation may be submitted, verified, registered, and stored by photographic, electronic, or other means as prescribed by the State Registrar.

SECTION 500 - LIVE BIRTH REGISTRATION

501. General

A. A report of live birth for each live birth which occurs in this State shall be submitted to the Bureau of Vital Statistics, or as otherwise directed by the State Registrar, within five calendar days after such live birth and shall be registered if it has been completed and submitted in accordance with this section.

B. The physician, institution, or other person providing prenatal care shall provide the prenatal care information required for the report to the institution where the delivery is expected to occur not less than 30 calendar days prior to the expected delivery date. Any subsequent prenatal care information shall be submitted to the institution prior to submission of report of live birth.

C. When a live birth occurs in an institution or en route thereto, the person in charge of the institution or his or her authorized designee shall obtain all data required by the State Registrar, prepare the report, certify that the child was born alive at the place and time and on the date stated either by signature or by an approved electronic process, and submit the report within the required five calendar days.

D. In obtaining the information required for the report, all institutions shall use information gathering procedures, including worksheets, provided or approved by the State Registrar. Institutions may establish procedures to transfer, electronically or otherwise, information required for the report from other systems. Such procedures shall be reviewed and approved by the State Registrar prior to implementation to ensure that the information being transferred is the same as that being requested for the report.

E. When a live birth occurs outside an institution:

(1) the information for the report of live birth shall be submitted in the format specified by the State Registrar and in the following order of priority within five calendar days of the live birth by:

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(a) the medical institution at which the mother and child are examined within five calendar days of the live birth; or

(b) a licensed midwife or physician in attendance at the live birth; or

(c) the mother with documentary evidence as described in Section 502; or

(d) the Coroner in cases where investigation is required.

(2) an order from the Family Court in this State shall be required to register a live birth when the report submitted does not include the minimum acceptable documentation required in the regulations or the State Registrar has cause to question the validity or adequacy of the documentary evidence.

F. When a live birth occurs on a moving conveyance within the United States and the child is first removed from the conveyance in this State, the live birth shall be registered in this State and the place where it is first removed shall be considered the place of live birth. When a live birth occurs on a moving conveyance while in international waters or air space or in a foreign country or its air space and the child is first removed from the conveyance in this State, the live birth shall be registered in this State, but the report shall show the actual place of live birth insofar as can be determined.

G. For purposes of live birth registration and maternity determination:

(1) The woman who gives live birth to the child shall be recorded as the birth mother and the information required by the report of live birth shall be that of the birth mother;

(2) Thereafter, a court of competent jurisdiction may determine that a woman other than the live birth mother is the biological or genetic mother and order that the original live birth record be so amended. The original live birth record shall then be placed under seal.

H. For the purposes of live birth registration and paternity determination:

(1) If the mother was married at the time of either conception or live birth, or between conception and live birth, the name of the husband shall be entered on the report as the father of the child.

(2) If the mother was not married at the time of either conception or live birth or between conception and live birth, the name of the father shall not be entered on the report without an acknowledgment of paternity as prescribed by State law and signed by the mother and the person to be named as the father. The acknowledgment shall be filed with the State Registrar.

(3) If the father is not named on the report of live birth, non-identifiable information about the father may not be entered on the report.

(4) Thereafter, paternity of a child may be determined by a court of competent jurisdiction pursuant to South Carolina law. The name of the father and surname of the child shall be entered on the report of live birth in accordance with the finding of the court when a valid court order is submitted to the Bureau of Vital Statistics. The original live birth record shall then be placed under seal.

I. The birth mother of the child shall verify the accuracy of the personal data to be entered on the report to permit the submission of the report within the five calendar days as prescribed in Section 501A.

(1) If the mother is incapacitated or deceased, the legal father or other informant as determined appropriate by the State Registrar shall provide and verify the accuracy of the information.

(2) If the mother or other informant does not verify the accuracy of the personal data entered within the prescribed five days, the report of live birth shall be filed without verification.

J. Reports of live birth submitted after five calendar days, but within one year from the date of live birth shall be registered in the standard format of live birth reports in the manner prescribed above. Such reports shall not be marked or flagged "Delayed."

K. The State Registrar may require additional evidence in support of the facts of live birth.

502. Out-of-Institution Live Birth

A. When a live birth occurs in this State outside of an institution, and there is found to be no live birth registration and the report of live birth is to be registered before the first birthday, additional evidence in support of the facts of live birth may be required.

B. For an unattended birth when the mother is responsible for submitting the report of live birth, the following documentary evidence is required.

- (1) Evidence of pregnancy;
- (2) Evidence that the infant was born alive;
- (3) Evidence of the mother's presence in this State on the date of the live birth;

C. When the State Registrar has cause to question the validity or adequacy of the documentary evidence submitted for an out of institution live birth, the report of live birth shall not be registered without an order from the Family Court establishing the facts of birth.

503. Infants of Unknown Parentage; Foundling Registration

A. When an infant up to 30 days of age and of unknown parentage is brought to an emergency room or admitted to an institution, the person in charge of the institution shall submit the report of live birth within five calendar days to the Bureau of Vital Statistics with the following information:

- (1) The date and city and/or county of finding;
- (2) Sex and approximate live birth date of child as determined by a physician or licensed health care provider;
- (3) Name and address of the person or institution submitting this report;
- (4) Name given to the child by the custodian of the child, if applicable;
- (5) Other data required by the State Registrar.

B. The place where the child was found shall be entered as the place of live birth.

C. Information submitted under this section shall constitute the basis for the report of live birth for the child.

D. The report for an infant of unknown parentage shall be registered in the current format for live births and shall:

- (1) have foundling plainly marked or flagged on the report;

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- (2) show the required facts as determined by approximation and have parentage data left blank;
- (3) show the name and title of the person or institution submitting the report under section 503A.

E. If the child is identified and a live birth registration is found or obtained, the report submitted under this Section and any live birth registration resulting from that report shall be voided and placed in a sealed file and shall not be subject to inspection except upon order of the Family Court or by the State Registrar for purposes of administering the vital statistics program.

F. When an infant over 30 days of age and of unknown parentage is found, a court order shall be required to file a report of live birth. The court order shall establish the facts of birth in Section 503A.

SECTION 600 – DELAYED REGISTRATION OF BIRTHS

601. General

A. The following minimum facts must be established by documentary evidence:

- (1) the full name of the person at the time of live birth;
- (2) the date of live birth;
- (3) live birth in South Carolina;
- (4) the full name of the mother prior to first marriage;

(5) the full name of the father if parents were married at the time of birth. Otherwise, the name of the father shall not be entered on the delayed certificate unless the child has been adopted or legitimated, or paternity has been determined by the court or a paternity acknowledgment accompanies the establishment of the delayed certificate.

B. All delayed births are to be filed on a special “delayed certificate of birth” form adopted by the State Registrar.

C. Each delayed certificate of birth shall be signed by the person whose birth is to be filed if of legal age and is competent to swear to the accuracy of the facts stated therein; otherwise, the certificate shall be signed by a parent or legal guardian.

602. Documentary Evidence Requirements

To be acceptable for registration, the name of the person at the time of the live birth and the date and place of live birth entered on a delayed registration of live birth shall be supported by at least:

A. Three pieces of acceptable documentary evidence that will establish to the satisfaction of the State Registrar the facts and date of live birth as alleged in the application;

B. Facts of parentage shall be supported by at least one document.

603. Documentary Evidence Acceptability

A. The acceptability of all documentary evidence submitted shall be determined by the State Registrar.

B. Documents must be from independent sources and shall be in the form of the original record or a duly certified copy thereof or a signed statement from the custodian of the record or document.

C. All documents submitted in evidence:

(1) For persons more than ten years of age must have been established at least ten years prior to the date of application;

(2) For persons ten years of age or younger must be dated at least one year prior to the date of application or within the first year of life;

(3) Shall not be contradictory.

D. When the State Registrar finds reason to question the validity or adequacy of any evidence submitted, he or she may reject the evidence and advise the applicant of the reasons for this action.

604. Abstraction of Documentary Evidence

A. The State Registrar or his or her designated representative shall abstract on the delayed registration of live birth a description of each document submitted to support the facts. This description shall include:

(1) the title or description of the document;

(2) the name and address of the custodial organization;

(3) the creation date of the original document;

(4) all live birth facts required by Section 601 contained in each document accepted as evidence.

B. Original documents submitted in support of the delayed live birth registration shall be returned to the applicant after review. Copies of all accepted documents shall be maintained by the State Registrar.

605. Verification by the State Registrar

The State Registrar, or his or her designated representative, shall verify:

A. That no prior report of live birth is registered in this State for the person whose live birth is to be recorded;

B. That he or she has reviewed the evidence submitted to establish the facts of live birth;

C. That the abstract of the evidence appearing on the delayed record of live birth accurately reflects the nature and content of the document.

606. Dismissal After One Year

An application for a delayed registration of live birth that has not been completed within one year from the date of application may be dismissed at the discretion of the State Registrar. Upon dismissal, the State Registrar shall so advise the applicant and documents submitted in support of such application shall be returned to the applicant.

607. Delayed Birth Records Amended by Court Order

A live birth originally registered as a delayed live birth shall remain in the delayed registration format, regardless of subsequent legal change of status or amendment. The amended certificate will clearly indicate the information

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changed by court order and be marked as amended by court order. Any certification of such record shall contain a summary of the court order submitted to substantiate the amended delayed registration.

SECTION 700 – DEATH REGISTRATION

701. General

A. A report of death for each death which occurs in this State shall be submitted to the Bureau of Vital Statistics, or as otherwise directed by the State Registrar, within five calendar days after death or the finding of a dead body and prior to final disposition, and shall be registered if it has been completed and submitted in accordance with this section.

(1) If the place of death is unknown but the dead body is found in this State, the report of death shall be completed and submitted in accordance with this section. The place where the body is found shall be noted as the place of death.

(2) When death occurs in a moving conveyance within the United States and the body is first removed from the conveyance in this State, the death shall be registered in this State and the place where it is first removed shall be deemed the place of death. When a death occurs on a moving conveyance while in international waters or air space or in a foreign country or its air space and body is first removed from the conveyance in this State, the death shall be registered in this State, but the report shall show the actual place of death insofar as can be determined.

(3) If the date of death is unknown, the medical certifier shall determine the date by approximation. If the date cannot be determined by approximation, the date found shall be entered and identified as date found.

B. The funeral director or person acting as such who first assumes custody of the dead body shall submit the report of death to the Bureau of Vital Statistics. In cases where there is no funeral director or person acting as such, the coroner shall submit the report of death.

(1) He or she shall obtain the personal data from the next of kin or the best qualified person or source available and shall obtain the medical certification from the person responsible therefore.

(2) The funeral director or person acting as such shall provide the report of death containing sufficient information to identify the decedent to the medical certifier within 48 hours after death unless the medical certification has already been submitted.

C. When a death is presumed to have occurred within this State but the body cannot be located, a death certificate may be prepared by the State Registrar upon receipt of an order of a court of competent jurisdiction, which shall include the finding of facts required to complete the death record. Such a death record shall be marked “presumptive” and shall show on its face the date of filing and shall identify the court and the date of the decree.

D. When a death occurring in this State has not been registered as prescribed by this Section, a report of death may be submitted to the State Registrar using the current format of the report of death provided the physician at the time of death or the medical examiner or coroner and the funeral director or person acting as such are available to complete the report of death. If the physician at the time of death, county coroner or medical examiner and the funeral director or person acting as such are unavailable or decline then the death shall not be registered except upon receipt of an order from a court with competent jurisdiction over the Department. If the report of death is submitted more than one year after the date of death, the record shall be marked as “delayed” and any certified copy shall be marked as such.

E. In obtaining the information required for the report, funeral directors or persons acting as such shall use information gathering procedures, including worksheets, provided or approved by the State Registrar. Physicians, coroners or institutions may establish procedures to transfer, electronically or otherwise, information required for the medical certification from other systems. Such procedures shall be reviewed and approved by the State Registrar prior to implementation to ensure that the information being transferred is the same as that being requested for the report.

702. Judicial Procedures to Register a Death

A death may be registered by the State Registrar, upon receipt of an order of a court of competent jurisdiction within this state.

A. The court order to establish a death record shall include all of the following information:

- (1) decedent’s legal name (first, middle, surname and suffix, if any);
- (2) date of death as determined from the evidence presented;
- (3) place of death, including county, as determined from the evidence presented;
- (4) decedent’s date of live birth, State or country of live birth, sex and parent(s) name(s) prior to first marriage;
- (5) decedent’s residence, including county and State, at time of death;
- (6) decedent’s marital status at time of death;
- (7) name, prior to first marriage, of surviving spouse (if any); and
- (8) the information necessary to complete the medical certification including the cause and manner of death. If the death occurred from an injury, information on how and when the injury occurred. If such information is unknown, the order shall indicate such.

B. All certifications issued shall show the date of the court order and the name of the court issuing that order.

C. If the death was registered pursuant to Section 701C the record shall be marked or flagged “Presumptive.”

SECTION 800 – FETAL DEATH REGISTRATION

801. General

A. A report of each fetal death of 350 grams or more, or if weight is unknown, of 20 completed weeks gestation or more, based on clinical estimate of gestation at delivery, which occurs in this State shall be submitted within five calendar days after delivery to the Bureau of Vital Statistics or as otherwise directed by the State Registrar and shall be registered if it has been completed and submitted in accordance with this Section. All induced terminations of pregnancy shall be reported in the manner prescribed in Section 1000 and shall not be reported as fetal deaths.

B. When a fetus is delivered in an institution or en route thereto, the person in charge of the institution or his or her designated representative shall obtain all data required by the State Registrar to prepare and submit the report. In obtaining the information required by the fetal death report, all institutions shall use information gathering procedures including worksheets provided or approved by the State Registrar. Institutions may establish procedures to transfer, electronically or otherwise, information required by the fetal death report from

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other systems. Such procedures shall be reviewed and approved by the State Registrar prior to implementation to ensure that the information being transferred is the same as that being requested on the fetal death report.

C. When a fetus is delivered outside an institution, the physician in attendance at or immediately after delivery shall prepare and submit the report.

D. When a fetal death required to be reported by this Section occurs without medical attendance at or immediately after the delivery or when inquiry is required by state law, the coroner shall investigate the cause of fetal death and shall prepare and submit the report within five calendar days.

E. If the cause of fetal death is unknown or pending investigation, the cause of fetal death shall be noted as such on the report.

F. When a fetal death occurs in a moving conveyance and the fetus is first removed from the conveyance in this State or when a fetus is found in this State and the place of fetal death is unknown, the fetal death shall be reported in this State. The place where the fetus was first removed from the conveyance or the fetus was found shall be considered the place of fetal death.

G. Reports of fetal death are statistical reports to be used only for public health purposes. Such reports shall be disposed of when all statistical processing of the reports has been accomplished. However, the State Registrar may establish a data file of such reports so they will be available for future research and such file may be retained for as long as the State Registrar deems necessary.

SECTION 900 – DISPOSITION AND TRANSPORTATION OF HUMAN REMAINS

901. Permits Governing the Disposal or Transportation of Dead Human Bodies

A. The subregistrar or the coroner in the county in which the death occurred shall issue a burial-removal-transit permit within forty-eight hours after death.

B. The funeral director, or person acting as such, who first assumes custody of a dead body or fetus shall obtain a burial-removal-transit permit prior to final disposition or removal of the body or fetus from the State.

C. In cases where disposition is handled by an institution or coroner, the subregistrar or coroner shall complete a Burial-Removal-Transit permit with the exception of the funeral home information and signature of the funeral director and shall forward to the Bureau of Vital Statistics no later than forty-eight hours after death.

D. Permits must be submitted by the subregistrar or the coroner to the Bureau of Vital Statistics.

E. A burial-removal-transit permit issued under the law of another state which accompanies a dead body or fetus into this state shall be authority for final disposition of the body or fetus in this State.

902. Removal of Body

Before taking charge of a dead human body or fetus, the funeral director or person acting as such shall:

A. contact the attending physician and receive assurance from him or her that death is from natural causes and that the physician will assume responsibility for certifying to the cause of death; or

B. contact the coroner if the case comes within his or her jurisdiction and receive authorization from him or her to remove the body.

903. Authorization for Disinterment and Reinterment

A. Except as otherwise provided by statute, a permit for disinterment and reinterment of human remains shall be required prior to disinterment of a dead body or fetus.

B. A disinterment permit shall be issued only upon receipt of the form prescribed by the State Registrar signed by the next of kin and the person who is to perform the disinterment or upon receipt of an order of a court of competent jurisdiction directing such disinterment. The permit shall be permission for disinterment, transportation, and reinterment.

C. Human remains deposited in a receiving vault shall not be considered a disinterment when removed from the vault for final disposition.

D. The funeral director to whom the permit is issued shall retain a copy. A copy shall be used during transportation and filed with the sexton or person in charge of the cemetery of reinterment. The funeral director shall return a copy to the Bureau of Vital Statistics showing the date of reinterment.

E. The permit requirement of this section shall not apply to disinterment or reinterment of a dead body or fetus when death occurred before 1915.

904. Disposition of Body or Fetus by Hospital Officials Authorized by Next of Kin

Hospital officials who dispose of bodies of persons or fetuses dead of natural causes, with legal permission of the next of kin and not for hire or profit, are responsible for filing the record of fetal death or of death. In all cases, including a reportable fetal death, a burial-removal-transit permit must be obtained for the disposition of the remains.

SECTION 1000 – REPORTS OF INDUCED TERMINATION OF PREGNANCY

1001. General

A. Each induced termination of pregnancy which occurs in this State, regardless of the length of gestation, shall be reported to the Bureau of Vital Statistics within seven calendar days by the person in charge of the institution in which the induced termination of pregnancy was performed. If the induced termination of pregnancy was performed outside an institution, it shall be reported by the attending medical provider.

B. Reports of induced termination of pregnancy are statistical reports to be used only for public health purposes. Such reports shall be disposed of when all statistical processing of the reports has been accomplished. However, the State Registrar may establish a data file of such reports so they will be available for future research and such file may be retained for as long as the State Registrar deems necessary.

SECTION 1100 – CORRECTION AND AMENDMENT OF VITAL RECORDS

1101. General

A. Live birth records are presumed to contain accurate information on the facts of live birth when they are registered. Live birth records will be amended or corrected only to rectify errors in the facts of live birth, except as provided for in these regulations.

B. A delayed record of live birth placed on file with supporting documentation or by judicial procedure shall not be amended except to reflect changes upon receipt of a certified court order.

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C. Certificates of marriage and reports of divorce must be corrected by the custodian of the official record from which the report was prepared. The custodian shall submit the amended certificate to the Department with a statement listing the items changed and evidence presented to support each item changed. Any corrected records shall be marked amended when issued by the Department.

D. Sealed records shall not be subject to inspection except upon order of the Family Court. The state registrar may inspect such information for purposes of properly administering the vital statistics program.

E. Changes to birth or death records must be requested by a person entitled by law to obtain a certified copy of the record to be amended.

1102. Correction of Birth and Death Records

A. Any certification item on a live birth or death record may be corrected by the Bureau of Vital Statistics within one year of the event if the Bureau of Vital Statistics becomes aware of incorrect information on a record. Any facility or individual responsible for the original submission of data shall assist in the collection of evidence of the error and correct information upon request of the Bureau of Vital Statistics.

B. Correction of items that do not appear on certifications may be made by the Bureau of Vital Statistics upon identification or query.

C. When such corrections are made by the Bureau of Vital Statistics, a notation as to the source of the information, the date the change was made, and the identity of the authorized vital statistics employee making the change shall be made on the record in such a way as not to become a part of any certification issued. Any certified copy shall not be marked as "Amended."

1103. Administrative Amendment of Vital Records

A. Unless otherwise provided in these regulations or in the statute, all administrative amendments to live birth and death records shall be supported by documentary evidence and a notarized affidavit setting forth:

- (1) information to identify the record;
- (2) the items to be amended;
- (3) the incorrect information as it appears; and
- (4) the correct information as it should appear and supported by documentary evidence.

B. To amend a live birth record, an affidavit of correction shall be initiated and signed by the parents, the legal guardian, or the registrant if 18 years of age.

C. To amend personally identifiable information on a death record, an affidavit of correction shall be signed by the informant or, in the case of the death or incapacity of the informant, the next of kin of the deceased.

D. The medical certification items on a death record may only be amended upon receipt of a signed statement or approved electronic notification from the physician or medical examiner, or coroner who originally certified the cause of death. In the absence or inability of the physician, the cause of death may be amended upon receipt of a signed statement or an approved electronic notification from his or her duly authorized medical associate, or the chief medical officer of the institution in which death occurred, or a medical examiner, or coroner who assumes jurisdiction of the case. The State Registrar may require documentary evidence to substantiate the requested amendment.

E. Upon acceptance of the requested amendment by the State Registrar, records of live birth and death shall be amended by the State Registrar by adding the new information to the record in a manner that preserves the existing information for audit purposes.

F. A notation indicating the record was amended shall be shown on certifications of the record. The date of the change and what item was changed shall also be shown on certifications of the record.

1104. Documentary Evidence Required to Amend or Correct Vital Records

A. With the exception of corrections as outlined in Section 1102, or an amendment to the medical certification, one or more items of documentary evidence must be presented that support the alleged facts. All documents presented must contain sufficient information to clearly indicate that they pertain to the registrant on the record for which the amendment or correction has been requested.

(1) Documents presented must be from independent sources. Family documents such as records from bibles or genealogical records are not acceptable.

(2) Documents must be in the form of the original record or must be a duly certified copy or excerpt thereof from the original custodian of the record.

(3) For live birth records, the documents submitted must have been established prior to the registrant's (18th) birthday or at least ten years prior to the date of application for the amendment.

(4) For death records, the documents submitted must have been established at least 10 years prior to death unless otherwise specified by the State Registrar.

B. The State Registrar shall evaluate the evidence submitted in support of any amendment, and when he or she finds reason to doubt its validity or adequacy, the amendment may be rejected and the applicant advised of the reasons for this action.

1105. Addition of Registrant's First or Middle Names on Live Birth Records

A. Until the registrant's first birthday, first or middle names may be added upon receipt of an affidavit signed by the parents named on the record or the legal guardian of the registrant.

B. After one year from the date of live birth, a legal change of name order must be submitted from a court of competent jurisdiction to amend or add a first or middle name.

1106. Date of Birth Amendments to Live Birth Records

A. The date of live birth cannot be corrected to a date that is after the date the live birth record was registered.

B. The date of live birth may be corrected up to 30 calendar days with a certified copy of the record from the hospital of birth or with two supporting documents provided that date is not after the date the live birth record was registered. At least one of the documents must have been created within 90 calendar days of the alleged date of live birth.

C. Other administrative corrections to the date of live birth may be made provided that a minimum of three documents adequately support that the registrant has consistently used the date from childhood and the change does not make the live birth date after the date the live birth record was registered. At least one of the documents must have been created within seven years of the alleged date of live birth. The change cannot be made if that change would conflict with any live birth record registered in the Bureau of Vital Statistics for other children of the same mother.

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1107. Amendments to Death Records

A. When the marital status is shown as married and a surviving spouse is listed on the death record of the decedent then the marital status shall be changed to:

(1) widowed and the spouse removed if a death certification for the spouse is submitted documenting that the spouse died prior to the death of the decedent.

(2) divorced or never married and the spouse removed if a certification of divorce/annulment is submitted documenting that the event occurred prior to the death of the decedent.

B. If the marital status is shown as married and surviving spouse is listed as unknown or is blank on the death record, then a marriage certification must be provided to add the name of the surviving spouse.

C. If the marital status is shown as married and the surviving spouse is listed on the death record then an order from a court of competent jurisdiction will be needed to change that spouse to a different person.

D. When the marital status is shown as divorced, widowed, or never married and no surviving spouse is listed on the death record of the decedent then the marital status shall be amended to married and the surviving spouse added upon receipt of:

(1) a certified copy of a marriage record showing that the person to be listed as surviving spouse was married to the decedent and an affidavit of correction signed by the informant and the alleged surviving spouse; or

(2) an order from a court of competent jurisdiction finding that the person was married to the decedent at the time of the decedent's death.

E. Other changes to marital status and surviving spouse will be made only upon the finding of a court of competent jurisdiction in an order that determined the marital status of the decedent and identifies the surviving spouse, if appropriate.

F. Amendment to other items on the death record:

(1) Signatures shall not be amended.

(2) Other personal and statistical items on the death record shall be amended with supporting documentary evidence that is acceptable to the State Registrar.

1108. Amendment of the Same Item More than Once

Once an amendment of an item is made on a vital record, except for cause and manner of death to be amended by the physician, medical examiner, or coroner or clerical error on the part of the State Registrar, that item shall not be amended again except upon receipt of an order from a court of competent jurisdiction.

1109. Sealed Amendments and Replacement Records of Live Birth

A. The replacement record of live birth prepared pursuant to state law shall be on the form in use at the time of its preparation and shall include the following items and such other information necessary to complete the record of live birth:

(1) the name of the child;

- (2) the date, city, and county of live birth as transcribed from the original report of live birth;
- (3) the names and personal information of the parents after establishment of parentage;
- (4) the State file number assigned to the original record of live birth;
- (5) the original date of registration.

B. The information necessary to locate the existing report of live birth and to complete the replacement report of live birth shall be submitted to the State Registrar on forms prescribed or approved by him or her.

C. After preparation of the replacement record of live birth, the prior record of live birth and the evidence upon which the replacement record of live birth was based are to be placed in a sealed file. Such file shall not be subject to inspection except upon order of the Family Court or by the State Registrar for purposes of properly administering the vital statistics program.

D. With the exception of an adoption of an adult, certifications issued shall not be marked amended.

E. Upon receipt of notice of annulment of adoption, the original certificate of birth shall be restored to its place in the files. The adoptive certificate and evidence shall not be subject to inspection except upon order of the Family Court.

F. If no certificate of birth is on file for the person for whom a replacement record is to be established under this section, a delayed certificate of birth must be filed with the State Registrar before a new record of live birth is established. A delayed certificate of birth shall not be required when the date and place of birth and parentage have been established in an adoption proceeding.

1110. Amendments by Court Order

A. Upon receipt of a certified copy of a court order changing a birth or death record on file in the Bureau of Vital Statistics and upon request of an entitled person, the Bureau of Vital Statistics shall record the changes by completion of a special form. Such form shall include the original information as it appears on the original certificate, the information as changed by the court order, identification of the court which issued the order and the date of the order, and sufficient information about the registrant or decedent to link the special form to the original record.

B. When an electronic certification is issued, the items amended by the court and the date of the amendment must be noted. When a certified copy of the original record is issued, a copy of the special form must be attached.

C. Birth and death records amended by court order shall be marked "Amended by Court Order".

SECTION 1200 – CERTIFICATIONS FROM THE SYSTEM OF VITAL STATISTICS

1201. General

A. A certification of a live birth, death, marriage or report of divorce, or any part thereof, issued in accordance with this Section, shall be considered for all purposes the same as the original and shall be prima facie evidence of the facts stated therein.

B. The applicant for a certification shall be required to submit a signed application, proof of identity, and evidence of entitlement. Upon receipt of an application and before issuing a certification:

- (1) Proof of identity must be acceptable to the Bureau of Vital Statistics.

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(2) Evidence of entitlement must demonstrate that the applicant is qualified to receive a certification.

(3) The Bureau of Vital Statistics may verify with originating agencies the proof of identity documents and evidence of entitlement submitted in support of an application.

C. All certifications of vital records registered in the State system shall be issued from the State's central database.

D. For the purpose of obtaining certified copies of death records on behalf of the deceased's family at the time of registration, a funeral director or person acting as such shall be deemed a legal representative.

E. No certification shall be issued without a first name for the registrant except by subpoena or to a government agency for adoption or custody purposes.

F. Information listed on live birth, death, marriage or divorce records as administrative, statistical, medical, or health use only shall not be included in a certification of the vital record.

G. Verification of the facts contained in a vital record may be furnished by the Bureau of Vital Statistics to any government agency in the conduct of its official duties. The request for verification must:

(1) include the facts of birth and be in a format prescribed or approved by the Bureau of Vital Statistics; or

(2) be submitted electronically through an automated system approved by the Bureau of Vital Statistics if the requester attests to having the certification and can provide the State file number and date of registration.

H. When the Bureau of Vital Statistics receives information that a record may have been registered, corrected or amended through fraud or misrepresentation, he or she may withhold issuance of any certification of that record pending inquiry by appropriate authorities to determine whether fraud or misrepresentation has occurred.

(1) If upon conclusion of the inquiry no fraud or misrepresentation is found, certifications shall be issued upon the request of a qualified applicant.

(2) If upon conclusion of the inquiry there is reasonable cause to suspect fraud or misrepresentation, the Bureau of Vital Statistics shall give the person named in the record notice in writing of his or her intention to void said record or cancel the amendment. The notice shall give such person an opportunity to appear and show cause why the record should not be voided or cancelled. The notice may be served on such person or in the case of a minor, on his or her parent or legal guardian by registered mail to his or her last known address.

(3) Unless such person or his or her parent or legal guardian shall, within thirty days after the date of mailing, show cause why the certificate shall not be voided or amendment cancelled, the record shall be so voided or amendment cancelled.

(4) The voided record or amendment and evidence shall be retained but shall not be subject to inspection or copying except upon order of a court with competent jurisdiction over the Department or by the Bureau of Vital Statistics for purposes of administering the vital statistics program.

I. When the Bureau of Vital Statistics receives information that an application for a certification may have been submitted for purposes of fraud or misrepresentation, he or she may withhold issuance of the certification requested pending inquiry by appropriate authorities to determine whether fraud or misrepresentation has occurred.

(1) If upon conclusion of the inquiry no fraud or misrepresentation is found, certification shall be issued.

(2) If upon conclusion of the inquiry there is reasonable cause to suspect fraud or misrepresentation, the requested certification shall not be issued and the Bureau of Vital Statistics shall provide copies of the application and evidence to appropriate authorities for further investigation.

(3) The application and evidence shall be retained but shall not be subject to inspection or copying except upon order of a court with competent jurisdiction over the Department or by the Bureau of Vital Statistics for purposes of administering the vital statistics program.

J. All applications and supporting documentation submitted for the purpose of issuing certifications of vital records shall be confidential and shall not be released except upon receipt of an order from a South Carolina court of competent jurisdiction.

K. Certifications of vital records may be made by mechanical, electronic, or other reproductive processes.

L. Each certification issued shall be certified as a true representation of the facts on file, the date issued, the state file number, and the registrar’s signature or an authorized facsimile thereof. Each copy issued shall show the date of filing and copies issued from records marked “Delayed”, “Amended” or “Amended by Court Order” shall be similarly marked and show the effective date.

SECTION 1300 - FEES

Fees generated by the following fee schedule shall be retained and expended by the Department to offset the cost of operation of the Vital Records System.

FEE SCHEDULE		
a.	Records Search (includes one certification, if located)	\$ 12.00
b.	Additional Similar Certifications of the Same Record ordered	\$ 3.00
c.	Expedited Service (additional to other required fees)	\$ 5.00
d.	Index Verification for Government Agencies	\$ 2.00
e.	Special Filing Fees (additional to search fee)	
	(1) Correction of certificate by affidavit	\$ 15.00
	(2) Amended certificate (adoption, legitimation court order, paternity acknowledgment)	\$ 15.00
	(3) Delayed Registration of Birth	\$ 15.00
f.	Fees collected at the county health departments for record searches, amendments of records, delayed birth registration and additional copies of the same record requested at the same time shall be distributed as follows: 50% to the county health departments and 50% to the Vital Records Central office. Any fee increase above the State Fiscal Year 1997 fee structure shall be returned to the Vital Records Central office (Office of Public Health Statistics and Information Systems, Division of Vital Records)	

Fiscal Impact Statement:

The amendments have no substantial fiscal or economic impact on the State or its political subdivisions. Implementation of this regulation will not require additional resources beyond those allowed. There is no anticipated additional cost by the Department or State Government due to any inherent requirements of this regulation.

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Statement of Need and Reasonableness:

DESCRIPTION OF REGULATION:

Purpose: The amendments to Regulation 61-19, Vital Statistics, make substantive changes to the reporting of vital events, strengthens the confidentiality and security of the system of vital records in South Carolina, updates terminology and increased uniformity with the national model law and regulations for reporting and certifying vital events.

Legal Authority: The legal authority for Regulation 61-19 is 1976 Code Section 44-63-10 et seq.

Plan for Implementation: The amendments will take effect upon approval by the S.C. General Assembly and publication in the State Register. An electronic copy of Regulation 61-19, which includes these latest amendments, will be published on the Department's Laws and Regulations website. Subsequently, this regulation will be published on the S.C. Legislature Online website in the S.C. Code of Regulations. Printed copies will be made available at cost by request through the DHEC Freedom of Information Office. The Department will also send an email to stakeholders and affected facilities and to other interested parties.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

The Department last updated Regulation 61-19 on June 28, 2002. Regulation 61-19 has not been updated since the Vital Statistics system in South Carolina underwent reengineering to utilize electronic filing of vital reports. Therefore, some of the procedures are outdated and/or are no longer applicable. The amendments improve security and fraud prevention and the protection of confidential information. Amendments are also needed to maintain uniformity in definitions and registration of vital events with the national system of vital statistics.

The amendments are reasonable to realize the above benefits because they provide an efficient procedure without any anticipated cost increase, provide clear standards and criteria for the regulated community, and support Department goals.

DETERMINATION OF COSTS AND BENEFITS:

This program is funded by the collection of fees for making certified copies of vital records and filing a record amendment in accordance with 1976 Code Section 44-63-110 and these regulations. The Code requires that the amount of the fees be established by the DHEC Board. The fee schedule is not being amended at this time except to recodify that section of the regulation to be consistent with the amended sections.

Implementation of these amendments will not require additional resources. There is no anticipated additional cost to the Department or state government or for the regulated community.

UNCERTAINTIES OF ESTIMATES:

There are no uncertainties of estimates relative to the costs to the State or its political subdivisions.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The amendments to Regulation 61-19 seek to support the Department's goals relating to the protection of public health through the anticipated benefits as stated above. There is no anticipated effect on the environment.

DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There is no anticipated detrimental effect on the environment associated with these amendments. If the revision is not implemented, the regulation will be maintained in its current form without realizing the benefits of the amendment herein.

Statement of Rationale:

The Department has amended sections 1 - 42 of Regulation 61-19, Vital Statistics, to improve the quality, security and fraud prevention, protection of confidential information and uniformity of state data by implementing standard reporting requirements, and definitions and procedures for registering vital events as described in the 2011 Model State Vital Statistics Act and Regulations issued by the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS). The National Association of Public Health Statistics and Information Systems has also endorsed the Model Act and Regulations. Registration and certification of vital events is a responsibility of individual States, but States and the CDC NCHS cooperate and work together to build and maintain a national vital records system. Section 43, Fees, is not being amended; only the outline designation is changed. Other revisions were made to improve the overall quality of the regulation pursuant to Legislative Council guidelines for drafting regulations.

Document No. 4595

DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61

Statutory Authority: 1976 Code Sections 13-7-10, 13-7-40 and 13-7-45 et seq.

61-64. X-Rays (Title B).

Synopsis:

R.61-64, X-Rays (Title B), is authorized by the Atomic Energy and Radiation Control Act at S.C. Code Section 13-7-10 et seq. and was last amended on June 26, 2009. This regulation provides for radiation control and applies to all persons who receive, possess, use, transfer, own, or acquire any x-ray producing device. The cost of running the program to implement the provisions of this regulation is partially funded by the collection of fees from the regulated community as mandated by the Act.

As a result of the 2012 statutory five-year review of this regulation and advancing technologies, the Department has determined it necessary to substantially amend R.61-64. The changes herein will strengthen equipment performance standards. Language changes were made to clarify many sections of the regulation by making them more specific, better organized, and the intent of the regulation more clear. The regulations increase the registration fees to allow for the hiring of six additional inspectors. The fee increase will provide funding for the hiring of additional inspectors to increase the frequency of inspections. The last fee increase was in June 2003.

A Notice of Drafting was published in the *State Register* on April 24, 2015.

See Section-by-Section discussion below and the Statement of Need and Reasonableness herein for more detailed information on these amendments.

Section-by-Section Discussion of Revisions:

The table of contents was revised to reflect the amendments.

Part I – General Provisions

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R.61-64 RHB 1.2.4

This subsection was deleted to be consistent with statute.

R.61-64 RHB 1.2.5 through RHB 1.2.12

These subsections were renumbered in alphanumeric order.

R.61-64 RHB 1.2.13

This subsection was renumbered to RHB 1.2.12 and text was added to incorporate 45 CFR 46 as research protocol.

R.61-64 RHB 1.2.14

This subsection was renumbered to RHB 1.2.13 and was revised to correct the reference.

R.61-64 RHB 1.4.4.2.1

This subsection subitem was revised by adding language clarifying the uses of radiation survey instrumentation and requiring all instruments to be calibrated at intervals not to exceed twenty-four (24) months.

R.61-64 RHB 1.4.4.2.2

This subsection subitem was revised by adding an alternative that equipment accuracy be within manufacturer's specifications.

R.61-64 RHB 1.4.4.2.4

This subsection subitem was deleted in its entirety. The requirement is addressed in RHB 1.4.4.2.2. RHB 1.4.4.2.5 was renumbered to RHB 1.4.4.2.4.

R.61-64 RHB 1.4.4.3

This subsection subitem was reworded for clarity concerning survey instrument manufacturer's instructions.

R.61-64 RHB 1.4.4.3.3

This subsection subitem was deleted in its entirety. RHB 1.4.4.3.4 was renumbered to RHB 1.4.4.3.3 and language was deleted for clarity and to remove the requirement for documentation.

R.61-64 RHB 1.4.4.4

This subsection subitem was added to clarify the requirements of instrumentation used in reference to Part VI. Text was also revised requiring dosimetry systems as referenced in Part VI to be calibrated within 24 months.

R.61-64 RHB 1.4.4.4.1 through RHB 1.4.4.4.3

Text from these subsection subitems was moved from RHB 6.6.3.3.1 through RHB 6.6.3.3.3 for reference purposes.

R.61-64 RHB 1.6.3

This subsection was revised to clarify the information required for the Department to review a request to operate equipment not currently covered in the regulations. This grants the Department and the South Carolina Technical Advisory Radiation Control Council the ability to research and evaluate potentially hazardous radiation equipment prior to the equipment being sold and used in the State of South Carolina. It also addresses that guidance documents can be found on the Department's website.

R.61-64 RHB 1.7.2

This subsection was revised to clarify the deadlines for corrective action plans for violations.

R.61-64 RHB 1.7.2.1

This subsection subitem was added to delineate requirements for corrective action plans for mammography inspections.

R.61-64 RHB 1.7.2.1.1

This subsection subitem was added to delineate requirements for corrective action plans for mammography inspections.

R.61-64 RHB 1.7.2.1.2

This subsection subitem was added to delineate requirements for corrective action plans for mammography inspections.

R.61-64 RHB 1.7.2.2

This subsection subitem was added to delineate requirements for corrective action plans for other x-ray modality violations.

R.61-64 RHB 1.7.2.2.1

This subsection subitem was moved from RHB 1.7.2 to delineate requirements for corrective action plans for other x-ray modality violations.

R.61-64 RHB 1.7.3

This subsection subitem was renumbered to RHB 1.7.2.2.2.

R.61-64 RHB 1.7.4 through RHB 1.7.5

These subsections were renumbered to RHB 1.7.3 through RHB 1.7.4.

R.61-64 RHB 1.10.2.4

This subsection subitem was revised to allow registrants no longer possessing equipment to discard records specific to the regulation.

R.61-64 RHB 1.11.3

This subsection was revised to delete the requirement to send a patient's social security number to the Department when reporting a misadministration. The numerical values of 10 and 3 were added to denote and clarify years.

R.61-64 RHB 1.13.4.2

The numerical value of \$25,000.00 was added for clarity.

R.61-64 RHB 1.13.4.4

This subsection subitem was revised to change operating procedures to operating conditions.

Part II – Registration of X-Ray Machines and Services

R.61-64 RHB 2.4.1.1.4

This subsection subitem was deleted in its entirety.

R.61-64 RHB 2.4.1.1.5

This subsection subitem was deleted in its entirety. RHB 2.4.1.1.6 was renumbered to RHB 2.4.1.1.4. RHB 2.4.1.1.7 was renumbered to RHB 2.4.1.1.5.

R.61-64 RHB 2.4.2.1.4

This subsection subitem was deleted in its entirety.

R.61-64 RHB 2.4.2.1.5

This subsection subitem was deleted in its entirety. RHB 2.4.2.1.6 was renumbered to RHB 2.4.2.1.4.

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R.61-64 RHB 2.4.2.1.7

This subsection subitem was renumbered to RHB 2.4.2.1.5 and revised for clarity. RHB 2.4.2.1.8 was renumbered to RHB 2.4.2.1.6.

R.61-64 RHB 2.4.3.1.4

This subsection subitem was deleted in its entirety.

R.61-64 RHB 2.4.3.1.5

This subsection subitem was deleted in its entirety. RHB 2.4.3.1.6 was renumbered to RHB 2.4.3.1.4.

R.61-64 RHB 2.4.4

This subsection was added to address the requirements for Out of State Facilities.

R.61-64 RHB 2.4.4.1

This subsection subitem was added to indicate the information which must be submitted to the Department prior to an Out of State Facility entering the state.

R.61-64 RHB 2.4.4.1.1

This subsection subitem was added to require the submission of the Out of State Facility name and address.

R.61-64 RHB 2.4.4.1.2

This subsection subitem was added to require the submission of the name of the Radiation Safety Officer.

R.61-64 RHB 2.4.4.1.3

This subsection subitem was added to require the submission of the type and make of x-ray equipment to be utilized.

R.61-64 RHB 2.4.4.1.4

This subsection subitem was added to require the submission of a radiation area survey as required by RHB 4.4 or 8.12.2.

R.61-64 RHB 2.4.4.2

This subsection subitem was added to require the submission of an operating schedule indicating when and where the equipment will be used.

R.61-64 RHB 2.4.4

This subsection was renumbered to RHB 2.4.5.

R.61-64 RHB 2.5.1

This subsection was revised for clarity in the event that the form number could change.

R.61-64 RHB 2.6.2

This subsection was revised for clarity in the event that the form number could change.

R.61-64 RHB 2.6.4.1

This subsection subitem was revised to include the class number.

R.61-64 RHB 2.6.4.2

This subsection subitem was revised to include the class number.

R.61-64 RHB 2.6.4.2.1

This subsection subitem was added for clarity and to include the breakdown for Class II vendors.

R.61-64 RHB 2.6.4.2.2

This subsection subitem was added for clarity and to include the breakdown for Class II vendors.

R.61-64 RHB 2.6.4.2.3

This subsection subitem was added for clarity and to include the breakdown for Class II vendors.

R.61-64 RHB 2.6.4.3

This subsection subitem was revised for clarity.

R.61-64 RHB 2.6.4.4

This subsection subitem was revised to include the class number.

R.61-64 RHB 2.6.4.5

This subsection subitem was revised to include the class number.

R.61-64 RHB 2.6.4.6

This subsection subitem was revised to include the class number.

R.61-64 RHB 2.6.4.7

This subsection subitem was revised to include the class number.

R.61-64 RHB 2.6.4.8

This subsection subitem was revised to remove the personnel dosimeter service class and to add the general health physics consulting, non-healing arts class.

R.61-64 RHB 2.6.4.9

This subsection subitem was revised to include the class number and to clarify this class is general health physics consulting, healing-arts and to add the services of equipment performance tests and acting as the radiation safety officer.

R.61-64 RHB 2.6.5

This subsection was revised for clarity in the event that the form number could change.

R.61-64 RHB 2.6.6.2

This subsection subitem was revised to include the breakdown for Class II vendors.

R.61-64 RHB 2.6.6.2.1

This subsection subitem was revised to require that the training must be documented.

R.61-64 RHB 2.6.6.2.3

This subsection subitem was revised to streamline the training requirement and to include training on testing of equipment.

R.61-64 RHB 2.6.6.7.2.1

This subsection subitem was revised to add the word “and” for clarity.

R.61-64 RHB 2.6.6.8

This subsection subitem was revised to remove the personnel dosimeter service class and to add the general health physics consulting, non-healing arts class.

R.61-64 RHB 2.6.6.8.1 through RHB 2.6.6.8.4

These subsections were added to include the training requirements for vendor Class VIII.

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R.61-64 RHB 2.6.6.9

This subsection subitem was revised to clarify that this class is for healing arts and to include equipment performance tests and acting as the radiation safety officer.

R.61-64 RHB 2.6.6.9.4

This subsection subitem was added to address the training requirements, as applicable, determined by the equipment type. Language was also added to clarify the time frame for compliance with the training requirements.

R.61-64 RHB 2.6.6.11 through 2.6.6.12

These subsections subitems were deleted in their entirety. These regulations are no longer applicable as these time-frames have since passed.

R.61-64 RHB 2.6.8

This subsection was deleted to be consistent with statute.

R.61-64 RHB 2.7.1.4

This subsection subitem was revised for clarity in the event that the form number could change.

R.61-64 RHB 2.7.2

This subsection was revised for clarity regarding vendor actions.

R.61-64 RHB 2.7.2.1

This subsection subitem was added to address vendors acting as the radiation safety officer at a registered x-ray facility.

R.61-64 RHB 2.7.3.6.5

This subsection subitem did not merit the necessity to have it in place and therefore it has been deleted in its entirety.

R.61-64 RHB 2.7.3.6.6

This subsection subitem was renumbered to RHB 2.7.3.6.5 and also revised to include additional information on the equipment performance test report.

R.61-64 RHB 2.7.5

This subsection was revised. The requirement changed is addressed in RHB 1.4.4.

R.61-64 RHB 2.7.5.1 through RHB 2.7.5.3

These subsection subitems were deleted in their entirety. These requirements are addressed in RHB 1.4.4.

R.61-64 RHB 2.8.2

This subsection was added to require out of state facilities to meet all applicable parts of this regulation.

R.61-64 RHB 2.9.3

This subsection was deleted in its entirety due to the fact that R.61-72 is no longer effective. R.61-72 will be removed from the code of regulations relatively soon.

R.61-64 RHB 2.9.4 through RHB 2.9.6

These subsections and subitems were renumbered in alphanumeric order.

R.61-64 RHB 2.10.6

This section was revised to modify the fee structure. In order to subsidize hiring of six additional inspectors to increase frequency of inspections, the regulation increases registration fees by \$31.

Part III – Standards for Protection Against Radiation

R.61-64 RHB 3.12.3

The title of this subsection was revised for clarity.

R.61-64 RHB 3.12.3.1

This subsection subitem was revised for clarity.

R.61-64 RHB 3.12.3.1.1

This subsection subitem was revised for clarity to include the assigning of a personal monitoring badge.

R.61-64 RHB 3.12.3.1.2

This subsection subitem was revised. The word “and” was added to ensure that when a lead apron is worn, the personnel monitoring device(s) would be worn correctly.

R.61-64 RHB 3.12.3.1.3

This subsection subitem was revised. The word “and” was added to ensure that the registrant understands all of the requirements for personnel monitoring device(s).

R.61-64 RHB 3.12.3.1.4

This subsection subitem was added to ensure that personnel monitoring devices are returned within 45 days of the end of the monitoring period and the results for the direct read dosimeters are read and recorded based on the manufacturer’s specifications.

R.61-64 RHB 3.12.3.1.5

This subsection subitem was added to ensure that documentation and explanation for any late, absent, or unused personnel monitoring devices is recorded.

R.61-64 RHB 3.12.3.1.6

This subsection subitem was added to ensure that personnel monitoring devices are worn in accordance with manufacturer guidelines.

R.61-64 RHB 3.12.4.1.3

This subsection subitem was revised to bring the requirement in line with the Conference of Radiation Control Program Directors Suggested State Regulations.

R.61-64 RHB 3.12.4.1.3.1

This subsection subitem was revised to bring the requirement in line with the Conference of Radiation Control Program Directors Suggested State Regulations.

R.61-64 RHB 3.12.4.1.4

This subsection subitem was deleted based on limited scientific evidence that a personnel monitoring badge would be required for individuals who hold patients or film during x-ray examinations more than three times a quarter.

R.61-64 RHB 3.12.4.1.5

This subsection subitem was deleted based on limited scientific evidence that individuals who operate mobile, portable, or peripheral bone densitometers exceed 10% of their maximum permissible dose.

R.61-64 RHB 3.12.4.1.6

This subsection subitem was renumbered to 3.12.4.1.4.

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R.61-64 RHB 3.12.5.2

This subsection subitem was revised to allow the Radiation Safety Officer to make the determination of what employees at the facility could participate in the personnel monitoring Effective Dose Equivalent Program and to ensure that personnel on the Effective Dose Equivalent Program are meeting the requirements outlined in subsection 3.12.5.

R.61-64 RHB 3.12.5.2.1

This subsection subitem was revised to ensure that the Radiation Safety Officer or other responsible person(s) reviews the documentation indicating that the x-ray protective equipment is being used.

R.61-64 RHB 3.12.5.2.2

This subsection subitem was revised to address periodic visits and documentation of these visits must be made by the Radiation Safety Officer or designee. The visits are to observe for adherence to proper radiation safety practices.

R.61-64 RHB 3.12.5.2.3

This subsection subitem was revised to clarify the fact that in the event that a violation of RHB 3.12.5 occurs, the Department has the authority to revoke the use of the Effective Dose Equivalency.

R.61-64 RHB 3.12.5.3

This subsection subitem was revised to give authority to the Radiation Safety Officer to determine any changes to the dose of permanent record. Language was added to require records of these actions for Departmental review.

R.61-64 RHB 3.18.2

This subsection was revised to decrease record retention from 5 years to 3 years.

R.61-64 RHB 3.19.2

This subsection addresses record retention pertaining to surveys and calibrations at the facility and was revised for clarity.

R.61-64 RHB 3.20.3.2

This subsection subitem was deleted in its entirety because there are no longer lifetime radiation exposure limits for occupationally exposed individuals.

R.61-64 RHB 3.20.3.3

This subsection subitem was renumbered to RHB 3.20.3.2 and revised to include the acceptance of the use of electronic means to report the individual's dose record.

R.61-64 RHB 3.20.4

This subsection subitem was renumbered to RHB 3.20.3 and revised since R.61-64 address x-ray radiation, this subsection was revised to delete "radioactive material." The requirement for the individual to sign was also deleted.

R.61-64 RHB 3.20.5 through 3.20.5.2

These subsection subitems were renumbered to RHB 3.20.4 through RHB 3.20.4.2.

R.61-64 RHB 3.20.6

This subsection was renumbered to RHB 3.20.5 and revised for clarity.

R.61-64 RHB 3.25.2.2

This subsection subitem was revised to delete the Social Security account number for reporting of individuals who may exceed radiation dose limits.

Part IV – Use of X-Ray in the Health Professions

R.61-64 RHB 4.2.2.6

This subsection subitem was revised to clarify requirements for posting SCRQSA certificates.

R.61-64 RHB 4.2.2.7

This subsection subitem was revised to change operating procedures to operating conditions.

R.61-64 RHB 4.2.3

This subsection was revised to require operators to demonstrate familiarity and competence with the facility's operating conditions. Operating procedures were deleted from this part.

R.61-64 RHB 4.2.3.1 through 4.2.3.7

These subsection subitems were deleted for consistency since operating procedures were deleted from the regulations.

R.61-64 RHB 4.2.6

This subsection was revised to require a technique chart for general radiographic systems not equipped with an operational anatomic programming option.

R.61-64 RHB 4.2.9.2

This subsection subitem was revised to allow the facility to use 0.25 mm lead equivalent aprons in lieu of the 0.5 mm lead equivalent aprons.

R.61-64 RHB 4.2.9.3

This subsection subitem was revised to clarify conditions of whole body protective barriers and to allow the facility to use 0.25 mm lead equivalent aprons in lieu of the 0.5 mm lead equivalent aprons.

R.61-64 RHB 4.2.9.4

This subsection was revised to correct the reference.

R.61-64 RHB 4.2.10

This subsection was revised to clarify conditions of shielding patients during x-ray procedures.

R.61-64 RHB 4.2.12.2

This subsection subitem was revised to delete statement pertaining to operating procedures.

R.61-64 RHB 4.2.12.6

This subsection subitem was revised to reword "should" to "shall."

R.61-64 RHB 4.2.13

This subsection was revised for clarity.

R.61-64 RHB 4.2.13.2

This subsection subitem was revised to reword "should" to "shall."

R.61-64 RHB 4.2.13.3

This subsection subitem was revised to add language that excludes handheld x-ray units from this requirement.

R.61-64 RHB 4.2.14.4

This subsection subitem was deleted in its entirety to bring the Regulation in line with the Conference of Radiation Control Program Directors Suggested State Regulations.

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R.61-64 RHB 4.2.15.2

This subsection subitem was deleted in its entirety removing the requirement regarding recording human holders in the log book.

R.61-64 RHB 4.2.15.3 through RHB 4.2.15.5

These subsection subitems were renumbered to RHB 4.2.15.2 through 4.2.15.4.

R.61-64 RHB 4.2.16.1

Text was added to this subsection subitem requiring facilities to keep records of equipment performance testing for five years or until the next Department inspection.

R.61-64 RHB 4.2.16.1.3.1

This subsection subitem was revised to clarify equipment performance testing for dental equipment. Text was added specifying intraoral and extraoral units be tested every two years. Text was also added requiring dental computed tomography and dental handheld units to be tested annually.

R.61-64 RHB 4.2.16.1.3.2

This subsection subitem was revised to change “computerized” to “computed” for consistency.

R.61-64 RHB 4.2.16.4.2

This subsection subitem was revised to require facilities to perform repeat analysis quarterly, regardless of the number of radiographs produced. Text was also added requiring records to be maintained for two years or until the next Department inspection.

R.61-64 RHB 4.2.16.4.3

This subsection subitem was deleted. RHB 4.2.16.4.5 was renumbered to RHB 4.2.16.4.3.

R.61-64 RHB 4.2.16.4.4

This subsection subitem was deleted. RHB 4.2.16.4.6 was renumbered to RHB 4.2.16.4.4.

R.61-64 RHB 4.3.12.1

This subsection subitem was revised to add text requiring facilities retain documentation of adherence to protocols established by the manufacturers of digital imaging acquisition systems.

R.61-64 RHB 4.3.13

This subsection is unnecessary and redundant. There is existing authority granting the Department the ability to make rules and regulations.

R.61-64 RHB 4.4.1

This subsection was revised to clarify when shielding plans are required. Verbiage from the current RHB 4.4.1 was moved to RHB 4.4.1.1.

R.61-64 RHB 4.4.1.1

This subsection subitem was added to include the requirement for shielding plans.

R.61-64 RHB 4.4.1.2

This subsection subitem was added to address space utilized as a radiation area for greater than five (5) consecutive days.

R.61-64 RHB 4.4.2

This subsection was revised to clarify equipment replacement.

R.61-64 RHB 4.4.2.1

This subsection subitem was added to clarify requirements for the replacement of an existing x-ray machine, control or generator and notification to the Department.

R.61-64 RHB 4.4.2.2

This subsection subitem was added to clarify requirements for the replacement with equipment with increased capabilities which would render the original plan inadequate.

R.61-64 RHB 4.4.2.3

This subsection subitem was added to address shielding plans when parameters change.

R.61-64 RHB 4.4.4.2

This subsection subitem was revised to include the updated National Council of Radiation protection and Measurements, Report Number 151 for therapy facilities.

R.61-64 RHB 4.4.8.1.2

This subsection subitem was revised to reference RHB 4.4.6 which addresses the requirements for the radiation area survey.

R.61-64 RHB 4.5

This section was revised to add the word “Intraoral” for clarity.

R.61-64 RHB 4.5.11.4

This subsection subitem was added to clarify shielding plans are not required for intraoral dental radiographic installations.

R.61-64 RHB 4.6.3.1

This subsection subitem was revised to clarify the requirements for Dental CT Installations.

R.61-64 RHB 4.6.4

This subsection is unnecessary and redundant. There is existing authority granting the Department the ability to make rules and regulations. This subsection will now address the requirements for hand-held intraoral equipment.

R.61-64 RHB 4.6.4.1

This subsection subitem was added to ensure that the backscatter shield designed to protect the operator during an x-ray exposure is non-removable, is 0.25mm lead equivalent, and at a minimum be six inches in diameter.

R.61-64 RHB 4.6.4.2

This subsection subitem was added to ensure that the facility maintains documentation that the operator of a hand-held intraoral device has completed the necessary manufacturer training and that this training has been approved by the Department.

R.61-64 RHB 4.6.4.3

This subsection subitem was added to ensure that the facility adopts and follows the protocols provided by the manufacturer and approved by the Department.

R.61-64 RHB 4.6.4.4

This subsection subitem was added to ensure that the operator of a hand-held intraoral device is protected from radiation by requiring the use of a lead apron and thyroid collar.

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R.61-64 RHB 4.6.4.5

This subsection subitem was added to allow the operator to use a stand in lieu of holding the hand-held intraoral device.

R.61-64 RHB 4.6.4.6

This subsection subitem was added to ensure that the registrant secures the hand-held intraoral device from unauthorized removal or use.

R.61-64 RHB 4.7.4.2.3

This subsection subitem was revised to correct numbering. It was previously numbered incorrectly as 4.7.7.2.3.

R.61-64 RHB 4.8.1

This subsection was revised to correct numbering and exempt mobile radiographic equipment from having a permanently mounted exposure switch.

R.61-64 RHB 4.8.8

This subsection was revised to clarify equipment shall be considered stationary if it is used in a single location for greater than five consecutive days.

R.61-64 RHB 4.9.1.4

This subsection subitem was revised to delete the requirement to include precautionary measures in the facility's written operating procedures.

R.61-64 RHB 4.9.1.4.1 through RHB 4.9.1.4.2

These subsection subitems were added to address requirements of mobile fluoroscopes not already addressed.

R.61-64 RHB 4.9.4.3.5

This subsection subitem was added to address requirements of mobile fluoroscopes not already addressed.

R.61-64 RHB 4.9.4.3.5 through RHB 4.9.4.3.8.4

These subsection subitems were renumbered to RHB 4.9.4.3.6 through RHB 4.9.4.3.9.4

R.61-64 RHB 4.9.10

This subsection was revised to clarify equipment shall be considered stationary if it is used in a single location for greater than five consecutive days.

R.61-64 RHB 4.9.13.7

This subsection was revised to allow the facility to use 0.25 mm lead equivalent aprons in lieu of the 0.5 mm lead equivalent aprons.

R.61-64 RHB 4.10.4.3

This subsection subitem was revised to delete the requirement for operating procedures. RHB 4.10.1.4 was renumbered to 4.10.4.3.

R.61-64 RHB 4.11.2.3.1

This subsection subitem was deleted in its entirety as it is no longer applicable since these regulations are being revised.

R.61-64 RHB 4.11.2.4

This subsection subitem was deleted to align with national recommendations that either do not include or discourage the use of CT door interlocks.

R.61-64 RHB 4.11.2.5

This subsection subitem was renumbered to 4.11.2.4.

R.61-64 RHB 4.11.2.5.1

This subsection subitem was renumbered to 4.11.2.4.1.

R.61-64 RHB 4.11.2.5.2

This subsection subitem was renumbered to 4.11.2.4.2.

R.61-64 RHB 4.12.1

This subsection was revised to include requirements for individual's using equipment emitting ionizing radiation for diagnostic purposes.

R.61-64 RHB 4.12.22.1

This subsection subitem was revised to require persons holding patients receive training.

R.61-64 RHB 4.12.22.1.1

This subsection subitem was revised to include additional items to be covered in radiation protection training.

R.61-64 RHB 4.12.22.1.2

This subsection subitem was revised to include training for Digital Imaging Acquisition systems.

R.61-64 RHB 4.13.3

This subsection was revised to delete redundant verbiage.

R.61-64 Part IV - Appendix B, item 1.c)

This subitem was revised to streamline shielding plan submission requirements.

R.61-64 Part IV - Appendix B, item 1.f)

This subitem was deleted to streamline shielding plan submission requirements. Part IV - Appendix B subitem 1.g) was renumbered to 1.f).

R.61-64 Part IV - Appendix B, Item 3

This item was deleted to streamline shielding plan submission requirements.

R.61-64 Part IV - Appendix B, Item 4

This item was deleted to streamline shielding plan submission requirements. Part IV - Appendix B item 5 was renumbered to item 3.

R.61-64 Part IV – Appendix D

This section was revised to remove the National Average ESE (mR) from the Medical and Dental charts. The thickness chart was deleted and that text was added to the Medical chart for clarity. Text was added requiring dental facilities utilizing digital equipment to use techniques as not to exceed the ESE limits for “D” speed systems.

R.61-64 Part IV - Appendix F - Minimum Criteria for Performance Tests

The requirement was added for all applicable requirements of RHB 2.7.3.6.6.

R.61-64 Part IV - Appendix F - Medical Radiographic (Including veterinary facilities)

Items were numbered for clarity.

R.61-64 Part IV - Appendix F - Medical Radiographic (Including veterinary facilities)

Item 19 was added to include x-ray control placement.

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R.61-64 Part IV - Appendix F - Fluoroscopic
Items were numbered for clarity.

R.61-64 Part IV – Appendix F – Fluoroscopic
Primary Barrier Transmission (4.9.5) was moved to items that must be checked upon initial installation.

R.61-64 Part IV – Appendix F – Fluoroscopic
Item 5 was revised to be consistent with the referenced regulation.

R.61-64 Part IV - Appendix F - Fluoroscopic
Item 19 was added to include x-ray control placement.

R.61-64 Part IV - Appendix F - Fluoroscopic
Items to be checked upon initial installation were added for consistency.

R.61-64 Part IV - Appendix F - Radiation Therapy Simulation Systems
Items were numbered for clarity.

R.61-64 Part IV - Appendix F - Radiation Therapy Simulation Systems
Item 20 was added to include x-ray control placement.

R.61-64 Part IV - Appendix F - Computed Tomography (CT)
This item was revised to include dental CT as applicable.

R.61-64 Part IV - Appendix F - Computed Tomography (CT)
Items were numbered for clarity.

R.61-64 Part IV - Appendix F - Computed Tomography (CT)
Item 9 was added to include x-ray control placement.

R.61-64 Part IV - Appendix F - Dental
Items were numbered for clarity.

R.61-64 Part IV - Appendix F - Dental
Item 11 was added to include x-ray control placement.

Part V – Quality Standards and Certification Requirements for Facilities Performing Mammography

R.61-64 RHB 5.1.2.2.2
This subsection subitem was revised to include the correct numbering.

R.61-64 RHB 5.1.2.2.4
This subsection subitem was added to include requirements for out of state mobile mammography facilities as addressed in RHB 2.4.

R.61-64 RHB 5.5.4
This subsection subitem was revised to correct the title of the Director of Health Regulation.

R.61-64 RHB 5.6.1
This section was revised to modify the fee structure.

R.61-64 RHB 5.7.2.1.2
This subsection was revised to correct the reference.

R.61-64 RHB 5.7.3.1

This subsection subitem was revised to correct the reference. This subsection subitem was also revised to correspond with the current FDA standards.

R.61-64 RHB 5.11.1.4

This subsection subitem was deleted as it is no longer applicable.

R.61-64 RHB 5.11.6

This subsection subitem was revised to correct the references.

R.61-64 RHB 5.12.1

This subsection subitem was revised to include quality control tests for other modalities.

R.61-64 RHB 5.24.3.1

This subsection subitem was revised to correct the title of the Director of Health Regulation.

R.61-64 RHB 5.25.3

This subsection was revised to correct numbering. It was previously numbered incorrectly as 5.25.5.

R.61-64 RHB 5.25.3.1 through RHB 5.25.3.7

These subsection subitems were revised to correct numbering.

R.61-64 RHB 5.27

This section was revised to change operating procedures to operating conditions and correct numbering.

R.61-64 Part V, Appendix B

This section was revised to correct the reference.

Part VI – Use of Therapeutic Equipment

R.61-64 RHB 6.2

This section was revised in entirety. Text specifying shielding requirements was deleted. For consistency with the other parts of the regulation, text was added requiring facilities utilizing therapy equipment to meet all requirements of RHB 4.4.

R.61-64 RHB 6.3.2.1.1.4

This subsection subitem was revised to correct the reference.

R.61-64 RHB 6.3.3.1

To correctly identify the organization of the South Carolina Radiation Quality Standards Association, the word Radiation was added. This subsection subitem was also revised to delete licensed practitioners, as they are addressed later in this part.

R.61-64 RHB 6.3.3.3

To correctly identify the organization of the South Carolina Radiation Quality Standards Association, the word Radiation was added to this subsection subitem.

R.61-64 RHB 6.3.3.4

To correctly identify the organization of the South Carolina Radiation Quality Standards Association, the word Radiation was added to this subsection subitem.

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R.61-64 RHB 6.3.3.5

To correctly identify the organization of the South Carolina Radiation Quality Standards Association, the word Radiation was added to this subsection subitem.

R.61-64 RHB 6.3.3.6

To correctly identify the organization of the South Carolina Radiation Quality Standards Association, the word Radiation was added to this subsection subitem.

R.61-64 RHB 6.3.3.7

To correctly identify the organization of the South Carolina Radiation Quality Standards Association, the word Radiation was added to this subsection subitem.

R.61-64 RHB 6.3.4

This entire subsection was revised to add training requirements for therapeutic radiation machine authorized users to bring the requirement in line with the Conference of Radiation Control Program Directors suggested State Regulations. Text from RHB 6.3.4 was renumbered to RHB 6.3.5.

R.61-64 RHB 6.3.5

This subsection was renumbered to RHB 6.3.6.

R.61-64 RHB 6.3.6

This subsection was renumbered to RHB 6.3.7.

R.61-64 RHB 6.3.7

This subsection was renumbered to RHB 6.3.8.

R.61-64 RHB 6.4.4.1.4

This subsection subitem was revised for reference purposes. Text was deleted pertaining to instruments and text was added to reference Part I.

R.61-64 RHB 6.4.4.2.3

This subsection subitem was revised to reference Part I concerning calibration of dosimetry systems.

R.61-64 RHB 6.6.3.3

This subsection subitem was revised to reference Part I. Text was also changed requiring dosimetry systems as referenced in this Part to be calibrated annually.

R.61-64 RHB 6.6.3.3.1 through 6.6.3.3.3

These subsection subitems were deleted in this Part. They were moved to Part I and reworded for consistency.

R.61-64 RHB 6.6.3.3.4

This subsection subitem was deleted in its entirety due to the stability of the equipment.

Part VII – Radiation Safety Requirements for Analytical Equipment

R.61-64 RHB 7.2

This subsection addressing electron microscopes was revised to clarify the requirements for these devices.

R.61-64 RHB 7.3

This subsection addressing Hand-Held Analytical X-ray Equipment was revised to clarify the requirements for these devices.

R.61-64 RHB 7.3.1

This subsection subitem was revised to address the required registration of the device. Training requirements in this subsection subitem was moved and is addressed in the subsection of RHB 7.3.2.

R.61-64 RHB 7.3.2

This subsection was revised to address the training requirements. The interlock requirement for these types of devices was moved to the subsection RHB 7.3.3.

R.61-64 RHB 7.3.3

This subsection was revised to address the interlock requirements for these types of devices. The operator use of these devices, in accordance to the manufacturer's specifications was moved to the new subsection of RHB 7.3.4

R.61-64 RHB 7.3.4

This new subsection number was added to address the operator usage of this type of device based on manufacturer's specifications.

R.61-64 RHB 7.3.5

This new subsection was added to address operating procedures for facilities that utilize this type of device.

R.61-64 RHB 7.7.3

This subsection was revised to allow, under Departmental approval, the use of area radiation monitors in lieu of an annual radiation area survey.

R.61-64 RHB 7.9

This subsection was re-titled for clarity and to also include the Radiation Safety Officer.

R.61-64 RHB 7.9.1

This subsection subitem addressing operator training was moved to subsection RHB 7.9.2. The revised subsection subitem of 7.9.1 addresses the minimum personnel radiation safety requirements for radiation safety officers and operators.

R.61-64 RHB 7.9.1.1

This subsection subitem was reworded to direct the Radiation Safety Officer of the subjects in which they must be trained.

R.61-64 RHB 7.9.1.2

This subsection subitem was reworded to direct the Radiation Safety Officer (RSO) of analytical x-ray devices to the applicable sections in the regulations pertaining to radiation safety. It also requires the RSO to receive instruction and understanding in the facility's operating and emergency procedures.

R.61-64 RHB 7.9.1.3

This subsection subitem was reworded to ensure that the Radiation Safety Officer (RSO) of analytical x-ray devices have demonstrated competence in the use of the machine as well as any related tools and survey instruments.

R.61-64 RHB 7.9.1.4

This subsection subitem was moved to the additional subsection subitem of RHB 7.9.2.4.

R.61-64 RHB 7.9.1.5

This subsection subitem was moved to the additional subsection subitem of RHB 7.9.2.5.

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R.61-64 RHB 7.9.2

This subsection was revised and the wording from RHB 7.9.1 was placed here.

R.61-64 RHB 7.9.2.1

This new subsection subitem was added so that the wording from RHB 7.9.1.1 could be placed here.

R.61-64 RHB 7.9.2.2

This new subsection subitem was added so that the wording from RHB 7.9.1.2 could be placed here.

R.61-64 RHB 7.9.2.3

This new subsection subitem was added so that the wording from RHB 7.9.1.3 could be placed here.

R.61-64 RHB 7.9.2.4

This new subsection subitem was added so that the wording from RHB 7.9.1.4 could be placed here.

R.61-64 RHB 7.9.2.5

This new subsection subitem was added so that the wording from RHB 7.9.1.5 could be placed here.

R.61-64 RHB 7.9.3

This subitem was revised to address the requirement of documentation for instruction and competency for analytical x-ray devices.

R.61-64 RHB 7.9.3.1

This subsection subitem was moved to RHB 7.10.1.1.

R.61-64 RHB 7.9.3.2

This subsection subitem was moved to RHB 7.10.1.2.

R.61-64 RHB 7.9.3.3

This subsection subitem was moved to RHB 7.10.1.3.

R.61-64 RHB 7.9.4

This subsection was deleted.

R.61-64 RHB 7.10

Text from this section was renumbered to RHB 7.11. A new section was added as a title for operating procedures for consistency with other sections in this part.

R.61-64 RHB 7.10.1

Text from this section was renumbered to RHB 7.11.1. Text was moved from RHB 7.9.3.

R.61-64 RHB 7.10.1.1

This new subsection subitem was added and text was moved from RHB 7.9.3.1.

R.61-64 RHB 7.10.1.2

This new subsection subitem was added and text was moved from RHB 7.9.3.2.

R.61-64 RHB 7.10.1.3

This new subsection subitem was added and text was moved from RHB 7.9.3.3.

R.61-64 RHB 7.10.1.4

This new subsection subitem was added and text was added addressing operating procedures pertaining to the methods and occasions for conducting radiation surveys.

R.61-64 RHB 7.10.1.5

This new subsection subitem was added addressing operating procedures pertaining to the methods for controlling access to radiographic areas.

R.61-64 RHB 7.10.1.6

This new subsection subitem was added addressing operating procedures pertaining to the methods for locking and securing x-ray machines, when they are not in use or in storage.

R.61-64 RHB 7.10.1.7

This new subsection subitem was added addressing operating procedures pertaining to the maintenance of records.

R.61-64 RHB 7.10.2

Text from this section was renumbered to RHB 7.11.2. A new subsection was added requiring the facility provide copies of the operator training manual and operating procedures to the Department upon request.

R.61-64 RHB 7.10.2.1 to RHB 7.10.2.2

These subsection subitems were renumbered to RHB 7.11.2.1 and 7.11.2.2.

Part VIII – Radiation Safety Requirements for Industrial Uses of Radiographic Sources

R.61-64 RHB 8.6.1

This subsection was revised to delete the word “posting” for clarity.

R.61-64 RHB 8.6.2

This subsection was revised to clarify the posting requirements.

R.61-64 RHB 8.12.1.12 through RHB 8.12.1.12.1.2

These subsection subitems were added allowing exemptions for certified and/or certifiable cabinet x-ray systems in accordance with the Conference of Radiation Control Program Directors Suggested State Regulations.

Part IX – Definitions

This Section has been renumbered in alphanumeric order.

R.61-64 RHB 9.28

This section was added to define cabinet radiography in accordance with the Conference of Radiation Control Program Directors Suggested State Regulations.

R.61-64 RHB 9.36

This section was added to define certifiable cabinet x-ray system in accordance with the Conference of Radiation Control Program Directors Suggested State Regulations.

R.61-64 RHB 9.38

This section was added to define certified cabinet x-ray system in accordance with the Conference of Radiation Control Program Directors Suggested State Regulations.

R.61-64 RHB 9.64

This section formatting was revised for clarity.

R.61-64 RHB 9.127

This section was revised to correct the references.

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R.61-64 RHB 9.166

This section was added to define Operating Conditions.

R.61-64 RHB 9.169

This section was added to include the definition of an out of state facility.

R.61-64 RHB 9.195

This section was revised to correct the references.

R.61-64 RHB 9.276

This section was added to include the definition of an x-ray control.

Part X - Notices, Instructions, and Reports to Workers: Inspections

R.61-64 RHB 10.7.2

This subsection was revised to correct the title of the Director of Health Regulation.

R.61-64 RHB 10.8.1

This subsection was revised to correct the title of the Director of Health Regulation.

Part XI – Regional Calibration Laboratory

R.61-64 RHB 11.3.1

This subsection was revised by changing “Fee” to “Fees.” The portion in the chart identifying Dosimeter was revised for clarity.

Instructions: Replace R.61-64. X-Rays (Title B), in its entirety.

Text:

61-64. X-Rays (Title B).

Statutory Authority: 1976 Code Section 13-7-10 et seq.

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PART I
GENERAL PROVISIONS

RHB 1.1 Scope. Except as otherwise specifically provided, these regulations apply to all persons who receive, possess, use, transfer, own, or acquire any x-ray producing machine. The provisions of these regulations shall not be interpreted as limiting the intentional exposure of patients to radiation for the purpose of diagnosis, analysis, or therapy by persons licensed to practice one or more of the health professions within the authority granted to them by statute or regulation.

RHB 1.2 Prohibited Use.

1.2.1 It shall be unlawful to operate or maintain fluoroscopic devices for fitting or selling footwear.

1.2.2 It shall be unlawful to intentionally apply radiation to human beings except by, or under the direct supervision of, persons licensed to practice the health professions and authorized to use such radiation.

1.2.3 It shall be unlawful to use, receive, own, or possess x-ray equipment unless the facility is registered with the Department and is operated in compliance with all applicable provisions.

1.2.4 It shall be unlawful to use hand-held non-image intensified fluoroscopic screens.

1.2.5 It shall be unlawful to use plastic pointed position indicating devices on intraoral dental systems.

1.2.6 The use of any source of radiation may be prohibited when it is determined by the Department to be detrimental to public health and safety.

1.2.7 It shall be unlawful to use hand-held radiographic or fluoroscopic imaging devices, or hand-held therapy units, except for contact therapy units operated according to Part VI of these regulations.

1.2.8 It shall be unlawful to use fluoroscopy for positioning a patient for radiographic imaging, except when done by a licensed practitioner of the healing arts, or except for radiation therapy simulators.

1.2.9 It shall be unlawful for a person other than a licensed practitioner of the healing arts as defined by the South Carolina Department of Labor, Licensing, and Regulation to use fluoroscopy when the licensed practitioner of the healing arts is not physically present in the room, except during therapy simulations, maintenance activities, and training courses.

1.2.10 It shall be unlawful to use direct exposure x-ray film (without intensifying screens) for all radiological imaging other than intraoral dental radiography, therapeutic portal imaging, and industrial radiography.

1.2.11 It shall be unlawful to use a mammographic imaging system not specifically designed by the manufacturer for imaging of the breast.

1.2.12 It shall be unlawful to intentionally expose a human to electronically produced ionizing radiation except for healing arts purposes, or as part of a research protocol authorized by an institutional review board conforming to 45 CFR 46, 21 CFR 50 and 21 CFR 56.

1.2.13 No person shall make, sell, lease, transfer, lend, repair, or install x-ray equipment or the supplies used in connection with such equipment unless such supplies or equipment, when properly placed in operation and properly used will meet the requirements of these regulations. This includes but is not limited to such items as cones, filters, adequate timers, and fluoroscopic shutters (where applicable). Also, such persons shall be registered with the Department in accordance with RHB 2.6.

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RHB 1.3 Inspections.

1.3.1 Each registrant shall afford, at all reasonable times, the Department or its duly authorized representative the opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

1.3.2 Each registrant shall make available to the Department or its authorized representative for inspection, upon reasonable notice, records maintained pursuant to these regulations.

1.3.3 The Department shall have the right to enter at all reasonable times upon any private or public property, except property under the jurisdiction of the federal government, for the purpose of determining whether there is compliance with the provisions of the Act and regulations issued by the Department pursuant thereto.

1.3.4 The Department is authorized by law to enter and inspect property in order to determine compliance with Department regulations. Such entry and inspection falls under the health oversight activities exception of the Health Information Portability and Accountability Act (HIPAA). Therefore, when protected health information is necessary for determining compliance with Department regulations, protected health information may be used and disclosed to the Department without the subject's authorization.

RHB 1.4 Test and Surveys.

1.4.1 Each registrant shall make or cause to be made such surveys as are necessary for him to comply with these regulations.

1.4.2 Each registrant shall perform, upon instructions from the Department, or shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary including, but not limited to, tests of:

1.4.2.1 Sources of radiation;

1.4.2.2 Facilities wherein sources of radiation are used or stored;

1.4.2.3 Radiation detection and monitoring instruments; and

1.4.2.4 Other equipment and devices used in connection with utilization or storage of sources of radiation.

1.4.3 Results of such tests and surveys shall be submitted to the Department upon request.

1.4.4 Radiation Survey Instruments

1.4.4.1 The radiation survey instrument used shall have a minimum operation range consistent with the radiation field being measured.

1.4.4.2 Each radiation survey instrument shall be maintained annually.

1.4.4.2.1 Each radiation survey instrument used for equipment performance testing and radiation area surveys shall be calibrated at intervals not to exceed 24 months and after each instrument servicing.

1.4.4.2.2 Each radiation survey instrument shall be calibrated such that the accuracy is within 20 percent or within the manufacturer specifications, whichever is less, and traceable to a national standard that can be demonstrated.

1.4.4.2.3 Each radiation survey instrument shall be calibrated at two or more widely separated points, other than zero, on each scale.

1.4.4.2.4 Records of these calibrations shall be maintained for inspection by this Department.

1.4.4.3 The manufacturer's instructions of the survey instrument shall be made available to the instrument users. This shall include any restrictions of the operating techniques required for the proper operation of the instrument.

1.4.4.3.1 The registrant shall adhere to the manufacturer's instructions in all respects.

1.4.4.3.2 The user shall be able to demonstrate familiarity and competence with these instructions.

1.4.4.3.3 The operator shall check each survey instrument with a dedicated check source each day of use to ensure the instrument is operating properly.

1.4.4.4 Calibration radiation measurements required by Part VI shall be performed using a dosimetry system:

1.4.4.4.1 Having a calibration factor traceable to a national standard;

1.4.4.4.2 Calibrated within the preceding 24 months and after any servicing that may have affected its calibration;

1.4.4.4.3 Calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

RHB 1.5 Exemptions.

1.5.1 The Department may, upon application by any user, or upon its own initiative grant such exemptions from the requirements of these regulations as it determines are authorized by law, and will not result in undue hazard to health, life, or property. Applications for exemptions shall specify why such exemption is necessary.

1.5.2 Before granting an exemption, the Department shall determine that there is reasonable and adequate assurance that:

1.5.2.1 The occupational dose to any individual adult will not exceed those specified in RHB 3.4.

1.5.2.2 The dose to an individual member of the public will not exceed those specified in RHB 3.9.

1.5.2.3 There is no significant hazard to life or property.

RHB 1.6 Additional Requirements.

1.6.1 The Department may, by rule, regulation, or order, impose upon any registrant such requirements in addition to those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

1.6.2 The Department is authorized to inspect and investigate the premises and operations and personnel of any radiation installation, whether or not such installation is required to be registered by the Department, for the purpose of studying and evaluating the health hazard(s) caused by the use and operation of such machines and material.

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1.6.3 Equipment Not Covered In Regulations. Prior to the sale and operation of x-ray producing equipment not specifically covered in these regulations, the seller shall submit for review and approval to the Department a listing of manufacturer's specifications for the equipment, an analysis of exposure rates for the equipment, independent peer reviewed radiation safety studies of the equipment, training materials in the use of the equipment, and verification of compliance with the United States Food and Drug Administration. In addition, the seller shall provide the written operating procedures and user's manual of the equipment . Guidance documents regarding new modalities may be found on the Department's website.

1.6.4 Radiation Safety Officer. The registrant shall designate an individual who will be responsible for radiation protection at the facility. Such individual shall:

1.6.4.1 Be qualified by training and experience concerning all hazards and precautions involved in operating the equipment for which he is responsible;

1.6.4.2 Develop and implement a program of radiation safety for effective compliance with the applicable requirements of these regulations;

1.6.4.3 Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the equipment;

1.6.4.4 Ensure that surveys are made, procedures are carried out, and radiation safety instructions are given as required by these regulations.

RHB 1.7 Violations.

1.7.1 The Department may obtain an injunction or other court order prohibiting any violation or any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder shall be guilty of a misdemeanor and, upon conviction, shall be punished by fine or imprisonment or both, as provided by the Act.

1.7.2 Any person found in violation of any regulation shall notify the Department, in writing, with respect to action that has been taken or planned to correct the violation.

1.7.2.1 Mammography Violation Response

1.7.2.1.1 If the MQSA (Mammography Quality Standards Act) report results in a Level 1, repeat Level 1, or repeat Level 2 finding, a written Corrective Action Plan shall be provided to the Department within 15 calendar days of the date of citation.

1.7.2.1.2 If the MQSA report results in a Level 2 or repeat Level 3 finding, a written Corrective Action Plan shall be provided to the Department within 30 calendar days of the date of citation.

1.7.2.2 All Other Violation Response

1.7.2.2.1 A written Corrective Action Plan shall be provided in writing within twenty (20) calendar days from the date of citation with respect to action that is planned to correct the violation.

1.7.2.2.2 All violations shall be corrected within sixty (60) calendar days from the date of citation. The Department shall be notified in writing of all action taken to correct the violations.

1.7.3 The Department is authorized to hold public hearings, compel attendance of witnesses, make findings of fact and determinations and to assess fines and civil penalties relating to violations of the provisions of the Act or any regulation, temporary or permanent order, or final determination of the Department.

1.7.4 The Department may impose a civil penalty not to exceed Twenty-five Thousand Dollars (\$25,000) on a person who violates a provision of the Act, rules, regulations, or orders issued. Each day of continued violation shall constitute a separate offense in computing the civil penalty. Civil penalties shall be assessed as specified in RHB 1.13.

RHB 1.8 Enforcement.

1.8.1 Upon determination by the Department that the Act or these regulations have been violated or that a public health risk exists, the Department will:

1.8.1.1 Provide written notification to the non-compliant facility as soon as possible after violations are noted which:

1.8.1.1.1 Cites each section of the Act or regulations violated.

1.8.1.1.2 Specifies the manner in which the registrant failed to comply.

1.8.1.1.3 Requires submission of a timely and comprehensive corrective action plan, including a time schedule for completion of the plan.

1.8.1.1.4 Establishes a firm time schedule within which a corrective action plan must be submitted. The Department will approve the plan and proposed time schedule for its completion if the plan is adequate.

1.8.1.2 In cases where the registrant fails to comply with the conditions of the written notification, the Department will seek further enforcement action, appropriate penalties and direct remedial relief.

1.8.1.3 If the registrant fails to comply with the requirements of the Regulations within ten days, or in cases where there is an imminent hazard to human health and safety, the Department will take one or a combination of the following steps:

1.8.1.3.1 Issue an administrative order which:

1.8.1.3.1.1 Imposes an appropriate civil penalty; or

1.8.1.3.1.2 Requires corrective action; or

1.8.1.3.1.3 Impounds or orders the impounding of sources of radiation in accordance with the Act;

1.8.1.3.1.4 Revokes the facility's registration in accordance with Part II; or

1.8.1.3.2 Requests the Department attorney or the attorney general to seek court action to enjoin violations and seek conviction for a simple misdemeanor; or

1.8.1.3.3 Take enforcement action that the Department feels appropriate and necessary and is authorized by law.

1.8.2 Under an actual or potential condition posing a risk to any individual comparable to a Major severity level violation, the Department may immediately impound or order the impounding of sources of radiation in accordance with the Act.

RHB 1.9 Impounding.

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1.9.1 The Department may immediately impound or order the impounding of sources of radiation in the possession of any person who fails to comply with these regulations or provisions of the Act, or when the Department deems a situation to constitute an emergency.

RHB 1.10 Records.

1.10.1 Each registrant shall keep records showing the receipt, transfer, use, storage, and disposal of all sources of radiation and major components, including, but not limited to controls, tubes, tables, cassette holders, and transformers. These records shall be maintained by the registrant until disposal is authorized by the Department. Such authorization shall be made in writing. All records shall be readily available at the facility for Department review. Additional record requirements are specified elsewhere in these regulations.

1.10.2 The registrant shall maintain the following information for each x-ray system for inspection by the Department:

1.10.2.1 Model and serial numbers of all tubes, controls, and beam limiting devices;

1.10.2.2 Tube rating charts and cooling curves, for units certified by the Food and Drug Administration, and for units regulated under Part IV and Part V;

1.10.2.3 Aluminum equivalent filtration of the useful beam, including any routine variation for units regulated under Part IV and Part V;

1.10.2.4 Records of surveys, equipment performance tests, maintenance, and modifications performed on the x-ray system(s), with the names of persons who performed such services. Records shall be maintained for five years; until the next Department inspection; or until the registrant no longer possesses the equipment.

1.10.2.5 A copy of all correspondence with the Department regarding that x-ray system.

1.10.3 Each registrant possessing more than 10 radiation machine controls shall maintain a current inventory listing that indicates the model number, serial number, shielding acceptance number (if applicable), date of last equipment performance test, location and status of each control. The inventory listing shall be made available to the Department upon request.

1.10.4 All records required by these regulations shall be accurate and true.

RHB 1.11 Records and Reports of Misadministration.

1.11.1 Therapy Misadministrations.

When a misadministration involves any therapy procedure, the registrant shall notify the Department by telephone, fax, or electronic mail no later than 24 hours after discovery of the misadministration. The registrant shall also notify the referring physician and the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant that he or she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within twenty four (24) hours, the registrant shall notify the patient as soon as possible thereafter. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

1.11.1.1 The registrant shall submit a written report to the Department within fifteen (15) days after the discovery of the misadministration. The report must not include the patient's name or other information that could lead to identification of the patient. The written report must include the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what

improvements are needed to prevent recurrence; the action taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian; and if not, why the individual involved was not informed; and if the patient was notified, what information was provided to the patient.

1.11.1.2 The registrant shall furnish the following to the patient within 15 days after discovery of the misadministration if the patient was notified:

1.11.1.2.1 A copy of the report that was submitted to the Department; or

1.11.1.2.2 A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the Department can be obtained from the registrant.

1.11.2 Diagnostic Misadministrations. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for the Department review, and maintain the record as directed in RHB 1.11.3.

1.11.3 Each registrant shall retain a record of each therapy misadministration for ten (10) years and three (3) years for each diagnostic misadministration. The record must contain the names of all individuals involved in the event (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's identification number if one has been assigned, a brief description of the event misadministration, the effect on the patient, what improvements are needed to prevent recurrence; and the actions taken to prevent recurrence.

1.11.4 Aside from the notification requirement, nothing in RHB 1.11.1 through 1.11.3 shall affect any rights or duties of registrants and physicians in relation to each other, registrants, patients or responsible relatives or guardians.

RHB 1.12 Communications.

1.12.1 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, South Carolina 29201

1.12.2 Material False Statements. It shall be unlawful 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.

RHB 1.13 Administration of Civil Penalties.

1.13.1 Assessment - Assessment of civil penalties shall be based on the following criteria:

1.13.1.1 the seriousness of the violation(s);

1.13.1.2 previous compliance history;

1.13.1.3 the amount necessary to deter future violations;

1.13.1.4 efforts to correct the violation; and

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1.13.1.5 any other mitigating or enhancing factors.

1.13.2 Severity Levels - The seriousness of violations shall be categorized by one of the following severity levels.

1.13.2.1 Major- Violations that are most significant and have a direct negative impact on occupational or public health and safety, or which represent a significant deviation from the requirements of this regulation.

1.13.2.2 Moderate- Violations that are of more than minor significance, but if left uncorrected, could lead to more serious circumstances, or which represent a moderate deviation from the requirements of this regulation.

1.13.2.3 Minor- Violations that are of minor safety significance, or which represent a minor deviation from the requirements of this regulations.

1.13.2.4 In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

1.13.3 Application - Examples of violations in each severity level are given in RHB 1.13.4.3. While examples are given for determining the appropriate severity level for violations, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Department of Health and Environmental Control places on a particular type of violation of state requirements. Adjustments to the values listed in RHB 1.13.4.1 under each severity level may be made for the presence or absence of the following factors:

1.13.3.1 Prompt Identification and Reporting. Reduction of a civil penalty may be given when a Registrant identifies the violation and promptly reports the violation to the Department. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the Registrant does not take immediate action to correct the problem upon discovery.

1.13.3.2 Corrective Action to Prevent Recurrence. Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the Registrant takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty. On the other hand, the civil penalty may be increased if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of Registrant initiative, and comprehensiveness of the corrective action - such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

1.13.3.3 Compliance History. Reduction of the civil penalty may be given for prior good performance in the general area of concern. In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as previous compliance history in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.

1.13.3.4 Prior Notice of Similar Events. The civil penalty may be increased for cases where the Registrant had prior knowledge of a problem as a result of a Registrant audit, or specific industry notification, and had failed to take effective preventive steps.

1.13.3.5 Multiple Occurrences. The civil penalty may be increased where multiple examples of a particular violation are identified during the inspection period.

1.13.3.6 The above factors are additive. However, the civil penalty will not exceed twenty five thousand dollars (\$25,000) for any one violation. Each day of noncompliance shall constitute a separate violation.

1.13.4 The Department shall issue civil penalties according to the following schedule:

1.13.4.1 Penalty Matrix

Deviation from Requirement: Potential for Harm:	Major (11-30)	Moderate (4-10)	Minor (1-3)
Major (11-70)	\$25,000-5,000	\$15,000-5,000	\$10,000-2,500
Moderate (6-10)	\$10,000-2,500	\$7,500-1,000	\$5,000-500
Minor (0-5)	\$5,000-1,000	\$3,000-500	\$2,500-250

Calculation of Base Penalty:

Each violation is assigned a relative point value as follows: Potential for Harm- 0-70, with 70 being maximum harm; Deviation from Requirement- 1-30, with 30 being the maximum deviation. Add the two values together, convert to a decimal value (15 to .15, for example), and multiply by the maximum per day per violation per civil penalty (\$25,000). This is the base civil penalty per violation. The base penalty may be increased for repeat violations, multi-day penalties, or degree of recalcitrance, willfulness, negligence, or indifference.

Minimum Increase for Repeat Violations Found on Follow-up Inspections or Reinspections

Second Offense (First Follow-up Inspection or First Reinspection)	15 %
Third Offense (Second Follow-up Inspection or Second Reinspection)	30 %
Fourth Offense (Third Follow-up Inspection or Third Reinspection)	45 %
Fifth and Subsequent Offenses	60 %

Multi-Day Penalties

Increase penalty 1% to 7% for each day of noncompliance.

Degree of Recalcitrance, Willfulness, Negligence, or Indifference

Increase Penalty 10% to 50%

1.13.4.2 The Department reserves the right to impose a civil penalty up to Twenty-five Thousand Dollars on a person who violates the regulations in such a manner so as to present an imminent hazard to human health and safety. The Twenty-five Thousand (\$25,000.00) Dollar civil penalty may be levied for the following:

1.13.4.2.1 Two or more incidents of workers receiving excess radiation exposures, when such exposures are contrary to the provisions of RHB 3.4.

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1.13.4.2.2 Two or more incidents of members of the general public, or non-radiation workers, receiving excess radiation exposures. (3.9)

1.13.4.2.3 Two or more incidents in a one year period of deliberate exposure of an individual except by or under the direct supervision of an individual licensed to engage in the healing arts. (1.2.2)

1.13.4.2.4 Two or more incidents on two consecutive inspections of failing to perform required equipment performance testing, surveys, tests, or evaluations. (1.4)

1.13.4.2.5 Four or more incidents in a one year period of making, selling, leasing, transferring, lending, assembling, or installing equipment without the equipment meeting all applicable regulations when properly placed in operation. (2.7.2)

1.13.4.2.6 Two or more incidents in a five year period of initiating a healing arts screening program without prior approval from the Department. (4.2.11.2)

1.13.4.2.7 Two or more incidents on two consecutive inspections of failing to provide a safety device on open-beam configuration analytical x-ray equipment. (7.5.1)

1.13.4.2.8 Two or more incidents on two consecutive inspections of ESEs that vary from the average ESE by more than a factor of 2, as determined by Appendix D of Part IV. (4.2.13.2)

1.13.4.2.9 Operation of a mammography facility without possessing a current, valid certificate issued by the Department, as required by RHB 5.2.

1.13.4.2.10 Two or more incidents of a registrant failing to ensure that operators of x-ray equipment possess a valid, current certificate from the South Carolina Radiation Quality Standards Association. (4.2.2, 6.3.3.1)

1.13.4.3 Example of Violations with Potential for Harm

Major

Workers receiving excess radiation exposures, when such exposures are contrary to the provisions of RHB 3.4.

Members of the general public, or non-radiation workers, receiving excess radiation exposures. (3.9)

Deliberate exposure of an individual except by or under the direct supervision of an individual licensed to engage in the healing arts. (4.2.11)

Two or more incidents on three consecutive inspections of failing to perform required equipment performance tests, surveys, or evaluations. (1.4)

Two or more incidents in a one year period of making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)

Exposure to an individual for training, demonstration, or other purposes when there are not healing arts requirements or proper prescription provided. (4.2.11.1)

Two or more incidents on two consecutive inspections of a fluoroscopic system with a source to skin distance less than those specified in RHB 4.9.1.

Two or more incidents on two consecutive inspections of a fluoroscopic system with an x-ray field exceeding the length or width of the visible area of the image receptor by greater than five percent (5%), or the sum of the excess length and width of greater than six percent (6%). (4.9.2.2)

Initiating or conducting a healing arts screening program without prior approval from the Department. (4.2.11.2)

Failing to provide a safety device on open-beam configuration analytical x-ray equipment. (7.5.1)

ESEs that vary from the average ESE by more than a factor of 2, as determined by Appendix D of Part IV. (4.2.13.2)

A fluoroscopic x-ray system with a tabletop entrance exposure rate that exceeds the limits specified in 4.9.4 by more than a factor of 2.

Two or more incidents on two consecutive inspections of a fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier. (4.9.2.1)

Two or more incidents on two consecutive inspections where a required system or equipment designed to prevent or mitigate a serious safety event or unnecessary exposure is absent or inoperable.

An x-ray system having a malfunction such that inadvertent exposures could occur, e.g., a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

Two or more incidents on two consecutive inspections that have a potential for serious overexposure of patients, radiation workers, non-radiation workers, or a member of the public.

Moderate

Making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)

Routine holding of patients or films at a registrant's facility. (4.2.12.4)

Two or more incidents on two consecutive inspections of a registrant failing to ensure that an x-ray operator receives the training required by RHB 4.2.3.7 or RHB 6.3.3.9.

Two or more incidents on two consecutive inspections of lack of adequate filtration present in an x-ray machine. (4.3.5)

Two or more incidents on two consecutive inspections of failure to use exposure reduction devices properly (e.g., collimators, filtration). (4.3.5, 4.7.4.1, 4.7.14)

Two or more incidents on two consecutive inspections of having a fluoroscopic system with a tabletop entrance exposure rate that exceeds the limits specified in 4.9.4.

Two or more incidents on two consecutive inspections of ESEs that vary from the average ESE as determined by Appendix D of Part IV. (4.2.13.2)

Two or more incidents on two consecutive inspections of having a capacitor storage radiographic system such that the standby radiation exceeds the limits specified in RHB 4.3.4 by a factor of 2.

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Two or more incidents on two consecutive inspections of failure to provide appropriate warning devices as required by RHB 7.4.4.

Two or more incidents on two consecutive inspections of failure to secure unused ports on radiation source housings. (7.4.5.5)

Two or more incidents on two consecutive inspections of inadequate mechanical support of tube head. (4.3.8)

Use of mechanical timer. (4.3.11)

Use of x-ray equipment before submission and approval of a shielding plan. (4.4.3)

Two or more incidents in two consecutive inspections of failing to meet the x-ray control requirements of RHB 4.5.4.

Two or more incidents on two consecutive inspections of failure to provide shutters on open-beam configuration x-ray units. (7.5.6.2)

Two or more incidents on two consecutive inspections of failure to control access to equipment, or failure to control access to restricted areas. (7.5.3)

Two or more incidents on two consecutive inspections of an intraoral dental x-ray unit capable of operation in the above 50 kVp range for which the field size at the cone tip is greater than or equal to 9 centimeters or which exhibit a minimum SSD less than 18 centimeters. (4.5.1, 4.5.2)

Two or more incidents on two consecutive inspections of a mobile radiographic system for which the minimum source to skin distance is less than 30 centimeters. (4.8.12)

Minor

Two or more incidents on two consecutive inspections of having a capacitor storage radiographic system such that the standby radiation exceeds the limits specified in RHB 4.3.4.

Repeated violations (Two or more incidents on two consecutive inspections) not covered in a more severe category that have minor safety significance.

1.13.4.4 Examples of Violations Categorized by Deviation from the Requirement

Major

Failure to allow authorized Department personnel access to x-ray facilities or equipment to conduct inspections or investigations. (1.3.1)

Two or more failures on two consecutive inspections to correct violations within sixty days. (1.7.3)

Two or more incidents of a person who is not certified by the South Carolina Radiation Quality Standards Association using or exhibiting a title, sign, display or declaration that misleads the public to believe the person is authorized to apply ionizing radiation on humans for diagnostic or therapeutic purposes. (4.2.2.4, 6.3.3.6)

Continuation of registrant activities after revocation of registration.

Two or more incidents of making material false statements to the Department. (1.12.2)

Two or more failures of a person to apply for registration approval prior to beginning operation of an x-ray facility. (2.4)

Two or more failures of a registrant to register x-ray equipment. (2.1.1)

Two or more incidents of providing x-ray vendor services without being registered with the Department. (2.6.1)

Two or more failures on two consecutive inspections of a person to notify the Department in writing within thirty days when he has sold, leased, transferred, lent, assembled, or installed x-ray equipment. (2.5.3)

Two or more failures of a vendor to notify the Department of installation of equipment. (2.7.1)

Intentional exposure of a radiation monitoring device to deceptively indicate a dose. (3.12.2)

Two or more incidents on two consecutive inspections of failure to provide personnel monitoring if required. (3.12)

Two or more incidents on two consecutive inspections of failing to adhere to the facility's operating conditions.(4.2.3)

Two or more incidents on two consecutive inspections of management action to discriminate against an employee for attempting to communicate or for actually communicating with the Department. (10.7.3)

Two or more incidents of operation of an out of state x-ray machine for more than 365 days. (2.8)

Two or more incidents of a registrant failing to report or record misadministrations. (1.11)

Moderate

Two or more incidents on two consecutive inspections of failing to perform a repeat analysis. (4.2.16.4)

Two or more incidents on two consecutive inspections of failing to perform densitometric and sensitometric testing if required by RHB 4.2.17.2.7.

Two or more incidents on two consecutive inspections of failing to perform periodic measurements of entrance exposure rates on fluoroscopes. (4.9.4.3.6)

Failure of a person to register prior to providing or offering to provide x-ray services. (2.6.1)

Making, selling, leasing, transferring, lending, assembling, or installing equipment without it meeting all applicable regulations when properly placed in operation. (2.7.2)

Failure of a registrant to display each operator's current certificate from the South Carolina Radiation Quality Standards Association, as required by RHB 4.2.2.6 or RHB 6.3.3.8.

Failure of a registrant to register x-ray equipment with the Department. (2.1.1)

Failure of a registrant to notify the Department when he has sold, leased, transferred, lent, assembled, or installed x-ray equipment. (2.5.3)

Failure to notify the Department prior to operating an out-of-state x-ray machine in South Carolina. (2.8)

Failure to make notifications as required by RHB 3.25.1.

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Failure of a vendor to notify the Department of installation of equipment. (2.7.1)

Failure by a registrant to correct violations within sixty days. (1.7.3)

Failure to report misadministrations to the Department as required. (1.11)

Two or more incidents in two consecutive inspections of a registrant failing to verify that a person providing x-ray machine services or servicing is registered with the Department. (2.5.4)

Two or more incidents on two consecutive inspections of a registrant not notifying the Department within 20 days of a violation citation with regards to corrective action taken or planned to correct the violation. (1.7.2)

Minor

Failure to maintain required records including, but not limited to, patient logs, utilization logs, and technique charts.

Failure to post Department notices as required in RHB 10.2.

Failure to correctly label x-ray equipment.

1.14 Compliance with other Laws. The registrant shall comply with all other applicable federal, state and local regulations.

1.15 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 which can be given effect without the invalid provision or application, and to this end the provisions of the regulation are severable.

1.16 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.

PART II
REGISTRATION OF X-RAY MACHINES AND SERVICES

RHB 2.1 Scope. This part provides for the registration of x-ray machines, (controls and tubes), and facilities, and for the registration of persons providing x-ray machine installation, servicing, and/or services.

2.1.1 Except as specifically exempted in RHB 2.2, each person who receives, possesses, uses, or acquires an x-ray machine shall register the control and tubes of such machine with the Department in accordance with the requirements of this Part.

2.1.2 In addition to the requirements of this Part, all registrants are subject to the applicable provisions of other Parts of these regulations.

RHB 2.2 Exemptions.

2.2.1 Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

2.2.2 Television receivers, video display terminals, and computer monitors, when used without modification to their internal or external construction, are exempt from the requirements of this Part.

2.2.3 Any facility where a federal agency has exclusive jurisdiction is exempt from the requirements of this Part.

2.2.4 X-ray machines while in transit or storage incident thereto are exempt from the requirements of this Part.

RHB 2.3 Application and Review Fees.

2.3.1 Facility Application Fee. Each registrant shall pay a non-refundable application fee of sixty two dollars and fifty cents upon submission of the initial Facility Registration Approval Request form. A facility registration approval shall not be issued until payment of the application fee.

2.3.2 Shielding Plan Review Fee. Each registrant shall pay a non-refundable shielding plan review fee of sixty two dollars and fifty cents per x-ray control upon submission of any shielding plan. A shielding plan acceptance shall not be issued until payment of the review fee.

2.3.3 Vendor Application Fee. Each vendor shall pay a non-refundable application fee of sixty two-dollars and fifty cents upon submission of the initial Business Registration Approval Request form. A vendor registration approval shall not be issued until payment of the application fee.

2.3.4 Out-of-State Facility Application Fee. Any person proposing to bring an x-ray machine into the State, for any temporary use, shall pay a non-refundable application fee of sixty-two dollars and fifty cents upon submission of the initial Out-of-State Facility Form. An Out-of-State Facility approval shall not be issued until payment of the application fee.

RHB 2.4 Facility Registration Approval.

2.4.1 Fixed Installation-Fixed Facility. Any facility planning to install an x-ray producing machine in a fixed location shall meet the provisions of this Subpart.

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2.4.1.1 Prior to installation of any x-ray producing equipment, the facility where the installation will be shall submit to the Department the following information:

2.4.1.1.1 Facility Name, Location Address, and Mailing Address;

2.4.1.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.1.1.3 Type and make of x-ray equipment to be installed;

2.4.1.1.4 A shielding plan, if required by RHB 4.4 or 8.12.2;

2.4.1.1.5 The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale and/or installation, then the above information shall be provided for all companies involved.

2.4.1.2 Prior to installation of any x-ray producing equipment, the facility where the installation will be shall submit any application and shielding review fees as required by RHB 2.3.

2.4.1.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.1.4 A facility shall not install or cause to be installed any x-ray producing equipment until the Department has issued a facility registration approval.

2.4.2 Fixed Installation-Mobile Facility. Any facility planning to install an x-ray producing machine in a fixed location of a mobile facility shall meet the provisions of this Subpart.

2.4.2.1 Prior to installation of any x-ray producing equipment, the facility where the equipment will be installed shall submit to the Department the following information:

2.4.2.1.1 Facility Name and Mailing Address where correspondence may be sent;

2.4.2.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.2.1.3 Type and make of x-ray equipment to be installed;

2.4.2.1.4 An operating schedule, indicating when and where the equipment will be used;

2.4.2.1.5 A radiation area survey as required by RHB 4.4 or 8.12.2;

2.4.2.1.6 The name, address, and contact person of the company selling and installing the equipment. If more than one company is involved in the sale or installation, then the above information shall be provided for all companies involved.

2.4.2.2 Prior to installation of any x-ray producing equipment, the facility where the equipment will be installed shall submit any application and shielding review fees as required by RHB 2.3.

2.4.2.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.2.4 A facility shall not install or cause to be installed any x-ray producing equipment until the Department has issued a facility registration approval.

2.4.3 Mobile or Portable Equipment. Any facility acquiring or using mobile or portable x-ray producing equipment shall meet the provisions of this Subpart.

2.4.3.1 Prior to acquisition of any mobile x-ray producing equipment, the facility where the equipment will be used shall submit to the Department the following information:

2.4.3.1.1 Facility Name, Location Address and Mailing Address;

2.4.3.1.2 The name of the radiation safety officer, who is responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.3.1.3 Type and make of x-ray equipment to be used;

2.4.3.1.4 The name, address, and contact person of the company selling the equipment. If more than one company is involved in the sale, then the above information shall be provided for all companies involved.

2.4.3.2 Prior to acquisition of any mobile x-ray producing equipment, the facility where the equipment will be used shall submit any application and shielding review fees as required by RHB 2.3.

2.4.3.3 Upon review of the above information, the Department shall issue a facility registration approval.

2.4.3.4 A facility shall not use any x-ray producing equipment until the Department has issued a facility registration approval.

2.4.4 Out of State Facility. Any person proposing to bring an x-ray producing machine into the State, for any temporary use, shall meet the provisions of this Subpart.

2.4.4.1 Prior to entering the state, the Out of State Facility shall submit to the Department the following information:

2.4.4.1.1 Facility Name and Mailing Address where correspondence may be sent;

2.4.4.1.2 The name of the radiation safety officer responsible for radiation protection, and the individual's qualifications to serve in such a capacity;

2.4.4.1.3 Type and make of x-ray equipment to be utilized; and

2.4.4.1.4 A radiation area survey, as required by RHB 4.4 or 8.12.2.

2.4.4.2 An operating schedule, indicating when and where the equipment will be used, shall be submitted to the Department 5-days prior to equipment use in the State.

2.4.5 It shall be unlawful for any person to install x-ray producing equipment until the facility acquiring that equipment has received a facility registration approval from the Department.

RHB 2.5 Equipment Registration Requirements, Users of X-ray Machines.

2.5.1 Initial Equipment Registration. Every person who possesses an x-ray machine shall register the machine's control and tubes with the Department, within thirty days of the date of installation. Registration shall be made on the form furnished by the Department.

2.5.1.1 Upon registration of a control, the Department shall issue the facility a registration sticker to be placed on each control. The registration sticker shall be placed on the control panel in a clearly visible location.

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2.5.1.2 When a control is removed from a facility, the facility shall remove the registration sticker.

2.5.1.3 A registration sticker on a control, displaying the facility's proper name, shall be considered indicative of a facility's and a control's registration status, as required to be confirmed by RHB 2.7.2.

2.5.2 Renewal of Equipment Registration. The Department shall provide an annual re-registration statement to all registrants. The re-registration statements shall be reviewed, corrected, signed, and returned to the Department within 30 days.

2.5.3 Report of Change. The registrant shall report to the Department, within thirty days, any changes of status affecting any x-ray machine or facility. Report of a change of status shall be made in writing, and forwarded to the Department.

2.5.4 Verification of Service Representative. Each registrant shall require any person furnishing x-ray machine servicing or services as described in this Part to provide evidence that he has been registered with the Department as a vendor in accordance with these regulations.

2.5.5 Leasing of Equipment. When a facility leases x-ray equipment, it shall be the facility's responsibility to register the equipment and to ensure that the equipment is maintained to meet these regulations.

RHB 2.6 Registration Requirements-Servicing and Services (VENDOR)

2.6.1 Each person who is engaged in the business of selling, leasing or installing or offering to sell, lease or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish any equipment services in this State shall apply for registration as a vendor with the Department within thirty days following the effective dates of these regulations or thereafter prior to furnishing or offering to furnish any such services.

2.6.1.1 In-house personnel employed by a facility or corporation shall be exempt from the registration requirement, provided such personnel:

2.6.1.1.1 Shall meet the education, training, and experience requirements for the appropriate vendor Class and

2.6.1.1.2 Shall exclusively service one facility or corporation.

2.6.1.2 Documentation of education, training, and experience for in-house service personnel shall be maintained by the facility or corporation and available for Department review.

2.6.2 Application for vendor registration shall be completed on forms furnished by the Department and shall contain all information required by the Department as indicated on the forms, and accompanying instructions. This information shall include:

2.6.2.1 The name, address, and telephone number of the individual or company to be registered, along with the owner(s) of the company;

2.6.2.2 The description of the services to be provided;

2.6.2.3 The name, training, and experience of each person who provides services;

2.6.2.4 The date of the application and the signature of the individual responsible for the company;

2.6.2.5 A sample of equipment performance test procedures and forms, if registering as a Class II vendor;

2.6.2.6 A sample of a shielding plan, if registering as a Class III, Class IV, Class VII, or Class IX vendor;

2.6.2.7 Any additional information the Department determines to be necessary for evaluation of the application for registration;

2.6.3 Each person applying for registration under this Part shall specify that he has read and understands the applicable requirements of these regulations.

2.6.4 For the purpose of this section, equipment services are:

2.6.4.1 Class I - Direct sale and transfer of radiation machines and machine components to end users;

2.6.4.2 Class II - Installation or servicing of radiation machines and associated radiation machine components;

2.6.4.2.1 Class II-A - Installation of radiation machines and associated radiation machine components;

2.6.4.2.2 Class II-B - Servicing of radiation machines and associated radiation machine components;

2.6.4.2.3 Class II-C - Perform "Equipment Performance Tests" as outlined in RHB 4.2.16. Refer to Appendix F;

2.6.4.3 Class III - Diagnostic radiographic facility and shielding design;

2.6.4.4 Class IV - Diagnostic fluoroscopic facility and shielding design;

2.6.4.5 Class V - Diagnostic area radiation survey, e.g., shielding evaluation;

2.6.4.6 Class VI - Radiation instrument calibration;

2.6.4.7 Class VII - Therapeutic facility and shielding design, area radiation surveys, or calibration;

2.6.4.8 Class VIII - General health physics consulting, non-healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, facility and shielding design, area radiation surveys, and acting as the radiation safety officer;

2.6.4.9 Class IX - General health physics consulting, healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs and radiation safety training programs, facility and shielding design, area radiation surveys, equipment performance tests, and acting as the radiation safety officer; and

2.6.4.10 Such other equipment services which can affect compliance with these Regulations by a registrant, as determined by the Department.

2.6.5 Report of Change. The vendor shall notify the Department in writing, within thirty days of any changes that would render the information contained on the company and/or employee registration form no longer accurate. Changes shall include, but not be limited to, changes in employee's status, new employees, and in vendor Class or services.

2.6.6 Training and Educational Requirements for Equipment Services. Each person registered pursuant to RHB 2.6 shall be qualified by reason of education, training and experience to provide the service for which registration is requested. The following are minimum qualifications for specific types of services:

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2.6.6.1 Class I - Sales of radiation machines and machine components to end users: The applicant must certify knowledge of familiarity with the rules and regulations which govern the possession, installation and use of radiation machines in South Carolina.

2.6.6.2 Class II - A, B, or C - Installation and service of radiation machines and machine components including the making of diagnostic radiation output measurements to verify performance associated with the installation or service:

2.6.6.2.1 Documented manufacturer's equipment school of service, testing, or equivalent training;

2.6.6.2.2 Maintenance and installation for the type of machine use (e.g., dental intraoral, medical diagnostic or medical fluoroscopic) or equivalent training;

2.6.6.2.3 Training in principles of radiation protection; and a minimum of three months of experience in installation, service, and/or testing of radiation machines and machine components.

2.6.6.3 Class III - Diagnostic radiographic facility and shielding design:

2.6.6.3.1 Documented training in principles of radiation protection;

2.6.6.3.2 Documented training in shielding design; and

2.6.6.3.3 One year of experience in diagnostic radiographic facility and shielding design for the specific type of machine application.

2.6.6.4 Class IV - Diagnostic fluoroscopic facility and shielding design:

2.6.6.4.1 Documented training in principles of radiation protection;

2.6.6.4.2 Documented training in shielding design; and

2.6.6.4.3 One year of experience in diagnostic fluoroscopic facility and shielding design for the specific type of machine application.

2.6.6.5 Class V - Diagnostic area radiation survey, e.g., shielding evaluation:

2.6.6.5.1 Documented training in principles of radiation protection;

2.6.6.5.2 Documented training in shielding evaluation; and

2.6.6.5.3 One year of experience performing area radiation surveys.

2.6.6.6 Class VI - Radiation instrument calibration:

2.6.6.6.1 The applicant must possess a current radioactive materials license if instrument calibration is done utilizing radioactive materials or registration authorizing radiation instrument calibration;

2.6.6.6.2 Training in principles of radiation protection;

2.6.6.6.3 Training in operation and calibration of radiation detection and measurement instrumentation;

2.6.6.6.4 One year experience in an instrument calibration laboratory;

2.6.6.6.5 Shall submit a description of the procedures that will be utilized in performing instrument calibrations.

2.6.6.7 Class VII - Therapeutic facility and shielding design, area radiation survey, or calibration:

2.6.6.7.1 Certification by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x-ray and gamma ray physics, or certification by the American Board of Medical Physics in therapeutic radiological physics; or

2.6.6.7.2 Having the following minimum training and experience:

2.6.6.7.2.1 A Master's or a Doctoral degree in Physics, Biophysics, Radiological Physics, or Health Physics or Medical Physics; one year full-time training in therapeutic radiological physics; and

2.6.6.7.2.2 One year full-time experience in a therapeutic facility where the individual's duties involve calibration and spot checks of a medical accelerator, and includes personal calibration and spot check of at least one machine;

2.6.6.7.3 Shall submit a description of the procedures that will be utilized in performing therapeutic calibrations including a list of all guides and references to be employed.

2.6.6.7.4 Shall submit a copy of all forms, reports and documents that will be supplied to registrants; and shall submit one sample of each specific type, e.g., therapy, accelerator.

2.6.6.8 Class VIII - General health physics, non-healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, facility and shielding design, area radiation surveys, and acting as the radiation safety officer;

2.6.6.8.1 One year experience in non-healing arts facility design and area radiation surveys.

2.6.6.8.2 Baccalaureate degree in physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; or

2.6.6.8.3 Baccalaureate degree in physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years graduate training in medical or health physics; or

2.6.6.8.4 Certification by the American Board of Radiology in diagnostic radiological physics, therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in comprehensive practice, or certification by the American Board of Medical Physics.

2.6.6.9 Class IX - General health physics consulting, healing arts, e.g., independent diagnostic radiation output measurements, dose analysis, design of safety programs, and radiation safety training programs, facility and shielding design, area radiation surveys, equipment performance tests, and acting as the radiation safety officer:

2.6.6.9.1 Baccalaureate degree in a physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years of progressive experience in medical or health physics; or

2.6.6.9.2 Baccalaureate degree in a physical science (e.g., physics, chemistry or radiologic science), engineering or related field and two years graduate training in medical or health physics; or

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2.6.6.9.3 Certification by the American Board of Radiology in diagnostic radiological physics, therapeutic radiological physics, radiological physics, roentgen-ray and gamma ray physics, or x-ray and radium physics; certification by the American Board of Health Physics in comprehensive practice, or certification by the American Board of Medical Physics.

2.6.6.9.4 All training requirements of RHB 2.6.6.2, 2.6.6.3, 2.6.6.4, 2.6.6.5, 2.6.6.7, as applicable. Any person registered prior to the effective date of this regulation as a vendor of this Class shall meet the education, training, and experience requirements no later than 24 months after the effective date of these regulations.

2.6.6.10 For the purpose of RHB 2.6, the required work experience may be gained while working for a manufacturer or while working under the direct supervision of a vendor registered in the particular class.

2.6.7 Any branch office of a vendor shall be considered a separate entity and shall be registered separately pursuant to RHB 2.6.

RHB 2.7 Vendor Obligation.

2.7.1 Any person who sells, leases, transfers, lends, moves, assembles or installs x-ray machines in this State shall notify the Department within thirty days of:

2.7.1.1 The name and address of persons who have received these machines;

2.7.1.2 The manufacturer, the control and tube(s) model number, the control and tube(s) serial number of each radiation machine transferred; and

2.7.1.3 The date of transfer of each x-ray machine.

2.7.1.4 Notification to the Department shall be made on forms furnished by the Department and shall be submitted to the Department each month by Class I and Class II vendors regardless of whether x-ray equipment was sold that month.

2.7.2 No person shall make, sell, lease, transfer, lend, maintain, calibrate, test, repair, assemble, reassemble, reinstall or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used meet the requirements of these regulations. Each vendor shall ensure that the facility it is providing with services or supplies is registered with the Department prior to providing services or supplies.

2.7.2.1 Any vendor acting as a Radiation Safety Officer on behalf of a registered facility shall be registered as a Class VIII or IX vendor and shall meet all applicable parts of this regulation.

2.7.3 Each vendor shall maintain records for review by the Department. These records shall include, at a minimum:

2.7.3.1 All information required by RHB 2.7.

2.7.3.2 A copy of the shielding plan, if one was required, and if provided by that vendor;

2.7.3.3 Tests performed at the time of installation to ensure that the equipment complies with these regulations. A copy of these results shall be provided to the registrant at the time of installation;

2.7.3.4 Records of any routine maintenance, repair, alterations, or reassembly of x-ray equipment. Records of maintenance, repair, alterations, or reassemblies shall include the date that the service was performed and the

legible signature of the person performing the service. A copy of these records shall be provided to the registrant at the time the service is provided;

2.7.3.5 Names of all employees and their dates of employment with the vendor. Records shall also be maintained of training provided to the employees during their term of employment.

2.7.3.6 Records of equipment performance testing, including data collected during the testing.

2.7.3.6.1 A copy of the equipment performance test must be provided to the facility either at the time of testing or within thirty days of the testing date.

2.7.3.6.2 The report of equipment performance testing shall include the testing of all items listed in Part IV, Appendix F, except as noted in the Appendix.

2.7.3.6.3 The equipment performance test record provided to the facility must clearly indicate all equipment parameters tested and must include a designation, such as “Pass/Fail” or “Compliant/Non-compliant”, that is easily understandable by the facility. Use of any designation other than “Pass/Fail” or “Compliant/Non-compliant” shall be approved by the Department prior to use on equipment performance reports of testing.

2.7.3.6.4 The equipment performance test record shall include a summary of findings and recommendations for necessary improvements and/or corrective actions.

2.7.3.6.5 The record of equipment performance shall include the date that the testing was performed; the legible signature of the person performing the service; manufacturer, model number, serial number, and the calibration date of the instrument used to perform the test; the manufacturer, serial number, model number, and location of the equipment.

2.7.4 All records required by this Part shall be maintained by the vendor until their disposal is authorized by the Department. All records shall be accurate and factual.

2.7.5 Each vendor shall maintain sufficient calibrated and operable instruments to perform the testing appropriate to the class in which the vendor is registered. Instruments must be calibrated with sources consistent with the conditions under which they are used. Records shall be maintained of the calibrations performed on instrumentation used for testing. All provisions of RHB 1.4.4 apply.

RHB 2.8 Out of State Facilities.

2.8.1 No person shall bring any radiation machine into the state, for any temporary use, unless such person has given a written notice to the agency at least five working days before the machine is to be used in the state. The notice shall include the type of radiation machine; the nature, duration, and scope of use; and the exact location(s) where the radiation machine is to be used. If, for a specific case, the five working day period would impose an undue hardship on the person, he may, upon application to the agency, obtain permission to proceed sooner.

2.8.2 Such facilities shall meet all applicable parts of this regulation.

RHB 2.9 Modification, Revocation, Termination of Registrants.

2.9.1 The terms and conditions of all registrations are subject to amendment, revision, or modification and all registrations are subject to suspension or revocation by reason of:

2.9.1.1 Amendments to the Act;

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2.9.1.2 Rules and regulations adopted pursuant to provisions of the Act; or

2.9.1.3 Orders issued by the Department.

2.9.2 Any registration may be revoked, suspended, or modified in whole or part:

2.9.2.1 For any material false statement in the application or in any statement of fact required by provisions of this part;

2.9.2.2 Because of any statement of fact, any report, record, inspection, or other means which would warrant the Department to refuse to grant a registration on original application; or

2.9.2.3 For violations of, or failure to observe any of the terms and conditions of the Act, the registration, these regulations, or any order of the Department.

2.9.3 Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, prior to the institution of proceedings for modification, revocation, or suspension of a registrant, the Department shall:

2.9.3.1 Call to the attention of the registrant in writing the facts or conduct which may warrant these actions, and

2.9.3.2 Provide an opportunity for the registrant to demonstrate or achieve compliance with all regulations.

2.9.4 The Department may terminate a registration upon written request submitted by the registrant to the Department.

2.9.5 The provisions of this part shall apply to both registration of x-ray equipment and registration of x-ray services (vendors).

RHB 2.10 Annual Fees.

2.10.1 Any person issued or granted a registration for the possession and use of x-ray machine(s) shall pay an annual registration fee per machine tube. Vendors and Out of State Facilities shall pay an annual flat fee. The annual registration fee shall be due on January 15 of each year.

2.10.2 Persons failing to pay the fees required by RHB 2.10.1 by March 15 of that year shall also pay a penalty of Fifty Dollars. If the required fees are not paid by April 15 of that year, the registrant shall be notified by certified mail to be sent to his last known address that his registration is revoked, and that any activities permitted under the authority of the registration must cease immediately.

2.10.3 A registrant suspended for failure to pay the required fee under RHB 2.10.2 may be reinstated by the Department upon payment of the required fee, the penalty of Fifty Dollars and an additional penalty of One Hundred Dollars, if the registrant is otherwise in good standing and presents to the Department a satisfactory explanation for his failure to pay the required fee.

2.10.4 Payment of fees shall be made in accordance with the instructions of a "Statement of Fees Due" issued annually by the Department.

2.10.5 Fees required by RHB 2.10.1 for an x-ray machine, out of state facility, or vendor registration which is issued during a calendar year shall be prorated for the remainder of that year based on the date of issuance of the registration.

2.10.6 Schedule of Fees. Chapter 7, Nuclear Energy, Article 1, Atomic Energy and Radiation Control Act, Section 13-7-45, (A)(1) requires the Department to establish a schedule for the collection of annual fees for the licensing, registration, and certification of users of sources of ionizing radiation.

Type of Equipment	Fee
Radiographic	\$131
Fluoroscopic	\$131
Combination Rad/Fluoro	\$231
Dental	\$93.50
Therapy (medical)	\$156
Diffraction	\$99.75
X-ray Fluorescence	\$99.75
Accelerator (industrial)	\$156
Electron Microscope	\$68.50
Spectrograph	\$99.75
Cephalometer	\$131
Panoramic	\$81
Cabinet X-ray	\$124.75
CT Scanner, and/or PET/CT, SPECT, Dental CT	\$131
C-Arm Fluoroscopic	\$131
Mammography	(See RHB 5.6)
Stereotactic Mammography	\$131
Baggage Checker	\$99.75
Bone Densitometer	\$131
Lithotripter	\$131
Simulator	\$131
Other	\$131
Out of State Facilities	\$187.25
Vendors and Installers	\$187.25

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PART III STANDARDS FOR PROTECTION AGAINST RADIATION

RHB 3.1 Purpose and Scope

3.1.1 This Part establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to registrations issued by the Department pursuant to these regulations.

3.1.2 The requirements of this Part are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this Part. However, nothing in this Part shall be construed as limiting actions that may be necessary to protect health and safety.

3.1.3 Except as specifically provided in other Parts of these regulations, this Part applies to persons registered by the Department to receive, possess, use, install, service, transfer, or dispose of sources of radiation. The limits in this Part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

RHB 3.2 Implementation

3.2.1 Any existing registration condition that is more restrictive than this Part remains in force until there is an amendment of the registration.

3.2.2 If a registration condition exempts a registrant from a provision of a previous Part III in effect on or before the effective date of these regulations, it also exempts the registrant from the corresponding provision of this Part III.

3.2.3 If a registration condition cites provisions of a previous Part III in effect prior to the effective date of these regulations, which do not correspond to any provisions of this Part, the registration condition remains in force until there is an amendment or renewal of the registration that modifies or removes this condition.

3.2.4 For determining the doses specified in this Part, a dose from x-rays up to 3 MeV may be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate.

RHB 3.3 Authority and Responsibility for the Radiation Protection Programs

3.3.1 Each registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this Part. See RHB 3.18 for record keeping requirements relating to these programs.

3.3.2 The registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

3.3.3 The registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

3.3.4 The registrant shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

3.3.4.1 Identify radiation safety problems;

3.3.4.2 Initiate, recommend, or provide corrective actions;

3.3.4.3 Stop unsafe operations; and,

3.3.4.4 Verify implementation of corrective actions.

3.3.5 The registrant shall establish either monthly or quarterly investigative limits to ensure individuals will not exceed annual occupational exposure limits.

RHB 3.4 Occupational Dose Limits for Adults.

3.4.1 The registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to RHB 3.6, to the following dose limits:

3.4.1.1 An annual limit, which is the more limiting of:

3.4.1.1.1 The total effective dose equivalent being equal to 5 rem (0.05 Sv); or

3.4.1.1.2 The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv).

3.4.1.2 The annual limits to the lens of the eye, to the skin, and to the extremities which are:

3.4.1.2.1 An eye dose equivalent of 15 rem (0.15 Sv), and

3.4.1.2.2 A shallow dose equivalent of 50 rem (0.5 Sv) to the skin or to any extremity.

3.4.1.3 Any individual exceeding his/her annual occupational exposure limit shall not be exposed to additional occupational radiation for the remainder of the calendar year.

3.4.2 Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. Dose limits for planned special exposures are provided in RHB 3.6.

3.4.3 The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure. The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

3.4.4 If an occupationally exposed adult is likely to receive in one year, from sources external to the body, a dose in excess of fifty percent (50%) of the limits in RHB 3.4.1, the registrant shall monitor all of the individual's occupationally received doses, and shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

RHB 3.5 Compliance with Requirements for Summation of External and Internal Doses. If a registrant is also a radioactive material licensee of the Department, all regulations of Title A pertaining to dose limits are applicable. Nothing in this Part relieves a registrant from complying with Title A.

RHB 3.6 Planned Special Exposures. A registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the dose received under the limits specified in RHB 3.4 provided that each of the following conditions is satisfied:

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3.6.1 The registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical.

3.6.2 The registrant, and employer if the employer is not the registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

3.6.3 Before a planned special exposure, the registrant ensures that each individual involved is:

3.6.3.1 Informed of the purpose of the planned operation; and

3.6.3.2 Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

3.6.3.3 Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

3.6.4 Prior to permitting an individual to participate in a planned special exposure, the registrant ascertains prior doses as required by RHB 3.20 during the lifetime of the individual for each individual involved.

3.6.5 Subject to RHB 3.4.2, the registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

3.6.5.1 The numerical values of any of the dose limits in RHB 3.4.1 in any year; and

3.6.5.2 Five times the annual dose limits in RHB 3.4.1 during the individual's lifetime.

3.6.6 The registrant maintains records of the conduct of a planned special exposure in accordance with RHB 3.21 and submits a written report in accordance with RHB 3.27.

3.6.7 The registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to RHB 3.4.2.

RHB 3.7 Occupational Dose Limits for Minors. The annual occupational dose limits for minors are ten (10) percent of the annual occupational dose limits specified for adult workers in RHB 3.4.

RHB 3.8 Dose to an Embryo/Fetus.

3.8.1 The registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). See RHB 3.22 for record keeping requirements.

3.8.2 The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in RHB 3.8.1.

3.8.3 The dose to an embryo/fetus shall be taken as the sum of:

3.8.3.1 The deep dose equivalent to the declared pregnant woman; and

3.8.3.2 The dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

3.8.4 If by the time the woman declares pregnancy to the registrant, the dose to the embryo/fetus has exceeded 0.45 rem (4.5 mSv), the registrant shall be deemed to be in compliance with RHB 3.8.1 if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

RHB 3.9 Dose Limits for Individual Members of the Public

3.9.1 Each registrant shall conduct operations so that:

3.9.1.1 The total effective dose equivalent to individual members of the public from the registered operation does not exceed 0.1 rem (1 mSv) in a year, and

3.9.1.2 The dose in any unrestricted area from external sources does not exceed 0.002 rem (0.02 mSv) in any one hour.

3.9.2 If the registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

3.9.3 A registrant, or an applicant for a registration may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). This application shall include the following information:

3.9.3.1 Demonstration of the need for and the expected duration of operations in excess of the limit in RHB 3.9.1; and

3.9.3.2 The registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

3.9.3.3 The procedures to be followed to maintain the dose ALARA.

3.9.4 Retrofit shall not be required for locations within facilities where only radiation machines existed prior to the effective date of these Regulations, and met the previous requirements of 0.5 rem (5 mSv) in a year.

RHB 3.10 Compliance with Dose Limits for Individual Members of the Public.

3.10.1 The registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in RHB 3.9.

3.10.2 A registrant shall show compliance with the annual dose limit in RHB 3.9 by:

3.10.2.1 Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit; or

3.10.2.2 Demonstrating that if an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

RHB 3.11 Surveys

3.11.1 Each registrant shall make, or cause to be made, surveys that:

3.11.1.1 Are necessary for the registrant to comply with this Part; and

3.11.1.2 Are necessary under the circumstances to evaluate:

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3.11.1.2.1 Radiation levels; and

3.11.1.2.2 The potential radiological hazards that could be present.

3.11.2 The registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.

RHB 3.12 Personnel Monitoring

3.12.1 All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with RHB 3.4, with other applicable provisions of these regulations, or with conditions specified in a registration shall be processed and evaluated by a dosimetry processor:

3.12.1.1 Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

3.12.1.2 Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

3.12.2 Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

3.12.3 Personnel Monitoring Devices.

3.12.3.1 Personnel Monitoring (or other dosimeters approved by the Department) shall meet the following requirements:

3.12.3.1.1 The monitoring device shall be assigned to and worn only by one individual; and

3.12.3.1.2 When a lead apron is worn, the monitoring device shall be worn at the collar, outside the apron; and

3.12.3.1.3 If a personnel monitoring device is lost or damaged, the worker shall cease work immediately until a replacement badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the badge. In the event a replacement badge is not available, the Radiation Safety Officer shall be contact immediately to evaluate the probable radiation exposure to the worker until a replacement device is received; and

3.12.3.1.4 The Registrant shall ensure that personnel monitoring devices are returned within 45 days of the end of the monitoring period. Direct read dosimeters must be read according to the manufacturer specifications and the results from the readings recorded and available for departmental review; and

3.12.3.1.5 Documentation providing explanation of any late, absent or unused personnel monitoring devices must be recorded and available for Departmental review; and

3.12.3.1.6 Personnel monitoring devices must be worn in accordance with manufacturer guidelines.

3.12.3.2 Control badges are used to measure background radiation. They shall be stored away from the radiation area. Control badges are not to be worn as a personnel monitoring device. Ensure the control badge is returned with the lot of badges with which it was issued.

3.12.3.3 Upon departmental approval, area monitors may be used in place of personnel monitoring devices.

3.12.4 Each registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum:

3.12.4.1 Each registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

3.12.4.1.1 Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in RHB 3.4; and

3.12.4.1.2 Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in RHB 3.7 or 3.8; and

3.12.4.1.3 Individuals entering a high or very high radiation area.

3.12.4.1.3.1 Personnel monitoring devices shall be worn appropriately by personnel working with medical fluoroscopic equipment.

3.12.4.1.4 Such other individuals as the Department deems necessary.

3.12.5 Determination of Dose

3.12.5.1 When two monitoring devices are worn (one outside and one under the apron) the one outside will be considered the permanent record for the individual.

3.12.5.2 The Radiation Safety Officer may give consideration that an Effective Dose Equivalent be used as the permanent record provided that all provisions of RHB 3.3 apply. The Radiation Safety Officer must ensure individuals utilizing the Effective Dose Equivalent shall meet the following requirements:

3.12.5.2.1 Protective equipment must be used. The use of protective equipment shall be routinely documented in each room and this documentation shall periodically be reviewed by the Radiation Safety Officer, or other responsible persons to determine if it is being completed correctly.

3.12.5.2.2 Periodic visits must be made by the radiation safety officer or his designee for personal observation adherence to proper radiation safety practices. Documentation of these reviews must be available for Departmental review.

3.12.5.2.3 The Department may immediately revoke the use of the Effective Dose Equivalent upon determination that a violation of RHB 3.12.5 has occurred.

3.12.5.3 Adjustments to the dose of permanent record shall be determined by the Radiation Safety Officer prior to any changes to the record. Records of these actions shall be maintained for Departmental review.

3.12.6 When an individual who has been given responsibility that involves occupational exposure to x-rays declares that she is pregnant, the employer must, at her request, provide her with an additional personnel monitoring device to be worn on the trunk underneath the leaded apron, when such apron is worn. The fetal badge shall be processed and evaluated on a monthly basis, at a minimum.

RHB 3.13 Control of Access to High Radiation Areas.

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3.13.1 The registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

3.13.1.1 A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

3.13.1.2 A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

3.13.1.3 Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

3.13.2 In place of the controls required by RHB 3.13.1 for a high radiation area, the registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

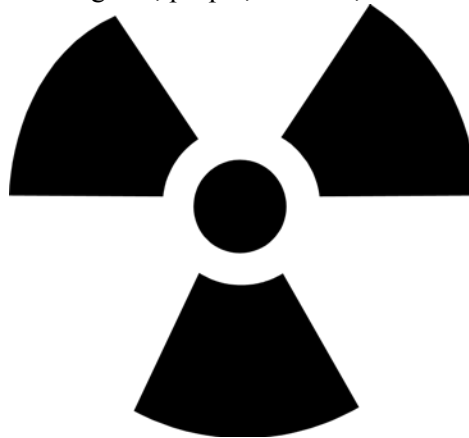
3.13.3 The registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

3.13.4 The registrant shall establish the controls required by RHB 3.13.1 and 3.13.3 in a way that does not prevent individuals from leaving a high radiation area.

RHB 3.14 Control of Access to Very High Radiation Areas. In addition to the requirements in RHB 3.13, the registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rad (5 Gy) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation.

RHB 3.15 Caution Signs.

3.15.1 The radiation symbols prescribed by this regulation shall be the conventional three-bladed design as shown. The cross-hatched area shall be magenta, purple, or black, and the background shall be yellow.



3.15.2 Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in this Part, the registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

RHB 3.16 Posting Requirements.

3.16.1 Posting of Radiation Areas. The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

3.16.2 Posting of High Radiation Areas. The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

3.16.3 Posting of Very High Radiation Areas. The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

3.16.4 Exceptions to Posting Requirements. A registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

3.16.4.1 The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Part; and

3.16.4.2 The area or room is subject to the registrant's control.

RHB 3.17 General Provisions for Records.

3.17.1 Each registrant shall use the SI units becquerel, gray, sievert and coulomb per kilogram, or the special units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Part.

3.17.2 The registrant shall make a clear distinction among the quantities entered on the records required by this Part, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent, deep dose equivalent, or committed effective dose equivalent.

3.17.3 Form of Records. Each record required by this Part shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The registrant shall maintain adequate safeguards against tampering with and loss of records.

RHB 3.18 Records of Radiation Protection Programs.

3.18.1 Each registrant shall maintain records of the radiation protection program, including:

3.18.1.1 The provisions of the program; and

3.18.1.2 Audits and other reviews of program content and implementation.

3.18.2 The registrant shall retain the records required by RHB 3.18.1.1 until the Department terminates each pertinent registration requiring the record. The registrant shall retain the records required by RHB 3.18.1.2 for 3 years after the record is made.

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RHB 3.19 Records of Surveys.

3.19.1 Each registrant shall maintain records showing the results of surveys and calibrations required by RHB 3.11. The registrant shall retain these records for 5 years after the record is made.

3.19.2 The registrant shall retain records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents for 5 years after the termination of the registration.

RHB 3.20 Determination and Records of Prior Occupational Dose.

3.20.1 For each individual who may enter the registrant's restricted or controlled area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to RHB 3.12, the registrant shall determine the occupational radiation dose received during the current year.

3.20.2 Prior to permitting an individual to participate in a planned special exposure, the registrant shall determine:

3.20.2.1 The internal and external doses from all previous planned special exposures; and

3.20.2.2 All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

3.20.2.3 All lifetime cumulative occupational radiation dose.

3.20.3 In complying with the requirements of RHB 3.20.1, a registrant may:

3.20.3.1 Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

3.20.3.2 Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, telegram, facsimile, letter, or other electronic means. The registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

3.20.4 The registrant shall record the exposure history, as required by RHB 3.20.1, on a clear and legible record, of all the information required. The record shall show each period in which the individual received occupational exposure to radiation. For each period for which the registrant obtains reports, the registrant shall use the dose shown in the report in preparing the record. For any period in which the registrant does not obtain a report, the registrant shall place a notation on the record indicating the periods of time for which data are not available.

3.20.5 If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant shall assume:

3.20.5.1 In establishing administrative controls pursuant to RHB 3.4.4 for the current year, that the allowable dose limit for the individual is reduced by 1.25 rem (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

3.20.5.2 That the individual is not available for planned special exposures.

3.20.6 The registrant shall retain the records of prior occupational dose and exposure history until the Department terminates each pertinent registration requiring this record. The registrant shall retain records for 5 years after the termination of the registration.

RHB 3.21 Records of Planned Special Exposures.

3.21.1 For each use of the provisions of RHB 3.6 for planned special exposures, the registrant shall maintain records that describe:

3.21.1.1 The exceptional circumstances requiring the use of a planned special exposure; and

3.21.1.2 The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

3.21.1.3 What actions were necessary; and

3.21.1.4 Why the actions were necessary; and

3.21.1.5 What precautions were taken to assure that doses were maintained ALARA; and

3.21.1.6 What individual and collective doses were expected to result; and

3.21.1.7 The doses actually received in the planned special exposure.

3.21.2 The registrant shall retain the records until the Department terminates each pertinent registration requiring these records.

RHB 3.22 Records of Individual Monitoring Results.

3.22.1 Record keeping Requirement. Each registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RHB 3.12, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before the effective date of this Part need not be changed. These records shall include the deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities.

3.22.2 Record keeping Frequency. The registrant shall make entries of the records specified in RHB 3.22.1 at intervals not to exceed 1 year.

3.22.3 Record keeping Format. The registrant shall maintain the records specified in RHB 3.22.1.

3.22.4 The registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

3.22.5 The registrant shall retain each required form or record until the Department terminates each pertinent registration requiring the record.

RHB 3.23 Records of Dose to Individual Members of the Public.

3.23.1 Each registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public in RHB 3.10.

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3.23.2 The registrant shall retain the records required by RHB 3.23.1 until the Department terminates each pertinent registration requiring the record.

RHB 3.24 Notification of Incidents.

3.24.1 Immediate Notification. Notwithstanding other requirements for notification, each registrant shall immediately report each event involving a source of radiation possessed by the registrant that may have caused or threatens to cause an individual to receive:

3.24.1.1 A total effective dose equivalent of 25 rem (0.25 Sv) or more; or

3.24.1.2 An eye dose equivalent of 75 rem (0.75 Sv) or more; or

3.24.1.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 250 rad (2.5 Gy) or more; or

3.24.2 Twenty-Four Hour Notification. Each registrant shall, within 24 hours of discovery of the event, report to the Department each event that may have caused, or threatens to cause, an individual to receive, in a period of 24 hours:

3.24.2.1 A total effective dose equivalent exceeding 5 rem (0.05 Sv); or

3.24.2.2 An eye dose equivalent exceeding 15 rem (0.15 Sv); or

3.24.2.3 A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 50 rem (0.5 Sv); or

3.24.3 The registrant shall prepare each report filed with the Department pursuant to this Part so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

3.24.4 Registrants shall make the reports required by this Part to the Department by telephone, telegram, mailgram, or facsimile to the Department.

3.24.5 The provisions of this Part do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to RHB 3.27.

RHB 3.25 Reports of Exposures and Radiation Levels Exceeding the Limits.

3.25.1 In addition to the notification required by RHB 3.25, each registrant shall submit a written report within 30 days after learning of any of the following occurrences:

3.25.1.1 Any incident for which notification is required by RHB 3.25;

3.25.1.2 Doses in excess of any of the following:

3.25.1.2.1 The occupational dose limits for adults in RHB 3.4;

3.25.1.2.2 The occupational dose limits for a minor in RHB 3.7;

3.25.1.2.3 The limits for an embryo/fetus of a declared pregnant woman in RHB 3.8; or

3.25.1.2.4 The limits for an individual member of the public in RHB 3.9.

3.25.2 The written report shall include the following:

3.25.2.1 A description of the extent of exposure of individuals to radiation, including, as appropriate:

3.25.2.1.1 Estimates of each individual's dose; and

3.25.2.1.2 The levels of radiation involved; and

3.25.2.1.3 The cause of the elevated exposures or dose rates; and

3.25.2.1.4 Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits.

3.25.2.2 For each individual exposed: the name and date of birth. With respect to the limit for the embryo/fetus in RHB 3.8, the identifying information shall be that of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

3.25.3 Reports made by registrants in response to the requirements of this Part shall be addressed to the department as specified in RHB 1.12.

RHB 3.26 Reports of Planned Special Exposures. The registrant shall submit a written report to the Department within 30 days following any planned special exposure conducted in accordance with RHB 3.6, informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RHB 3.21.

RHB 3.27 Reports of Individual Monitoring. The Department may require by registration condition, or order pursuant to RHB 1.6.1, annual reports of the results of individual monitoring carried out by the registrant for each individual for whom monitoring was required by RHB 3.12.

RHB 3.28 Notifications and Reports to Individuals.

3.28.1 Requirements for notification and reports to individuals of exposure to radiation are specified in RHB 10.4.

3.28.2 When a registrant is required pursuant to RHB 3.26 to report to the Department any exposure of an individual to radiation, the registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Department, and shall comply with the provisions of RHB 10.4.

RHB 3.29 Storage and Control of Radiation Sources

3.29.1 **Security of Stored Sources of Radiation.** The registrant shall secure from unauthorized removal or access sources of radiation that are stored in controlled or unrestricted areas.

3.29.2 **Control of Sources of Radiation not in Storage.** The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

RHB 3.30 Reports of Stolen, Lost, or Missing Radiation Sources.

3.30.1 **Telephone Reports.** Each registrant shall report to the Department by telephone, immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

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3.30.2 Written Reports. Each registrant required to make a report pursuant to RHB 3.31.1 shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

3.30.2.1 A description of the registered source of radiation involved, including the manufacturer, model and serial number, type and maximum energy of radiation emitted;

3.30.2.2 A description of the circumstances under which the loss or theft occurred; and

3.30.2.3 A statement of disposition, or probable disposition, of the registered source of radiation involved; and

3.30.2.4 Actions that have been taken, or will be taken, to recover the source of radiation; and

3.30.2.5 Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of registered sources of radiation.

3.30.3 Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

PART IV
USE OF X-RAY IN THE HEALTH PROFESSIONS

RHB 4.1 Scope. This part establishes requirements for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine.

RHB 4.2 General Safety Provisions.

4.2.1 An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes if so directed by the Department.

4.2.2 The registrant shall assure that all X-ray machines under his control are operated only by a radiologic technologist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association, or a licensed practitioner. For the purpose of this Part, a radiologic technologist is defined as a person who is a limited practice radiographer, radiographer, podiatric limited practice radiographer or limited chest radiographer certified by the American Registry of Radiologic Technologists or who is certified by the South Carolina Radiation Quality Standards Association or who has obtained a certificate acceptable to the South Carolina Radiation Quality Standards Association. A person who applies ionizing radiation to humans or performs x-ray exam setups, including, but not limited to, patient positioning and technique selection shall be considered a radiologic technologist.

4.2.2.1 No person other than a licensed practitioner or a radiologic technologist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for diagnostic purposes.

4.2.2.2 No person shall employ or designate as a radiologic technologist a person who does not hold a current, valid certificate issued by the South Carolina Radiation Quality Standards Association.

4.2.2.3 No person holding a certificate issued by the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for diagnostic purposes unless under the direction and supervision of a licensed practitioner and unless so directed by prescription of a licensed practitioner.

4.2.2.4 No person who is not certified by the South Carolina Radiation Quality Standards Association shall take, use, or exhibit the title of "limited practice radiographer", "podiatric limited practice radiographer", "limited chest radiographer", or "radiographer" or any other title, sign, display, or declaration that tends to lead the public to believe that the person is authorized to apply ionizing radiation on humans for diagnostic purposes.

4.2.2.5 A student enrolled in and attending a school or college of medicine, osteopathy, chiropractic, podiatry, radiologic technology, or a curriculum approved by the South Carolina Radiation Quality Standards Association, or a resident in an approved graduate education program of medicine, osteopathy, chiropractic, or podiatry may apply ionizing radiation to humans without a certificate from the South Carolina Radiation Quality Standards Association, as long as the student or resident is under the supervision of a licensed practitioner or direct supervision of a certified radiologic technologist appropriately trained to supervise the specific procedure.

4.2.2.6 The registrant shall display each operator's current South Carolina Radiation Quality Standards Association certificate or the registrant may post a notice to the public that these certificates are available for review upon request. The certificate or posting shall be displayed in public view, not obstructed by any barrier, equipment, or other object.

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4.2.2.7 The registrant shall ensure that each operator has received facility specific training to include the equipment and operating conditions. Documentation of this training for each operator shall be made available for Departmental review.

4.2.2.8 Dentists and their auxiliaries who meet the requirements of the South Carolina Dental Practice Act are exempt from the requirements of 4.2.2.1 through 4.2.2.6.

4.2.3 The operator shall be able to demonstrate familiarity and competence with the facility's operating conditions.

4.2.4 X-ray producing machines and associated equipment shall be maintained in such a condition to ensure that the patient and staff are not exposed to radiation unnecessarily.

4.2.5 If an x-ray system is identified as not being in compliance with the provisions of these regulations and cannot meet the regulations, or if the registrant is unwilling to make corrections, and if that system is accessible for use, it shall be rendered inoperable (i.e. dismantle the x-ray source from the source support assembly) if so ordered by the Department.

4.2.6 For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include:

4.2.6.1 Patient's body part and anatomical size, or body part thickness or age (for pediatrics), versus technique factors to be used;

4.2.6.2 Source to image receptor distance (SID) to be used (except for dental intra-oral radiography) and

4.2.6.3 If an AEC system is operated in a manual mode, the technique chart shall specify the requirements of RHB 4.2.6.1 and RHB 4.2.6.2.

4.2.6.4 The technique chart shall accurately reflect techniques currently in use at the facility.

4.2.7 A sign shall be posted so as to be easily seen by the patient to the effect that if there is a pregnancy or the possibility of a pregnancy, the physician shall be notified.

4.2.8 The effectiveness of protective equipment and apparel shall not be impaired. Lead aprons and gloves shall be checked at least annually for cracks and holes that could compromise the radiation protection it provides. This testing shall be documented. Records of this testing shall be kept two years, or until the next Department inspection, whichever is later.

4.2.9 Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure other than the patient being examined.

4.2.9.1 All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by not less than 0.5 mm lead equivalent material.

4.2.9.2 The x-ray operator, other staff, and ancillary persons shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent material.

4.2.9.3 Persons who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent and when feasible shall be so positioned that the nearest portion of the body is a least 2 meters from both the tube head and the nearest edge of the image receptor.

4.2.9.4 When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one quarter of the maximum permissible dose as defined in RHB 3.4 of these regulations, additional protective devices may be required by the Department.

4.2.10 Shielding of not less than 0.5 mm lead equivalent material shall be used for patients during x-ray procedures except in cases where the shielding would interfere with the diagnostic image desired.

4.2.11 Individuals shall not be exposed to the useful beam of electronically produced ionizing radiation except for healing arts purposes, and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

4.2.11.1 Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided. Demonstrations or training on new x-ray equipment must be performed with proper protection of the observers and operator(s). Phantoms, not humans, must be used for demonstrations and training.

4.2.11.2 Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix A of this part. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified within 15 days. Approval to conduct a healing arts screening program shall be renewed on an annual basis if deemed necessary by the Department.

4.2.12 When a patient or film must be provided with auxiliary support during a radiation exposure:

4.2.12.1 Mechanical holding devices shall be used when the technique permits.

4.2.12.2 The facility shall indicate the requirements for selecting a holder, and the procedure the holder shall follow.

4.2.12.3 The human holder shall be instructed in personal radiation safety and shall be protected as required by 4.2.9.

4.2.12.4 No person shall be used routinely to hold patients or film. All requirements of RHB 4.2.14 and 4.2.15 apply.

4.2.12.5 In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material.

4.2.12.6 When practical, a pregnant female shall not be used to hold film or patients.

4.2.12.7 Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved in x-ray operations who are not otherwise shielded.

4.2.13 Procedures and auxiliary equipment designed to minimize patient and personnel exposure shall be used.

4.2.13.1 The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging. The film cassettes shall provide good contact between the intensifying screens and the film.

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4.2.13.2 The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality. Appendix D provides patient exposures that are typical of good practices. These shall be used by the registrant in evaluating patient exposure.

4.2.13.3 Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation. Portable or mobile dental equipment, not to include handheld, shall be exempt from this regulation.

4.2.13.4 Radiologic technologists performing fluoroscopy as a localizing procedure shall be monitored by the supervising radiologist who is personally and immediately available.

4.2.14 Personnel Monitoring

4.2.14.1 All persons who are associated with the operation of an X-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses which are stated in RHB 3.4. In addition, the following requirements are made:

4.2.14.1.1 When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such device shall be utilized as follows:

4.2.14.1.2 When an apron is worn, and one monitoring device is worn, the monitoring device shall be worn at the collar outside of the apron. If more than one monitoring device is worn, the devices shall be worn in accordance with RHB 3.12.5.

4.2.14.1.3 The dose to the whole body based on the maximum dose attributed to any one critical organ shall be recorded in the reports required by RHB 3.22. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

4.2.14.2 Exposure of a personnel monitoring device to falsely indicate a dose delivered to an individual is prohibited.

4.2.14.3 When an individual who has been given responsibility that involves occupational exposure to x-rays declares that she is pregnant, the employer must, at her request, provide her with an additional personnel monitoring device to be worn on the trunk underneath the leaded apron, when such apron is worn.

4.2.15 X-ray Log.

4.2.15.1 Each facility shall keep an x-ray log containing the patient's name; the type of examination, given by title as denoted on the technique chart; identification of the operator performing the examination; and the dates the examinations were performed.

4.2.15.2 When the examination is performed using any type of fluoroscopy, the log shall include a record of the amount of time that fluoroscopy was performed or the number of times that the cumulative timer was reset. The fluoroscopy time is not required to be recorded for radiation therapy simulation units or instrument guided radiation therapy units.

4.2.15.3 X-ray log records shall be maintained for two years or until the next Department inspection, whichever is later.

4.2.15.4 Logs are not required for dental or veterinary x-ray equipment.

4.2.16 Quality Assurance

4.2.16.1 Each registrant covered under RHB 4.5 through 4.12 must have "Equipment Performance Tests" performed on each x-ray unit. The registrant is required to meet the minimum performance criteria and test frequency. Facilities utilizing x-ray equipment for teaching or demonstration purposes only are exempt from this Part. Appendix F provides the required minimum performance criteria that must be tested. Equipment performance tests results must include numerical data. Items found to be non-compliant during such testing shall be corrected within sixty (60) days of receipt of the report. Records showing the test results and the correction of any non-compliant items found must be retained for five years or until the next Department inspection, whichever is later. Equipment performance tests are to be performed:

4.2.16.1.1 At the time installation at all facilities, including veterinary facilities, or

4.2.16.1.2 Within thirty (30) days of installation, provided that the manufacturer's specified testing is performed at the time of installation and before patient use.

4.2.16.1.3 At the following specified intervals thereafter:

4.2.16.1.3.1 Dental intraoral and dental extraoral units shall be tested every two years. Dental computed tomography and dental handheld units shall be tested annually.

4.2.16.1.3.2 All medical x-ray equipment, including fluoroscopic, computed tomography, and radiation therapy simulators, shall be tested annually. Self calibrating bone densitometry systems are exempt from this requirement. Mammography units shall meet the requirements of Part V.

4.2.16.1.3.3 Veterinary facilities are required to have equipment performance tests performed at the time of installation, every five years, and at any time the Department deems necessary.

4.2.16.1.4 On any unit expected to remain at a facility for more than thirty (30) calendar days. If a unit is expected to remain at a facility for less than thirty (30) calendar days, the manufacturer's specified testing must be performed, at a minimum, prior to patient use. Mammography units shall meet the requirements of Part V.

4.2.16.2 The darkroom shall be light tight to the dark adapted eye and use proper safelighting such that a film exposed to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

4.2.16.3 If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast the grid shall:

4.2.16.3.1 Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray,

4.2.16.3.2 If of the focused type, be of the proper focal distance for the SID's being used.

4.2.16.4 Repeat Analysis.

4.2.16.4.1 Each registrant shall establish a repeat analysis program. An analysis of repeats shall include, at a minimum, the overall repeat rate and the causes for the repeats.

4.2.16.4.2 The repeat analysis shall be done at least quarterly. Records shall be maintained for two years or until the next Department inspection, whichever is later.

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4.2.16.4.3 Facilities with a single operator may document reasons for repeats on the patient log in lieu of a repeat analysis rate.

4.2.16.4.4 Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement.

4.2.17 X-ray Film Processing. Each installation using a radiographic x-ray system and using analog imaging systems (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

4.2.17.1 Manual Film Processing Systems

4.2.17.1.1 Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

4.2.17.1.2 A dedicated darkroom thermometer shall be used. The thermometer shall be used to adjust the film processing time according to solution temperature.

4.2.17.1.3 A dedicated darkroom timer with an adjustable preset function shall be used. The timer shall be used to adjust film processing time according to solution temperature.

4.2.17.1.4 Documentation shall be kept of the frequency at which film processing chemicals are changed. At a minimum, the interval as recommended by the chemical manufacturer shall be used.

4.2.17.1.5 Safelight. If a safelight is used, it shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.

4.2.17.1.6 The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

TIME TEMPERATURE CHART

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 ½
25.0	77	2 ½
24.4	76	3
23.9	75	3
23.3	74	3 ½
22.8	73	3 ½
22.2	72	4
21.7	71	4
21.1	70	4 ½
20.6	69	4 ½
20.0	68	5
19.4	67	5
18.9	66	5 ½
18.3	65	6

17.8	64	6 ½
17.2	63	7
16.7	62	8
16.1	61	8 ½
15.6	60	9 ½

4.2.17.1.7 Radiographs shall not be "sight developed."

4.2.17.2 Automated Processors and Other Closed Processing Systems.

4.2.17.2.1 The temperature of film processing chemicals shall be appropriate for the type of film(s) being processed at the film transport speed selected.

4.2.17.2.2 The film processing chemicals used and their replenishing rate (if applicable) shall be appropriate for the film transport speed selected.

4.2.17.2.3 Documentation shall be kept of the frequency at which film processing chemicals are changed. At a minimum, the interval recommended by the chemical manufacturer shall be used.

4.2.17.2.4 Safelight. If a safelight is used, it shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.

4.2.17.2.5 Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time *
°C	°F	Seconds
35	95	20
34	94	21
34	93	22
33	92	23
33	91	24
32	90	25

*Immersion time only, no crossover time included.

4.2.17.2.6 The specified developer temperature shall be available.

4.2.17.2.7 The sensitometric performance of an automatic processor shall be equivalent to other operating processor models set up to meet the above developer temperature and immersion time specifications. This is determined by processing identically exposed film through each model and comparing the results.

4.2.17.2.8 Densitometric and sensitometric performance testing.

4.2.17.2.8.1 Densitometric and sensitometric performance testing of the processor is required of facilities that process more than 250 films per week.

4.2.17.2.8.2 Control limits shall be established for each parameter monitored. Provisions for correctable action shall be undertaken whenever the pre-established control limits are exceeded.

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4.2.17.2.8.3 Documentation of testing must be maintained for at least two years or until the next Department inspection, whichever is later.

4.2.17.2.8.4 Facilities processing more than 250 films per day are required to perform this testing on each day that examinations are performed before any clinical films are processed that day.

4.2.17.2.8.5 Facilities that operate 24 hours per day must perform the required testing once each day.

4.2.17.2.8.6 Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement.

4.2.17.2.9 Records of processor maintenance shall be kept for at least two years or until the next Department inspection, whichever is later.

4.2.17.3 Other Requirements

4.2.17.3.1 Film pass boxes, if provided, shall be so constructed as to exclude light when film is placed in or removed from the boxes, and shall incorporate adequate shielding to prevent exposure of undeveloped film to stray radiation.

4.2.17.3.2 Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

4.2.17.3.3 Film cassettes and intensifying screens shall be inspected in accordance with the facility's approved procedures and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. Documentation of this periodic inspection and cleaning must be maintained for at least two years or until the next Department inspection, whichever is later.

4.2.17.4 Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base fog and speed.

4.2.17.5 Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

RHB 4.3 General Requirements for all Diagnostic X-ray Systems. All diagnostic x-ray systems shall meet the following requirements.

4.3.1 Warning Label. The control panel containing the main power switch shall bear the warning statement: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

4.3.1.1 The warning label shall be legible and its view unobstructed.

4.3.2 Battery Charge Indicator. On battery-powered generators, visual means shall be provided on the control panel to indicate that the battery is adequately charged.

4.3.3 Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliRoentgen in 1 hour when the X-ray tube is operated at its maximum technique factors.

4.3.4 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliRoentgen per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam limiting device fully open.

4.3.5 Beam Quality. The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential that is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (kVp)	Measured Potential (kVp)	Specified Dental Systems (mm Al)	All other Diagnostic (mm Al)
30 to 50	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

4.3.5.1 Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

4.3.5.2 For capacitor energy storage equipment, compliance with RHB 4.3.5 shall be determined with the maximum quantity of charge per exposure.

4.3.5.3 The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

4.3.5.4 All intraoral dental units manufactured after December 1, 1980 shall have at least 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.

4.3.6 Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RHB 4.3.5 is in the useful beam for the given kVp which has been selected.

4.3.7 Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure.

4.3.7.1 This indication shall be on both the X-ray control and at or near the tube housing assembly.

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4.3.8 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

4.3.9 Technique Indicators

4.3.9.1 The technique factors, whether manual or automatic exposure control, shall be indicated before the exposure begins. This requirement may be met by permanent markings on equipment having fixed technique factors.

4.3.9.2 Technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

4.3.9.3 The x-ray control shall provide visual indication of the production of x-rays.

4.3.9.4 X-ray systems utilizing arbitrary number or letter designators for kVp, time and milliAmperage shall be accompanied by a chart giving the value of physical factors for each arbitrary designator.

4.3.10 Focal Spot Indication. The focal spot shall be denoted in such a manner and area as to be easily seen on the tube housing.

4.3.11 Mechanical Timers. Use of mechanical timers is prohibited.

4.3.12 Imaging Systems other than Screen/Film. The provisions of this part are in addition to, and not in substitution for, applicable provisions of these regulations.

4.3.12.1 Users of digital imaging acquisition systems shall follow protocol established by the manufacturer of the digital imaging acquisition system. Records documenting adherence to this protocol shall be kept for at least two years or until the next Department inspection, whichever is later.

4.3.12.2 The manufacturer's current operating manual shall be available for Department review.

RHB 4.4 Shielding.

4.4.1 Shielding Plan Required.

4.4.1.1 Prior to construction of a new facility, modification, or renovation of an existing x-ray facility, or replacement of an x-ray machine, the floor plans and equipment arrangement shall be reviewed by a Class III, Class IV, Class VII, or Class IX vendor and submitted to the Department for review and acceptance.

4.4.1.2 A shielding plan shall be required for any space utilized as a radiation area for a period of greater than five (5) consecutive days.

4.4.2 Equipment Replacement.

4.4.2.1 A shielding plan is not required upon the replacement of an existing x-ray machine, control, or generator with like equipment and when there are no other changes which would render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor. The appropriate vendor shall notify the Department regarding such replacement. A form shall be provided by the Department for this notification and shall be exempt from RHB 2.3.2.

4.4.2.2 A shielding plan shall be required when a facility replaces an existing x-ray machine or control generator with a unit with increased capabilities which would render the original shielding plan inaccurate, as

determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor, or when the original shielding plan is not available.

4.4.2.3 A shielding plan shall be required when the parameters of the original shielding plan change to an extent so as to render the original shielding plan inaccurate, as determined by a Class III, Class IV, Class V, Class VII, Class VIII or Class IX vendor.

4.4.3 X-ray equipment shall not be installed or operated before a shielding plan for the unit has been reviewed and accepted by the Department.

4.4.4 Shielding Plan Requirements.

4.4.4.1 The registrant shall submit plans and a report, including any recommendations and all basic assumptions used, from the vendor to the Department. Applicable fees shall be submitted in accordance with RHB 2.3.2. In order for the Department to accept the submitted shielding plan, the information listed in Appendix B shall be submitted. The design considerations listed in Appendix C shall be followed.

4.4.4.2 Each installation shall be provided with such primary barriers and secondary barriers as are necessary to assure compliance with RHB 3.3, RHB 3.4 and RHB 3.5. The requirement shall be deemed to be met if the thickness of such barriers is equivalent to the thickness as computed in accordance with the National Council of Radiation Protection and Measurements, Report Number 147, "Structural Shielding Design for Medical X-ray Imaging Facilities;" the National Council of Radiation Protection and Measurements, Report Number 145, "Radiation Protection in Dentistry;" the National Council of Radiation Protection and Measurements, Report Number 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities," or an equivalent reference.

4.4.4.3 All wall, floor, and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 2.13 meters above the floor.

4.4.4.4 Secondary barriers shall be provided in all wall, floor and ceiling areas not having primary barriers.

4.4.4.5 The operator's station at the control shall be behind a protective barrier either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation that has been scattered only once.

4.4.4.6 Mobile and portable x-ray systems used in conjunction with a permanently installed cassette holder shall be considered a stationary radiographic system and shall meet the requirements for such an installation.

4.4.5 The acceptance of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Part III of these regulations.

4.4.6 Area Surveys. The registrant shall have a radiation area survey performed by a Class V, Class VII, or Class IX vendor, registered with the Department.

4.4.6.1 The survey shall be submitted to the Department for review and shall include a scale drawing of the room indicating the composition of the walls, floor, ceiling, windows, and doors, and the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided. The location and composition of the film bin shall also be included. The survey shall include an evaluation of the adequacy of each protective barrier, the operator's location, and the film storage area, if appropriate.

4.4.6.2 A copy of the radiation area survey shall be submitted to the Department within thirty days after installation of the x-ray equipment.

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4.4.6.3 Any deviation from the accepted shielding plan shall be documented and evaluated for adequacy.

4.4.6.4 The Department may determine that a survey is not required for some installations.

4.4.7 "As-built" Drawings.

4.4.7.1 Within 30 days after construction and installation are complete, the facility shall ensure that "as-built" drawings are submitted to the Department. The drawings must indicate the composition of the walls, floor, ceiling, windows and doors. The drawings must also indicate the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided, as well as the location and composition of the film bin, if present.

4.4.7.2 Any deviation from the accepted shielding plan shall be documented and evaluated for adequacy by a Class III, Class IV, Class VII, or Class IX vendor.

4.4.8 Bone Density And Mammography Installations.

4.4.8.1 Prior to installation of new or replacement equipment:

4.4.8.1.1 A shielding plan shall be submitted to the Department for review and acceptance or;

4.4.8.1.2 A written request shall be made by a Class V, Class VII, or Class IX vendor registered with the Department to perform a post-install survey in lieu of a shielding plan. All provisions of RHB 4.4.6 apply.

4.4.8.1.3 Applicable fee shall be submitted in accordance with RHB 2.3.2.

4.4.9 After installation of a radiation machine, the facility shall maintain for inspection by the Department:

4.4.9.1 A copy of the shielding plan, as required by RHB 4.4,

4.4.9.2 A copy of the Department's acceptance letter, and

4.4.9.3 A copy of the area survey or "as-built" drawing, as required by RHB 4.4.6 or 4.4.7.

RHB 4.5 Intraoral Dental Radiographic Installations. In addition to the provisions of RHB 4.3, the requirements of RHB 4.5 apply to x-ray equipment and associated facilities used for dental radiography.

4.5.1 Source to Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance, to not less than eighteen (18) centimeters.

4.5.2 Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field such that:

4.5.2.1 The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

4.5.2.2 An open ended Position Indication Device (PID) shall be used, and shall provide the same degree of protection as the housing. Pointed PIDs shall not be used.

4.5.2.3 The operator shall position the end of the PID as close as practicable to the skin of the patient.

4.5.3 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

4.5.3.1 It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

4.5.3.2 Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "Zero".

4.5.3.3 Timer reproducibility. The average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5(T_{max} - T_{min})$.

4.5.4 X-ray Control.

4.5.4.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.

4.5.4.2 Each x-ray control shall be located in such a way as to meet the following requirements:

4.5.4.2.1 Stationary x-ray systems installed after July 1, 1993, shall have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

4.5.4.2.2 For stationary x-ray systems without a protected area and installed before July 1, 1993, the exposure switch shall be such that the operator shall stand at least six feet away from the tube housing and out of the direct beam.

4.5.4.2.3 For mobile and portable x-ray systems, the exposure switch shall meet the requirements of 4.5.4.2.2.

4.5.4.2.4 Visual and/or audible indication, observable at or from the operator's protected position, shall be provided whenever x-rays are initiated and terminated.

4.5.5 Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5(E_{max} - E_{min})$.

4.5.6 Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the maximum rating, the average ratios of exposure to the indicated milliAmpere-seconds product obtained at any two tube current settings shall not differ by more than 0.10 times their sum: $[X1 - X2] < 0.10(X1 + X2)$ where X1 and X2 are the average mR/mAs values obtained at each of the two tube current settings.

4.5.7 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by the manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10% of the indicated value.

4.5.8 kVp limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

4.5.9 Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control and at or near the tube housing which has been selected.

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4.5.10 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

4.5.11 Structural Shielding.

4.5.11.1 Dental rooms containing x-ray machines shall be provided with primary and secondary barriers for all areas struck by the useful beam, as required by RHB 4.4.4.2.

4.5.11.2 When dental x-ray units are installed in adjacent rooms or areas, protective barriers shall be provided between the rooms or areas.

4.5.11.3 Pass throughs between adjacent areas shall be securely interlocked in a functional, permanent manner.

4.5.11.4 Shielding plans are not required for intraoral dental radiographic installations.

4.5.12 Operating Procedures.

4.5.12.1 Neither the dentist nor his assistant shall hold patients or films during exposure, nor shall any individual be regularly used for this service.

4.5.12.2 The tube housing and the PID shall not be hand-held during an exposure.

4.5.12.3 Dental fluoroscopy without image intensification shall not be used.

4.5.12.4 Each patient undergoing dental radiography shall be draped with a protective apron of not less than 0.25 millimeter lead equivalent to cover the gonadal area unless the patient refuses.

4.5.12.5 Only persons required for the radiographic procedure shall be in the radiographic room during exposures.

RHB 4.6 Extraoral Dental Radiographic Installations.

4.6.1 Cephalometric Installations

4.6.1.1 All provisions of RHB 4.4 and 4.7 apply.

4.6.1.2 The radiographic field shall be restricted to the area of the image receptor.

4.6.2 Panoramic Installations

4.6.2.1 All provisions of RHB 4.5 apply, except 4.5.1 and 4.5.2.1.

4.6.3 Dental CT

4.6.3.1 Where applicable, all provisions of RHB 4.4 and 4.11 apply, except RHB 4.11.2.3.

4.6.4 Hand-Held Intraoral Equipment

4.6.4.1 The hand-held x-ray system shall be equipped with a non-removable backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device.

4.6.4.2 The facility shall maintain documentation that each operator has completed training as specified by the manufacturer, and approved by the Department.

4.6.4.3 The facility shall adopt and follow protocols provided by the manufacturer and approved by the Department regarding the safe operation of the device.

4.6.4.4 When operating a hand-held intraoral dental radiographic unit, operators shall wear a 0.25 mm lead equivalent apron and thyroid collar.

4.6.4.5 If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.

4.6.4.6 The registrant shall secure the hand-held device from unauthorized removal or use.

RHB 4.7 Medical Radiographic Systems. The requirements of this Part apply to x-ray equipment and associated facilities used for radiography with stationary radiographic systems other than intraoral dental, fluoroscopic, computed tomography (CT), mammography or veterinary medical systems.

4.7.1 Stationary General Purpose Units. In addition to the other provisions of this part, all stationary general purpose units must also meet the following requirements:

4.7.1.1 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.7.1.2 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.7.1.3 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

4.7.1.4 The beam limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.7.1.5 Indication of field size dimensions and SID's used shall be specified in inches and/or centimeters on the collimator. The indications on the collimator shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.7.1.6 The beam limiting device shall be provided with SID scales that reflect the actual SID(s) used for radiographic procedures.

4.7.1.7 Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID.

4.7.2 X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

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4.7.3 Special Purpose X-ray Systems. In addition to the other provisions of this Part, all special purpose x-ray systems shall also meet the following requirements:

4.7.3.1 Means shall be provided to limit the x-ray field in the plane of the image receptor such that the x-ray field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.7.3.2 Means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

4.7.3.3 The above RHB 4.7.3.1 and 4.7.3.2 may be met with a system that meets the requirements for a general purpose X-ray system as specified in Part RHB 4.7.3, above or, when alignment means are also provided, may be met with either:

4.7.3.3.1 An assortment of removable, fixed aperture, beam limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

4.7.3.3.2 A beam limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

4.7.4 Radiation Exposure Control Devices.

4.7.4.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.7.4.2 X-ray Control.

4.7.4.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("deadman" switch) except for exposures of one-half (1/2) second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

4.7.4.2.2 Stationary x-ray systems shall have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

4.7.4.2.3 The X-ray control shall provide visual indication observable at or from the operator protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.7.4.2.4 The X-ray control shall be so placed that the operator can view the patient during any exposure and still stand in a protected area.

4.7.4.2.5 Automatic Exposure Controls. When an automatic exposure control is provided:

4.7.4.2.5.1 Indication shall be made on the control panel when this mode of operation is selected;

4.7.4.2.5.2 If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

4.7.4.2.5.3 The minimum exposure time for all equipment other than that specified in 4.7.4.2.5.2 shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

4.7.4.2.5.4 Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

4.7.4.2.5.5 A visible signal shall indicate when an exposure has been terminated at the limits required by 4.7.4.2.5.4, and manual resetting shall be required before further automatically timed exposures can be made.

4.7.4.2.6 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$.

4.7.5 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

4.7.6 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.

4.7.7 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

4.7.7.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

4.7.7.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.7.7.3 Measuring Compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. The two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

4.7.8 Light Localization.

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4.7.8.1 When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

4.7.8.2 Exemptions to RHB 4.7.8.1 shall be granted if the registrant demonstrates to the Department that their equipment is unable to meet these regulations, and the Department determines that patient safety or image quality is not compromised.

4.7.9 Certified Systems. In addition to the requirements of these rules, the registrant shall not make, nor cause to be made, any modification of components or installations of components certified pursuant to US Food and Drug Administration Regulation 21 CFR 1020 "Performance Standards for Ionizing Radiation Emitting Products" in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in 21 CFR 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, Food and Drug Administration.

4.7.10 Maintenance Schedule. On all equipment containing components certified pursuant to US Food and Drug Administration Regulation CFR 1020 "Performance Standards for Ionizing Radiation Emitting Products" the registrant shall perform, or cause to be performed, the schedule of maintenance provided by the manufacturer pursuant to 21 CFR 1020.30(h)(1)(ii). A log book of such maintenance shall be maintained for inspection by the Department.

4.7.11 SID Indication. Means shall be provided to indicate the SID. SIDs shall be indicated in inches and/or centimeters, and shall be indicated to within 2 percent.

4.7.12 Positive Beam Limitation. For units having an operable positive beam limitation (PBL) system, the following requirements must be met:

4.7.12.1 Neither the length nor width of the x-ray field shall differ from the corresponding image receptor dimensions by more than 3 percent of the SID; and

4.7.12.2 The sum of the length and width differences, without regard to sign, shall not exceed 4 percent of the SID.

4.7.12.3 The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

4.7.12.4 The positive beam limitation system shall be designed such that if a change in image receptor does not cause automatic return to positive beam limitation function and any change of image receptor size or SID must cause the automatic return.

4.7.12.5 PBL compliance shall be determined with the beam axis perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

4.7.13 The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device has been properly used or if evidence of collimation has been shown on at least three sides or three corners of the film, (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

4.7.14 Minimum Field Size. The minimum field size at an SID of 100 cm shall be equal to or less than 5 centimeters by 5 centimeters.

RHB 4.8 Mobile Radiographic Equipment.

4.8.1 All provisions of RHB 4.7.4 through 4.7.14 apply, except 4.7.12 and 4.7.4.2.2.

4.8.2 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.8.3 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.8.4 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

4.8.5 If provided, the beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.8.6 If collimator indications are provided, the indications shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.8.7 Means shall be provided to measure SIDs, and shall be accurate to within 2%.

4.8.8 Mobile and portable x-ray systems which are used in a single location for a period of greater than five consecutive days shall be considered a stationary radiographic system and shall meet the requirements of RHB 4.4.

4.8.9 Mobile and portable x-ray systems which are used at multiple locations shall be provided with an adequate protective barrier or protective apron for the operator and with a method of control which will permit the operator to be at least 6 feet from the tube head and the nearest edge of the useful beam during exposures.

4.8.10 Personnel monitoring shall be required for all operators of mobile and portable x-ray systems.

4.8.11 Tube stands. A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures.

4.8.12 All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.

RHB 4.9 Fluoroscopic X-ray Systems. All fluoroscopic x-ray systems shall be image intensified, and meet the following requirements. The requirements of this part apply to all stationary, portable, mobile, and C-arm type fluoroscopes.

4.9.1 Source-to-Skin Distance (SSD). The SSD shall not be less than:

4.9.1.1 thirty-eight (38) centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974.

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4.9.1.2 thirty-five and one half (35.5) centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974.

4.9.1.3 thirty (30) centimeters on all mobile and portable fluoroscopes, and

4.9.1.4 twenty (20) centimeters for mobile fluoroscopes used for specific surgical procedures. If removable, the appropriate spacer shall be replaced after the specific surgical procedure application is complete.

4.9.1.4.1 For stationary, mobile, or portable fluoroscopes manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than forty-five (45) cm, means shall be provided to limit the source-skin distance to not less than nineteen (19) cm. Such systems shall be labeled for extremity use only.

4.9.1.4.2 For those systems intended for specific surgical applications that would be prohibited at the source-skin distance specified above, provisions may be made for operation at shorter source-skin distances but in no case less than ten (10) cm.

4.9.2 Limitation of Useful Beam.

4.9.2.1 Primary Barrier

4.9.2.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

4.9.2.1.2 The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

4.9.2.2 X-ray field. Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition:

4.9.2.2.1 Means shall be provided to permit further limitation of the x-ray field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

4.9.2.2.2 All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less.

4.9.2.2.3 For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.9.2.2.4 Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

4.9.2.2.5 For uncertified image-intensified fluoroscopic equipment with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

4.9.2.3 Spot film devices which are certified components shall meet the following additional requirements.

4.9.2.3.1 Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

4.9.2.3.2 Spot film field size. Neither the length nor the width of the x-ray field in the spot film plane shall exceed the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

4.9.2.3.3 It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters.

4.9.2.3.4 The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

4.9.2.3.5 On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

4.9.3 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

4.9.4 Exposure Rate Limits. Entrance Exposure Rate Allowable Limits.

4.9.4.1 For equipment manufactured prior to May 19, 1995:

4.9.4.1.1 Equipment with automatic exposure rate control. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.1.1.1 During recording of fluoroscopic images, or

4.9.4.1.1.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.1.2 Equipment without automatic exposure rate control. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

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4.9.4.1.2.1 During recording of fluoroscopic images, or

4.9.4.1.2.2 When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.2 For equipment manufactured after May 19, 1995:

4.9.4.2.1 Equipment with automatic exposure rate control. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.2.1.1 During recording of fluoroscopic images, or

4.9.4.2.1.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 20 Roentgens (5.16 mC/kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.2.2 Equipment without automatic exposure control. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.2.2.1 During recording of fluoroscopic images, or

4.9.4.2.2.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 20 Roentgens (5.16 mC/kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.3 Compliance with 4.9.4.1 and 4.9.4.2 shall be determined as follows:

4.9.4.3.1 If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

4.9.4.3.2 If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

4.9.4.3.3 In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

4.9.4.3.4 For a variable SID C-arm type of fluoroscope the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement.

4.9.4.3.5 In a C-arm type of fluoroscope having an SID less than 45 centimeters, the exposure rate shall be measured at the minimum SSD.

4.9.4.3.6 In a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

4.9.4.3.7 Periodic measurement of entrance exposure rate shall be performed for both maximum and typical values in each mode used clinically annually, and after any maintenance of the system which might affect the exposure rate. Results of the most recent measurements in each mode used clinically shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and be included in the records required in RHB 4.2.16.1. The measurement results shall be stated in Roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

4.9.4.3.8 Conditions of measurement of maximum entrance exposure rate are as follows:

4.9.4.3.8.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

4.9.4.3.8.2 The kVp, mA, and other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate.

4.9.4.3.8.3 The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system.

4.9.4.3.8.4 Testing shall be performed in each mode used clinically.

4.9.4.3.9 Conditions of measurement of typical entrance exposure rate are as follows:

4.9.4.3.9.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

4.9.4.3.9.2 The kVp and mA shall be typical of clinical use of the x-ray system.

4.9.4.3.9.3 The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliAmpere and/or kiloVoltage typical of the use of the x-ray system.

4.9.4.3.9.4 Testing shall be performed in each mode used clinically.

4.9.5 Barrier Transmitted Radiation Rate Limits. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, shall not exceed 2 milliRoentgen (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate.

4.9.5.1 Measuring Compliance of Barrier Transmission.

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4.9.5.1.1 The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4.9.5.1.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

4.9.5.1.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4.9.5.1.4 Compression devices shall be removed from the useful beam during the measurement.

4.9.6 Indication of Potential and Current. During fluoroscopy and cinefluoroscopy the kV and mA shall be continuously indicated.

4.9.7 Fluoroscopic Timer.

4.9.7.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

4.9.7.2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

4.9.8 Control of Scattered Radiation.

4.9.8.1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

4.9.8.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

4.9.8.2.1 Is at least 120 centimeters from the center of the useful beam, or

4.9.8.2.2 The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RHB 4.2.9.2.

4.9.8.3 The Department may grant exemptions to RHB 4.9.8.2.2 where a sterile field will not permit the use of the normal protective barriers. Automatic exemptions will be granted for fluoroscopic procedures listed in Appendix E.

4.9.9 Spot-Filming Procedures. Fluoroscopic x-ray systems equipped with a spot-film device must meet the following requirements for spot-film procedures:

4.9.9.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.9.9.2 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$.

4.9.9.3 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

4.9.10 Mobile and Portable fluoroscopic x-ray systems which are used in a single location for a period of greater than five consecutive days shall be considered a stationary fluoroscopic system, and shall meet all the requirements of RHB 4.4.

4.9.11 Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 4.9.2, 4.9.4, 4.9.5, and 4.9.7 provided that:

4.9.11.1 Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays, unless the procedure requires the presence of other individuals.

4.9.11.2 Systems which do not meet the requirements of RHB 4.9.7 are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

4.9.12 Fluoroscopic Quality Assurance. In addition to the requirements of RHB 4.2.16, the fluoroscopic image resolution shall be tested as part of the quality assurance program. This shall be performed at least annually.

4.9.13 Vertical Fluoroscopic Imaging Systems.

4.9.13.1 SSD. The SSD shall not be less than 38 centimeters.

4.9.13.2 Limitation of Useful Beam. All provisions of 4.9.2 apply.

4.9.13.3 Entrance Exposure Rates. All provisions of 4.9.4 apply.

4.9.13.4 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

4.9.13.5 Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and mA shall be continuously indicated.

4.9.13.6 Fluoroscopic Timer.

4.9.13.6.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

4.9.13.6.2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

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4.9.13.7 Operators shall remain in a protected area during exposures, or shall be protected by aprons of not less than 0.25 mm lead equivalent material.

4.9.13.8 Spot-Filming Procedures. Fluoroscopic x-ray systems equipped with a spot-film device must meet the following requirements for spot-film procedures:

4.9.13.8.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.9.13.8.2 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5(T_{max} - T_{min})$.

4.9.13.8.3 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5(E_{max} - E_{min})$.

RHB 4.10 Bone Densitometry Systems. The requirements of this part apply to all stationary, portable, and mobile x-ray bone densitometry systems.

4.10.1 Registration. All provisions of RHB 2.3 and 2.4 apply.

4.10.2 Shielding.

4.10.2.1 Stationary units. The registrant shall submit a shielding plan, as required by RHB 4.4 to the Department for review and acceptance.

4.10.2.2 Peripheral units are exempt from 4.10.2.1.

4.10.3 Location. The bone densitometry system shall be placed in a controlled area. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during examination.

4.10.4 Administrative Requirements.

4.10.4.1 Personnel Monitoring. All provisions of RHB 3.12 and 3.22 apply.

4.10.4.2 Posting Requirements. All provisions of RHB 3.16.1, 4.2.7, and 10.2.1 apply.

4.10.4.3 Operators. All provisions of RHB 4.2.2 apply.

RHB 4.11 Computed Tomography (CT) X-ray Systems.

4.11.1 Equipment Requirements.

4.11.1.1 Tomographic Plane Indication and Alignment.

4.11.1.1.1 For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

4.11.1.1.2 For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

4.11.1.1.3 If a device using a light source is used to satisfy 4.11.1.1.1 or 4.11.1.1.2, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions.

4.11.1.2 Indication of CT Conditions of Operation. The CT x-ray system shall be designed to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

4.11.1.3 Initiation of Operation.

4.11.1.3.1 The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

4.11.1.3.2 Means shall be provided to require operator initiation of each individual scan or series of scans.

4.11.1.3.3 All emergency buttons/switches shall be clearly labeled as to their functions.

4.11.1.4 Termination of Exposure.

4.11.1.4.1 Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

4.11.1.4.2 A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 4.11.1.4.1.

4.11.1.4.3 The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than 0.5 second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.

4.11.1.5 Extraneous Radiation. The system shall perform such that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time that scans are not being performed does not exceed the levels permitted by RHB 4.3.3.

4.11.1.6 Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured After September 3, 1985.

4.11.1.6.1 The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

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4.11.1.6.2 If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 second. Indicators at or near the gantry shall be discernable from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

4.11.1.6.3 The deviation of indicated scan increment versus actual increment shall not exceed to within 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

4.11.2 Facility Design Requirements.

4.11.2.1 The control panel and x-ray control must be mounted in a permanently protected area outside the computed tomography room. The operator is required to remain in that protected area during the entire exposure.

4.11.2.2 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

4.11.2.3 Facilities designed with an open area in the control room that leads to the gantry shall mark this open area conspicuously indicating not to stand or sit in this area during x-ray exposures.

4.11.2.4 Viewing Systems.

4.11.2.4.1 Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

4.11.2.4.2 When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

4.11.3 Dose Measurements and Spot Checks.

4.11.3.1 Dose Measurement.

4.11.3.1.1 Dose measurements of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a Class IX Vendor.

4.11.3.1.2 Dose measurements of a CT x-ray system shall be performed at intervals specified by a Class IX Vendor and after any change or replacement of components which, in the opinion of the vendor could cause a significant change in the radiation output.

4.11.3.1.3 Measurements of the radiation output of the CT x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated or intercompared with a calibrated chamber within the preceding 2 years. The calibration of such system shall be traceable to a national standard.

4.11.3.1.4 Records of equipment performance tests performed shall be maintained for inspection by the Department.

4.11.3.2 Spot Checks.

4.11.3.2.1 Spot check procedures shall be developed by a Class IX vendor who specializes in diagnostic radiological physics.

4.11.3.2.2 All spot checks shall be included in the calibration required by RHB 4.11.3.1, and otherwise at time intervals and system conditions specified by a Class IX Vendor.

4.11.3.2.3 Spot checks shall include acquisition of images obtained with the phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by RHB 4.11.3.1. The images shall be retained, until a new dose measurement is performed, in one of two forms as follows:

4.11.3.2.3.1 Photographic copies of the images obtained from the image display view; and

4.11.3.2.3.2 Images stored in digital form of the most recent spot check on a storage medium compatible with the CT x-ray system.

4.11.4 Ancillary personnel who are not necessary for the safety of the patient shall not be present in the area of the CT unit while exposures are being made.

4.11.5 CT units used in radiation therapy treatment planning are exempt from the requirements of RHB 4.11.3.1. All other provisions of RHB 4.11 apply.

RHB 4.12 Veterinary Radiographic Systems.

4.12.1 Administrative Requirements. All provisions of RHB 4.2 apply, except 4.2.2, 4.2.7, 4.2.10, and 4.2.11. No person other than a licensed practitioner or an adequately trained individual, as required by RHB 4.12.22, shall use equipment emitting ionizing radiation for diagnostic purposes.

4.12.2 Radiation Protection. All provisions of RHB 4.2.9 apply, except 4.2.9.3.

4.12.3 Holding of Patients and Films. All provisions of RHB 4.2.12 apply. In addition:

4.12.3.1 Each human holder in a veterinary facility shall utilize protective apparel.

4.12.3.2 Each veterinary facility that holds patients shall provide personnel monitoring devices. If the human holder's hands are in or near the primary beam and lead gloves are not utilized, then ring badges shall also be provided and worn.

4.12.4 General Requirements. All provisions of RHB 4.3 and 4.4 apply.

4.12.5 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.12.6 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.12.7 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

4.12.8 The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.12.9 Indication of field size dimensions and SID's used shall be specified in inches and/or centimeters on the collimator. The indications on the collimator shall be such that aperture adjustments result in X-ray field

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dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.12.10 The beam-limiting device shall be provided with SID scales that reflect the actual SID(s) used for radiographic procedures.

4.12.10.1 Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

4.12.10.2 Diaphragms or cones when provided for collimating the useful beam to the area of clinical interest shall meet the requirements of RHB 4.7.2.

4.12.10.3 Minimum Field Size. The minimum field size at an SID of 100 cm shall be equal to or less than 5 cm X 5 cm.

4.12.11 Radiation Exposure Control Devices.

4.12.11.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer has been set to a zero or off position if either position is provided.

4.12.11.2 X-ray Control.

4.12.11.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("deadman" switch) except for exposures of one-half (1/2) second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

4.12.11.2.2 The X-ray control shall provide visual indication observable at or from the operator protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.12.11.2.3 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer test are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$.

4.12.12 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

4.12.13 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliRoentgen per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

4.12.14 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.

4.12.15 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

4.12.15.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

4.12.15.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.12.15.3 Measuring compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. These two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

4.12.16 Light Localization.

4.12.16.1 When a light field is used to define the x-ray field, it shall provide an average illumination of not less than 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

4.12.16.2 Exemptions to RHB 4.12.16.1 shall be granted if the registrant demonstrates to the Department that their equipment is unable to meet these regulations.

4.12.17 SID Indication. Means shall be provided to indicate the SID. SIDs shall be indicated in inches and/or centimeters, and shall be indicated to within 2 percent.

4.12.18 Fluoroscopic X-ray Systems. Veterinary fluoroscopic x-ray systems shall meet the following requirements:

4.12.18.1 Limitation of Useful Beam.

4.12.18.1.1 Primary Barrier.

4.12.18.1.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

4.12.18.1.1.2 The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

4.12.18.1.2 X-ray Field. The x-ray field produced by non-image intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition:

4.12.18.1.2.1 Means shall be provided for stepless adjustment of the field size;

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4.12.18.1.2.2 The minimum field size at the greatest SID shall be equal to or less than 5 centimeters by 5 centimeters.

4.12.18.1.2.3 For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition, means shall be provided to permit further limitation of the field.

4.12.18.2 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means shall be provided to permit completion of any single exposure of the series in process.

4.12.18.3 Barrier Transmitted Radiation Rate Limits.

4.12.18.3.1 The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliRoentgen (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate.

4.12.18.3.2 Measuring Compliance of Barrier Transmission.

4.12.18.3.2.1 The exposure rate due to transmission through the protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4.12.18.3.2.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

4.12.18.3.2.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4.12.18.4 Indication of Potential and Current. During fluoroscopy the kV and mA shall be continuously indicated.

4.12.18.5 Mobile Fluoroscopes. In addition to the other requirements of this Part, mobile fluoroscopes shall provide intensified imaging.

4.12.18.6 Control of Scattered Radiation.

4.12.18.6.1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

4.12.18.6.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to unattenuated scattered radiation emanating from above the tabletop unless that individual:

4.12.18.6.2.1 Is at least 120 centimeters from the center of the useful beam, or

4.12.18.6.2.2 The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apparel referred to in RHB 4.12.3.1.

4.12.19 X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4.12.20 Veterinary Computed Tomography X-ray Systems - Where applicable, all provisions of RHB 4.11 apply.

4.12.21 Veterinary Dental Systems— Where applicable, all provisions of RHB 4.5 apply.

4.12.22 Operator Requirements. The registrant shall assure that all x-ray machines under his control are operated only by individuals adequately instructed in safe operating procedures and competent in the safe use of the equipment.

4.12.22.1 The registrant shall require persons operating registered equipment and associate equipment and/or holding patients to receive, at a minimum, instruction in the following areas:

4.12.22.1.1 Radiation Protection. Training in radiation protection shall include, but is not limited to, protective clothing; patient holding; time, distance, and shielding; radiation protection standards; and the biological effects of radiation.

4.12.22.1.2 Darkroom Techniques/Digital Imaging Acquisition Systems. Training in darkroom techniques shall include, but is not limited to, developing chemicals; film protection; cassettes; and screens. Training in digital imaging acquisition systems shall follow protocol established by the manufacturer of the digital imaging acquisition system.

4.12.22.1.3 Machine Safety. Training in machine safety shall include machine functions; safety procedures; and recognizing problems.

4.12.22.1.4 General Operating Procedures. Training in general operating procedures shall include patient positioning for x-ray exams; radiographic techniques; use of personnel monitoring devices; and quality assurance procedures.

4.12.22.2 Instruction required by 4.12.22.1 shall begin within 30 days after employment. Training shall be provided for each type of exam that the operator will be required to perform at that facility. The registrant shall maintain a record of all training for each operator. Such records shall be made available for Departmental inspection.

RHB 4.13 Medical Specimen Unit.

4.13.1 Administrative Requirements. All provisions of RHB 4.2.2.7 apply.

4.13.2 Radiation Protection. Upon installation, the medical specimen unit shall not be operated until a physical radiation survey of the unit and areas adjacent to the unit has been performed. A radiation survey of the unit and areas adjacent to the unit shall also be performed at least annually, and after any repair, modification,

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or maintenance on the system. Documentation of the surveys shall be maintained for inspection by the Department.

4.13.3 Tests of all safety devices such as interlocks shall be conducted annually for medical specimen units. Documentation of such tests shall be maintained for inspection by the Department.

4.13.4 Radiation emitted from the medical specimen unit shall not exceed 0.5 milliRoentgens per hour at a point five centimeters from the external surface.

4.13.5 When not in operation the medical specimen unit shall be secured.

Part IV - Appendix A

Information To Be Submitted By Persons Proposing To Conduct Healing Arts Screening. Persons requesting that the Department approve a healing arts screening program shall submit the following information for review and approval:

1. Name and address of the applicant, and where applicable, the names and addresses of agents within the State.
2. Diseases or conditions for which the X-ray examinations are to be used.
3. Description in detail of the X-ray examinations proposed in the screening program.
4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.
5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the X-ray examinations.
6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these regulations.
7. A description of the diagnostic film quality control program.
8. A copy of the technique chart for the X-ray examinations procedures to be used.
9. The qualifications of each individual who will be operating the X-ray system(s).
10. The qualifications of the individual who will be supervising the operators of the X-ray system(s).
11. The name and address of the individual who will interpret the radiograph(s).
12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.
13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the X-ray examinations.

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Part IV - Appendix B

Information on Radiation Shielding Required for Plan Review. The following information must be provided to the Department for review and acceptance of a shielding plan:

1. Plans shall show, at a minimum, the following:

a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; the location of the x-ray control panel, and the location of the wall bucky or chest board, if applicable.

b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

c) An accurate drawing of the room(s) concerned.

d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

e) The type of x-ray equipment and the maximum technique factors.

f) Location of the darkroom and the area where the film will be stored. Any shielding which will be used to protect the film must be noted. The use of filmless systems shall be indicated in writing.

2. Information on the anticipated workload of the x-ray system(s). Give the number of individual exposures per week. This is the total number of exposures (not patients) taken each week. This figure should include allowances for future growth so that the shielding will continue to remain adequate.

3. Individual barrier radiation shielding specifications and descriptions of all assumptions that were used in the shielding calculations.

Part IV - Appendix C

Design Requirements for an Operator's Booth

1. Space Requirements:

- a) The operator shall be allotted not less than 7.5 square feet (0.697 m²) of unobstructed floor space in the booth.
- b) The operator's booth may be any geometric configuration with no dimension less than 2 feet (0.61m).
- c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments.
- d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette cannot reach the operator's station in the booth.

2. Structural Requirements:

- a) The booth walls shall be permanently fixed barriers of at least 7 feet (2.13m) high.
- b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed.
- c) Shielding shall be provided to meet the requirements of RHB 4.4.

3. X-ray Control Placement:

The x-ray control for the system shall be fixed within the booth and:

- a) Shall be at least 40 inches (1.02m) from any open edge of the booth wall which is nearest to the source of radiation, excluding mammography equipment and intraoral dental. If the exposure switch is separate from the control panel, the exposure switch shall be at least 40 inches (1.02m) from any open edge of the booth wall which is nearest to the source of radiation.
- b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

- a) Each booth shall have at least one viewing device which will:
 - i) Be so placed that the operator can view the patient during any exposure, and
 - ii) The device shall be so placed that the operator can have full view of any occupant of the room and shall be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have an interlock controlling the exposure which will prevent the exposure if the door is not closed.
- b) When the viewing system is a window, the following requirements also apply:
 - i) It shall have a viewing area of at least 1 square foot (0.0929 m²)

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ii) The design of the booth shall be such that the operator's expected position when viewing the patient and operating the x-ray system is at least 18 inches (0.457m) from the edge of the booth.

iii) The material constituting the window shall have the same lead equivalence as that required in the booth's wall in which it is mounted.

c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B.

d) When the viewing system is by electronic means:

i) The camera shall be so located as to accomplish the general requirements of this Part, and

ii) There shall be an alternate viewing system as a backup for the primary system.

5. Alternative Design Criteria. The design considerations listed in Appendix C shall be followed. If design criteria in Appendix C cannot be followed, the registrant may offer alternative design criteria to the Department for acceptance as long as the same degree of safety is being met.

Part IV - Appendix D

Average Patient Exposure Guide

Medical ESE's

Compliance with RHB 4.2.13.2 may be determined if the patient's exposure at skin entrance (ESE) does not vary from the national averages listed below by more than 50%. Facilities should strive for an ESE that does not vary from the national average by more than 20%. Facilities utilizing digital imaging systems shall not exceed the ESE Limits as outlined for a 200 speed system.

ESE Limits

Projection	Thickness	200 Speed/Digital	400 Speed
PA Chest – Grid - Non Grid	23 cm	12 - 38 7 - 23	7 - 23 2 - 8
AP Abdomen	23 cm	245 - 735	150 – 450
AP Lumbar Spine	23 cm	225 - 675	175 - 525
Full Spine (AP)	23 cm	130 - 390	72 - 218
AP Cervical Spine	13 cm	67 - 203	47 - 142
Lateral Skull	15 cm	72 - 218	35 - 105
Ret Pyelogram (AP)	23 cm	297-893	297-893
Thoracic Spine (AP)	23 cm	204-612	204-612
DP Foot	8 cm	37 - 111	37 - 111
Cephalometric	15 cm	15 - 45	15 - 45

Notes:

- a) Patient thicknesses are expressed in centimeters (cm).
- b) All measurements are made in air (no phantom).
- c) If the film/screen speed cannot be determined, it will be assumed to be 200 speed.

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Mammography ESE's: Refer to RHB 5.11.5.10

Dental Intraoral ESE's:

This chart represents the range of exposures that will produce acceptable quality radiographs. Compliance with RHB 4.2.13.2 shall be considered met if the patient's exposure at skin entrance (ESE) is within the limits shown. Facilities utilizing digital imaging systems shall not exceed the ESE Limits as outlined for a "D" speed film system.

kVp	"D" Speed Film and Digital	"E" and "F" Speed Film
	ESE Limits	ESE Limits
50	340-690	176-384
55	280-600	152-324
60	248-528	132-276
65	216-480	112-240
70	192-420	96-204
75	136-312	80-168
80	120-276	72-144
85	104-240	64-126
90	96-216	56-108
95	88-192	48-64
100	80-168	40-56

Part IV - Appendix E

Automatic exemptions to RHB 4.9.8.2.2 will be granted for the following procedures:

1. Myelograms
2. Arthrograms
3. Angiograms
4. Percutaneous nephrostomies
5. Biliary drainage procedures
6. Percutaneous cholangiograms
7. T-tube cholangiograms
8. Sinograms or fistulograms
9. Fluoroscopic biopsy procedures

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Part IV - Appendix F

Minimum Criteria for Performance Tests

The following items must be tested. Each item tested must include an indication of Pass/Fail, Compliant/ Non-compliant, as required by RHB 2.7.3.6. Items marked with an asterisk (*) indicate that this item is not necessarily required to be tested by the vendor, but must be tested in order for the facility to meet the requirements of RHB 4.2.16.1. Each record of equipment performance testing shall be legible and include company name, service person name, and the date of the test, and all applicable requirements of RHB 2.7.3.6.6.

MEDICAL RADIOGRAPHIC (Including veterinary facilities)

1. Half-value layer (HVL) (4.3.5)
2. X-ray field/light field alignment (4.7.1.3, 4.8.4)
3. Exposure reproducibility (4.7.5)
4. mA/mAs linearity (4.7.7)
5. kVp accuracy (4.7.6)
6. Timer reproducibility and accuracy (4.7.4.2.6, 4.7.6)
7. X-ray beam/image receptor centering (4.7.1.7)
8. Collimator light illuminance (4.7.8)
9. Actual vs. indicated collimator field sizes (4.7.1.5, 4.8.6)
10. Positive beam limitation function, if operable (4.7.12)
11. Visual and audible indication of exposure (4.7.4.2.4)
12. Minimum field size (4.7.14)
13. Patient exposure at skin entrance, for most common exams performed at the facility (except veterinary facilities) (4.2.13.2)
14. Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
15. Grid uniformity and alignment (4.2.16.3)
16. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*
17. Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs (4.7.11)
18. Beam size(s) for fixed collimation, if applicable (4.7.3)
19. X-ray control placement (Appendix C, 3a)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:

1. Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)
2. Minimum source to skin distance on mobile radiographic units (4.8.12)
3. Proper indication of multiple tubes on units so equipped (4.7.4.2.3)

FLUOROSCOPIC

1. X-ray beam/Viewed image size comparison (4.9.2.2)
2. Exposure rate output measurement, using average techniques, using maximum techniques, and in high level exposure mode, if so equipped, in each mode routinely used (4.9.4)
3. Image intensifier interlock with unit in park position (4.9.2.1.2)
4. Cumulative timer function (4.9.7.1)
5. Control of scattered radiation (4.9.8)
6. High contrast resolution and low contrast performance
7. Minimum source to skin distance, upon initial installation (4.9.1)
8. Spot film beam size (4.9.2.3.2)
9. Spot film beam centering (4.9.2.3.4)

10. Spot film exposure reproducibility (4.9.9.3)
11. Spot film mA/mAs linearity (4.7.7)
12. Spot film timer reproducibility and accuracy (4.9.9.2, 4.7.6)
13. Proper function of spot film automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
14. Half-value layer (HVL) (4.3.5)
15. Cinefluorographic exposure rates (4.9.4)
16. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*
17. Integrity of bucky slot cover shielding and lead drapes (4.2.8)*
18. Continuous indication of kV and mA during fluoroscopy (4.9.6)
19. X-ray control placement (Appendix C, 3a)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:

1. Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)
2. Primary Barrier Transmission (4.9.5)

RADIATION THERAPY SIMULATION SYSTEMS

1. Half-value layer (HVL) (4.3.5)
2. X-ray field/light field alignment (4.7.1.3)
3. Exposure reproducibility (4.7.5)
4. mA/mAs linearity (4.7.7)
5. kVp accuracy (4.7.6)
6. Timer reproducibility and accuracy (4.7.4.2.6, 4.7.6)
7. X-ray beam/image receptor centering (4.7.1.7)
8. Actual vs. indicated collimator field sizes (4.7.1.5)
9. Positive beam limitation function, if operable (4.7.12)
10. Visual and audible indication of exposure (4.5.4.2.4)
11. Proper function of automatic exposure control devices, including AEC reproducibility, kV compensation, and minimum response time (4.7.4.2.5)
12. Grid uniformity and alignment (4.2.16.3)
13. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*
14. Actual vs. Indicated Source to Image Distance (SID), for all clinically used SIDs (4.7.11)
15. Exposure rate output measurement, using average techniques, using maximum techniques, and in high level exposure mode, if so equipped, in each mode routinely used (4.9.4)
16. Cumulative timer function (4.9.7.1)
17. Measurement of scattered radiation (4.9.8)
18. High contrast resolution and low contrast performance
19. Minimum source to skin distance, upon initial installation (4.9.1)
20. X-ray control placement (Appendix C, 3a)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status: Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)

COMPUTED TOMOGRAPHY (CT) (Including CT treatment planning systems used in radiation therapy, and dental CT where applicable)

1. Actual vs. indicated scan increment (4.11.1.6.3)
2. Measurement of radiation output (patient dose) (CT treatment planning systems are exempt) (4.11.3.1)
3. CT number calibration and constancy (4.11.3)

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4. High and low contrast resolution
5. Precision (noise)
6. Contrast scale
7. Spot checks as specified by a Class IX Vendor (4.11.3.2)
8. An area survey, upon initial installation
9. X-ray control placement (Appendix C, 3a)
10. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*

These items must be checked upon initial installation and after any maintenance or repair that could affect its status: Adherence to the accepted shielding plan (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)

DENTAL

1. Half-value layer (HVL) (4.3.5)
2. Exposure reproducibility (4.5.5)
3. mA/mAs linearity (4.5.6)
4. kVp accuracy (4.5.7)
5. Timer reproducibility and accuracy (4.5.3.3, 4.5.7)
6. Visual and audible indication of exposure (4.5.4.2.4)
7. Patient exposure at skin entrance, bitewing and/or periapicals (4.2.13.2)
8. Mechanical support of tubehead (4.5.10)
9. Integrity of pass through interlocks (4.5.11.3)
10. Integrity of lead aprons, gloves, and other protective clothing (4.2.8)*
11. X-ray control placement (4.5.4.2)

These items must be checked upon initial installation and after any maintenance or repair that could affect its status:

1. Adherence to the accepted shielding plan, if applicable (4.4) (Visual inspection of layout of equipment, location of exposure button, location of film, etc.)
2. Minimum source to skin distance (4.5.1)
3. X-ray beam size (4.5.2)
4. Proper indication of multiple tubes on units so equipped (4.5.9)

NOTE: Cephalometric units are considered medical units by the Department, and are subject to the requirements for medical radiographic units.

PART V
QUALITY STANDARDS AND CERTIFICATION
REQUIREMENTS FOR FACILITIES PERFORMING MAMMOGRAPHY

RHB 5.1 Scope. This Part establishes quality standards and certification requirements for facilities performing mammography to ensure that all mammography facilities are adequately and consistently evaluated for compliance with the standards provided.

5.1.1 Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix A of Part IV. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified within 15 days. Approval to conduct a healing arts screening program shall be renewed on an annual basis if deemed necessary by the Department.

5.1.2 Exemptions.

5.1.2.1 Mammography units used only during invasive interventions for localization or biopsy procedures are exempt from the requirements of this Part, except that such systems shall satisfy the criteria specified in RHB 5.25, and all parts to which RHB 5.25 refers.

5.1.2.2 Each mobile mammography facility based outside of South Carolina that operates in South Carolina and which has not been certified by the Department is exempt from the requirements of RHB 5.3 and RHB 5.6, provided that:

5.1.2.2.1 The mobile mammography facility is certified to perform mammography by FDA or other FDA-approved certifying agency at all times while conducting operations in South Carolina; and

5.1.2.2.2 The mobile mammography facility meets the requirements of RHB 5.28.

5.1.2.2.3 The mobile mammography facility shall comply with all other requirements in Part V.

5.1.2.2.4 The mobile mammography facility meets the requirements of RHB 2.3 and 2.4.

RHB 5.2 Requirements for Certification. A certificate issued by the Department is required for lawful operation of all mammography facilities subject to the provisions of this Part. Certificate holding facilities shall meet the requirements of RHB 5.6 and be accredited by an FDA-approved accreditation body.

RHB 5.3 Certificates.

5.3.1 In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body.

5.3.2 Following the Department's receipt of the accreditation body's decision to accredit a facility, the Department may issue a certificate to the facility, or renew an existing certificate, if the Department determines that the facility has satisfied the requirements for certification or recertification.

5.3.3 Provisional Certificates.

5.3.3.1 A new facility is eligible to apply for a provisional certificate. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process.

5.3.3.2 Following the Department's receipt of the accreditation body's decision that a facility has submitted the required information, the Department may issue a provisional certificate to a facility upon determination that

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the facility has satisfied the requirements for provisional certification. A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90 day extension of the provisional certificate.

5.3.4 Extension of Provisional Certificate.

5.3.4.1 To apply for a 90 day extension to a provisional certificate, a facility shall submit to its accreditation body a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

5.3.4.2 Following the Department's receipt of the accreditation body's decision that a facility has submitted the required information, the Department may issue a 90 day extension of the provisional certificate to the facility upon determination that the facility has satisfied the requirements for the 90 day extension.

5.3.4.3 There can be no renewal of a provisional certificate beyond the 90 day extension.

5.3.5 Interim Notices. The Department may issue an interim notice of mammography certification by facsimile to a facility if a delay is anticipated in providing a certificate to the facility under one or more of the following circumstances:

5.3.5.1 The Department has been notified by an accreditation body that the facility meets the requirements for a provisional or provisional reinstatement certificate and delivery of the certificate may be delayed;

5.3.5.2 The Department has been notified by an accreditation body that the facility has completed accreditation or reaccreditation and delivery of the certificate to the facility may be delayed; or

5.3.5.3 The Department has been notified by an accreditation body that the facility has timely submitted an application for accreditation or reaccreditation but the completion of the accreditation process may extend beyond the expiration date of a facility's existing certificate through no fault of the facility.

5.3.5.4 An interim notice shall authorize the facility to perform mammography until the facility receives its certificate but in no case for more than 45 days. No more than one interim notice may be issued to a facility per application for certification.

RHB 5.4 Reinstatement Policy. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA or the Department, or that has had its certificate suspended or revoked by FDA or the Department, may apply for reinstatement. If reinstated, the facility will be eligible for a provisional certificate.

5.4.1 Unless prohibited from reinstatement under 5.4.4, a facility applying for reinstatement shall:

5.4.1.1 Contact an FDA-approved accreditation body to determine the requirements for reapplication or accreditation;

5.4.1.2 Fully document its history as a previously provisionally certified or certified mammography facility, including the following information:

5.4.1.2.1 Name and address of the facility under which it was previously provisionally certified or certified;

5.4.1.2.2 Name of previous owner/lessor;

5.4.1.2.3 FDA facility identification number assigned to the facility under its previous certification; and

5.4.1.2.4 Expiration date of the most recent FDA provisional certificate or certificate.

5.4.1.3 Justify application for reinstatement of accreditation by submitting to the accreditation body, a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.

5.4.2 The Department may issue a provisional certificate to the facility if:

5.4.2.1 Following the Department's receipt of the accreditation body's decision that a facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and

5.4.2.2 The Department determines that the facility has taken sufficient corrective action since the lapse of, denial or revocation of its previous certificate.

5.4.3 After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for certification.

5.4.4 If a facility's certificate was revoked on the basis of an act described in 5.24, no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within two years of the date of revocation.

RHB 5.5 Appeals of adverse accreditation or reaccreditation decisions. The appeals procedures described in this Part are available only for adverse accreditation or reaccreditation decisions that preclude certification by the Department. Department decisions to suspend or revoke certificates that are already in effect shall be conducted in accordance with RHB 5.24.

5.5.1 Upon learning that a facility has failed to become accredited or reaccredited, the Department will notify the facility that the Department is unable to certify that facility without proof of accreditation.

5.5.2 A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the FDA. A facility shall avail itself of the accreditation body's appeal process before requesting a review from the Department.

5.5.3 In the event that a facility, after availing itself of the accreditation body's appeal process, receives an adverse accreditation or reaccreditation decision, the facility may within 30 days after such adverse decision submit a request for review of the adverse accreditation decision to the Department.

5.5.4 Within 30 days following receipt of such written request, the Director of Health Regulation shall review the facility's appeal.

5.5.5 A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

RHB 5.6 Fees

5.6.1 The Department shall assess each certified mammography facility an annual certification fee of \$1031 in accordance with RHB 2.10. This certification fee includes one mammographic tube. The Department shall assess each certified mammography facility an additional fee of \$231 per mammographic tube for each additional tube.

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5.6.2 The annual fee described in 5.6.1 applies to both fully and provisionally certified mammography facilities.

5.6.3 A new mammography facility issued an initial provisional certificate during the calendar year shall be issued a prorated fee for the remainder of the year, in accordance with RHB 2.10.

5.6.4 All fees shall be due and payable in accordance with RHB 2.10.

5.6.5 Follow-up Inspection Fees

5.6.5.1 In the event that the Department deems a follow-up inspection necessary, an inspection fee of \$500 shall be assessed upon the completion of the follow-up inspection.

5.6.5.2 The follow-up inspection invoice shall be issued in conjunction with the follow-up inspection report.

5.6.5.3 Payment of the follow-up inspection fee shall be due within thirty (30) calendar days of the date of the follow-up inspection fee invoice.

RHB 5.7 Personnel Requirements. The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities:

5.7.1 Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:

5.7.1.1 Initial qualifications. Unless the exemption in 5.7.1.3.1 applies, before beginning to interpret mammograms independently, the interpreting physician shall:

5.7.1.1.1 Be a licensed physician to practice medicine in this State;

5.7.1.1.2 Be certified in diagnostic radiology by either the American Board of Radiology, the American Osteopathic Board of Radiology, or Royal College of Physicians and Surgeons of Canada or have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of 5.7.1 of this Part.

5.7.1.1.3 Have a minimum of sixty hours of documented medical education in mammography, which shall include instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography and quality assurance and quality control in mammography. All sixty of these hours shall be Category I and have at least fifteen hours of the Category I hours shall have been acquired within three years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

5.7.1.1.4 Unless the exemption in RHB 5.7.1.3.2 applies, have interpreted or multi-read at least 240 mammograms examinations within the 6 month period immediately prior to the date that the physician qualifies as an interpreting physician. The interpretation or multi-reading shall be under direct supervision of a qualified interpreting physician.

5.7.1.2 Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

5.7.1.2.1 Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.1.1 of this Part, were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the twenty-four months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

5.7.1.2.2 Following the third anniversary of the end of the calendar quarter in which the requirements of 5.7.1.1 of this Part were completed, the interpreting physician shall have taught or completed at least 15 Category I continuing medical education units in mammography during the thirty six months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This training shall include at least six Category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

5.7.1.2.3 Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least eight hours of training in the new mammographic modality.

5.7.1.2.4 Units earned through teaching a specific course can be counted only once towards the fifteen units required by RHB 5.7.1.2.2, even if the course is taught multiple times during the previous 36 months.

5.7.1.3 Exemptions

5.7.1.3.1 Those physicians who qualified as interpreting physicians under FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of 5.7.1.1 of this Part. These physicians may continue to interpret mammograms provided they continue to meet the requirement of 5.7.1 and the continuing experience and education requirements of 5.7.1.2.

5.7.1.3.1.1 Any physician added to a facility after April 28, 1999, must provide documentation of initial qualifications. This documentation must be maintained by the facility for Department review.

5.7.1.3.2 Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any six month period during the last two years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are exempt from 5.7.1.1.4.

5.7.1.4 Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements, shall reestablish their qualifications before resuming the independent interpretation of mammograms as follows:

5.7.1.4.1 Interpreting physicians who fail to meet the continuing experience requirements of 5.7.1.2.1 shall interpret or multi-read at least 240 mammographic examinations within six months or less under the direct supervision of an interpreting physician; or interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations from the prior twenty-four months, whichever is less. The interpretations required shall be done within the six months immediately prior to resuming independent interpretation.

5.7.1.4.2 Interpreting physicians who fail to meet the continuing education requirements of 5.7.1.2.2 shall obtain a sufficient number of additional Category I continuing medical education credits in mammography

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to bring their total up to the required fifteen credits in the previous thirty-six months before resuming independent interpretation.

5.7.2 Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education requirements:

5.7.2.1 General Requirements

5.7.2.1.1 Be registered in active status with the American Registry of Radiologic Technologists in the field of radiography; and

5.7.2.1.2 All provisions of RHB 4.2.2 apply to the operators of mammography equipment.

5.7.2.2 Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under FDA's interim regulations or completed at least forty contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

5.7.2.2.1 Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

5.7.2.2.2 The performance of a minimum of twenty- five examinations under the direct supervision of an individual qualified under 5.7.2; and

5.7.2.2.3 At least eight hours of training in each mammography modality to be used by the technologist in performing mammography exams.

5.7.2.3 Continuing education requirements

5.7.2.3.1 Following the third anniversary date of the end of the calendar quarter in which the requirements of 5.7.2.1 and 5.7.2.2 were completed, the radiologic technologist who performs mammography shall have taught or completed at least fifteen continuing education units in mammography during the thirty-six months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any day in between the two. The facility will choose one of these dates to determine the 36 month period.

5.7.2.3.2 Units earned through teaching a specific course can be counted only once towards the fifteen hours of continuing education requirements required in 5.7.2.3.1, even if the course is taught multiple times during the previous 36 months.

5.7.2.3.3 At least six of the continuing education units required in 5.7.2.3.1 shall be related to each mammographic modality used by the technologist.

5.7.2.3.4 Requalification. Radiologic technologists who fail to meet the continuing education requirements of 5.7.2.3.1, shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous three years, at least six of which shall be related to each modality used by the technologist in mammography. The technologist shall not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

5.7.2.3.5 Before a radiologic technologist may begin independently performing mammography examinations using a mammographic modality other than one of those for which the technologist received

training under 5.7.2.3.3, the technologist shall have at least eight hours of continuing education units in the new modality.

5.7.2.3.6 Programs, courses or other activities intended to meet the requirement for initial, or requalification, mammography training or continuing education in mammography shall be approved by the Department.

5.7.2.3.7 Completion of initial or requalification mammography training and continuing education in mammography shall be verified to the Department.

5.7.2.4 Continuing experience requirements.

5.7.2.4.1 Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.2.1 and 5.7.2.2 were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the twenty-four months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

5.7.2.4.2 Requalification. Radiologic technologists who fail to meet the continuing experience requirements of 5.7.2.4.1 shall perform a minimum of twenty five mammography examinations under the direct supervision of a qualified radiologic technologist before resuming the performance of unsupervised mammography.

5.7.3 Medical Physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program shall meet the following:

5.7.3.1 Initial Qualifications. The medical physicist must be approved by the Department as a Class IX vendor, prior to providing or offering to provide services, as required in 2.6.1. Unless the alternative initial qualifications in RHB 5.7.3.2 apply, the medical physicist must:

5.7.3.1.1 Have a masters degree or higher in a physical science from an accredited institution, with no less than twenty semester hours or equivalent (e.g., thirty quarter hours) of college undergraduate or graduate level physics;

5.7.3.1.2 Have twenty contact hours of documented specialized training in conducting surveys of mammography facilities; and

5.7.3.1.3 Have the experience of conducting surveys of at least one mammography facility and a total of at least ten mammography units. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys shall be acquired under the direct supervision of a medical physicist who meets all the requirements of 5.7.3.1 and 5.7.3.3.

5.7.3.2 Alternative initial qualifications.

5.7.3.2.1 Have qualified as a medical physicist under FDA's interim-regulations and retained that qualification by maintenance of the active status of any licensure, approval or certification required;

5.7.3.2.2 Prior to April 28, 1999, obtained a bachelor's degree or higher in a physical science from an accredited institution with no less than ten semester hours or equivalent of college undergraduate or graduate level physics;

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5.7.3.2.3 Prior to April 28, 1999, have forty contact hours of documented specialized training in conducting surveys of mammography facilities; and

5.7.3.2.4 Prior to April 28, 1999, have the experience of conducting surveys of at least one mammography facility and a total of at least twenty mammography units. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography survey requirement. The training and experience requirements shall be met after fulfilling the degree requirement.

5.7.3.3 Continuing education and experience.

5.7.3.3.1 Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of 5.7.3.1 and 5.7.3.2 were completed, the medical physicist shall have taught, or completed, at least fifteen continuing education units in mammography during the thirty six-months immediately preceding the date of the facility annual inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammography modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required fifteen continuing education units in a 36-month period, even if the course is taught multiple times during the thirty-six months.

5.7.3.3.2 Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of 5.7.3.1 and 5.7.3.2 were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the twenty-four months immediately preceding the date of the facility's annual mammography inspection, or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement.

5.7.3.3.3 Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under 5.7.3.1 and 5.7.3.2, the physicist shall receive at least eight hours of training in surveying units of the new mammographic modality.

5.7.3.4 Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of 5.7.3.3 may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists shall reestablish their qualifications, as follows:

5.7.3.4.1 Medical physicists who fail to meet the continuing educational requirements of 5.7.3.3.1 shall obtain a sufficient number of continuing education units to bring their total units up to the required fifteen in the previous three years.

5.7.3.4.2 Medical physicists who fail to meet the continuing experience requirement of 5.7.3.3.2 shall complete a sufficient number of surveys under the direct supervision of a medical physicist who meets the qualification of 5.7.3.1 and 5.7.3.3 to bring their total surveys up to the required two facilities and six units in the previous twenty-four months. No more than one survey of a specific unit within a period of sixty days can be counted towards the total mammography unit survey requirement.

5.7.4 Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the Department. Records of personnel no longer employed by the

facility should not be discarded until the next annual inspection has been completed and the Department has determined that the facility is in compliance with the MQSA/State personnel requirements of this Part.

RHB 5.8 Equipment Requirements. The equipment requirements of this Part are intended to ensure that mammography equipment is capable of producing quality mammograms over the full range of clinical conditions.

5.8.1 Prohibited equipment. Xeromammography equipment shall not be used for mammography procedures. Radiographic equipment designed for general purpose or special non-mammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in 21 CFR, Section 1020.31(f)(3).

5.8.2 General. Only special purpose equipment designed for mammography shall be specifically used for mammography and shall be certified pursuant to 21 CFR, Section 1010.2 as meeting the applicable requirements of 21 CFR, 1020.30, effective as of April 1, 1997.

5.8.3 Motion of tube-image receptor assembly.

5.8.3.1 The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

5.8.3.2 The mechanism ensuring compliance with RHB 5.8.3.1 shall not fail in the event of power interruption.

5.8.4 Image receptor sizes.

5.8.4.1 Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

5.8.4.2 Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

5.8.4.3 Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

5.8.5 Beam limitation and light fields.

5.8.5.1 All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.

5.8.5.2 For any mammography system with a light beam that passes through the x-ray beam limiting device, the light shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

5.8.6 Magnification

5.8.6.1 Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

5.8.6.2 Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

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5.8.7 Focal Spot Selection

5.8.7.1 When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

5.8.7.2 When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

5.8.7.3 When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and /or focal spot actually used during the exposure.

5.8.8 Compression. All mammography systems shall incorporate a compression device that shall be used for all routine projections and for all projections except when necessity requires imaging without compression.

5.8.8.1 Application of compression. Effective October 28, 2002, each system shall provide:

5.8.8.1.1 An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

5.8.8.1.2 Fine adjustment compression controls operable from both sides of the patient.

5.8.8.2 Compression paddle:

5.8.8.2.1 Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of subsections 5.8.8.2.4 and 5.8.8.2.5 of this Section.

5.8.8.2.2 Except as provided in subsection 5.8.8.2.3 of this Part, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

5.8.8.2.3 Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

5.8.8.2.4 The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

5.8.8.2.5 The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

5.8.9 Technique factor selection and display.

5.8.9.1 Manual selection of milliAmpere seconds (mAs) or at least one of its component parts (milliAmpere (mA) and /or time) shall be available.

5.8.9.2 The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

5.8.9.3 Following AEC mode use, the system shall indicate the actual kiloVoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

5.8.10 Automatic exposure control.

5.8.10.1 Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid, magnification, nonmagnification and various target- filter combinations.

5.8.10.2 The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.

5.8.10.2.1 The size and available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle.

5.8.10.2.2 The selected position of the detector shall be clearly indicated.

5.8.10.3 The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

5.8.11 X-ray film. The facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

5.8.12 Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

5.8.13 Film processing solutions. When processing mammography films, the facility shall use chemical solutions that are capable of developing the film used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

5.8.14 Lighting. The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

5.8.15 Film masking devices. Facilities shall ensure that filmmasking devices that can limit the illumination area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians.

RHB 5.9 Medical Records and Mammography Reports

5.9.1 Contents and terminology. Each facility shall prepare a written report of the results of each mammography examination performed under its certificate. The mammography report shall include the following information:

5.9.1.1 The name of the patient and an additional patient identifier;

5.9.1.2 Date of examination;

5.9.1.3 The name of the interpreting physician who interpreted the mammogram;

5.9.1.4 Overall final assessment of findings, classified in one of the following categories:

5.9.1.4.1 "Negative." Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

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5.9.1.4.2 "Benign." Also a negative assessment;

5.9.1.4.3 "Probably Benign." Finding(s) has a high probability of being benign;

5.9.1.4.4 "Suspicious." Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

5.9.1.4.5 "Highly suggestive of malignancy." Finding(s) has a high probability of being malignant,

5.9.1.5 In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

5.9.1.6 Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.

5.9.2 Communication of mammography results to the patient. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy", the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

5.9.2.1 Patients who do not name a health care provider to receive the mammography report shall be sent the report described in RHB 5.9.1 within 30 days, in addition to the written notification of results in lay terms.

5.9.2.2 Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.

5.9.3 Communication of mammography results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

5.9.3.1 Provide a written report of the mammography examination, including the items listed in subsection 5.9.1 of this Section, to that health care provider as soon as possible, but no later than 30 days after the date of the mammography examinations; and

5.9.3.2 If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

5.9.4 Record keeping. Each facility that performs mammograms:

5.9.4.1 Shall, except as provided in RHB 5.9.4.2, maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility;

5.9.4.2 Shall upon request by, or on behalf of, the patient permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly.

5.9.4.3 Any fee charged to the patient for providing the services in RHB 5.9.4 shall not exceed the documented costs associated with this service.

5.9.5 Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

5.9.5.1 Name of patient and an additional patient identifier.

5.9.5.2 Date of examination.

5.9.5.3 View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body shall be used to identify view and laterality.

5.9.5.4 Facility name and location. At a minimum, the location shall include the city, state, and zip code of the facility.

5.9.5.5 Technologist identification.

5.9.5.6 Cassette/screen identification.

5.9.5.7 Mammography unit identification, if there is more than one unit in the facility.

RHB 5.10 Quality Assurance Requirements. Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

5.10.1 Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who shall be allowed adequate time to perform these duties.

5.10.1.1 Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of this Part. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

5.10.1.2 Interpreting physicians. All physicians interpreting mammograms for the facility shall:

5.10.1.2.1 Follow the facility procedures for corrective action when the images that they are asked to interpret are of poor quality; and

5.10.1.2.2 Participate in the facility's medical outcomes audit program.

5.10.1.3 Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in RHB 5.12 and RHB 5.13.

5.10.1.4 Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of RHB 5.11.

5.10.2 Quality assurance records.

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5.10.2.1 The lead interpreting physician, quality control technologist and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated.

5.10.2.2 These quality control records shall be kept for each test specified in RHB 5.11 until the next annual inspection has been completed and the Department has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

5.10.2.3 A report of the medical physicist's test results with numerical values shall be submitted to the Department annually as required by RHB 5.12.

RHB 5.11 Equipment Quality Assurance Tests

5.11.1 Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

5.11.1.1 The base plus fog density shall be within plus 0.03 of the established operating level.

5.11.1.2 The mid-density shall be within plus or minus 0.15 of the established operating level.

5.11.1.3 The density difference shall be within plus or minus 0.15 of the established operating level.

5.11.2 Weekly quality control tests. Facilities with screen-film systems shall perform a phantom image quality evaluation test, using an FDA-approved phantom, at least weekly.

5.11.2.1 The optical density of the film at the center of an image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

5.11.2.2 The optical density of the film at the center of the phantom image shall not change by more than plus or minus 0.20 from the established operating level.

5.11.2.3 The phantom image shall achieve at least the minimum score established by the accreditation body.

5.11.2.4 The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than plus or minus 0.05 from the established operating level.

5.11.3 Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

5.11.3.1 Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

5.11.3.2 Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

5.11.4 Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

5.11.4.1 Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.20, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

5.11.4.2 Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

5.11.4.3 Compression device performance. The maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 209 newtons (45 pounds).

5.11.5 Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

5.11.5.1 Automatic exposure control performance.

5.11.5.1.1 The AEC shall be capable of maintaining film optical density within plus or minus 0.30 of the mean optical density when the thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that shall be used so that optical densities within plus or minus 0.30 of the average under phototimed conditions can be produced.

5.11.5.1.2 After October 28, 2002, the AEC shall be capable of maintaining film optical density within plus or minus 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

5.11.5.1.3 The optical density of the film in the center of the phantom image shall not be less than 1.20.

5.11.5.2 Kilovoltage peak accuracy and reproducibility. The kVp shall be accurate within plus or minus 5 percent of the indicated or selected kVp at:

5.11.5.2.1 The lowest clinical kVp that can be measured by a kVp test device;

5.11.5.2.2 The most commonly used clinical kVp;

5.11.5.2.3 The highest available clinical kVp; and

5.11.5.2.4 At the most commonly used clinical setting of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02. The kVp shall be checked annually or upon new x-ray tube installation.

5.11.5.3 Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated by measuring focal spot dimensions or by determining system resolution. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution. For focal spot dimensions, the measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the following tolerance limits:

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Focal Spot Tolerance Limit

Nominal Focal Spot Size (mm)	Maximum Width(mm)	Measured Dimensions Length(mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

5.11.5.3.1 System Resolution.

5.11.5.3.1.1 Each x-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 cycles per millimeter (mm)(line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

5.11.5.3.1.2 The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

5.11.5.3.1.3 When more than one target material is provided, the measurement shall be made using the appropriate focal spot for each target material.

5.11.5.3.1.4 When more than one source-image receptor distance is provided, the test shall be performed at the SID most commonly used clinically

5.11.5.3.1.5 Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

5.11.5.3.2 Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in this Part. The focal spot shall be checked annually or upon new x-ray tube installation.

5.11.5.4 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 for any specific combination of selected technique factors. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$. This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.5 Timer Reproducibility. The coefficient of variation of the timer shall not exceed 0.05. This requirement shall be deemed to have been met if, with a selected timer setting, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$. This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.6 Timer Accuracy. Deviation of the selected time setting from indicated time values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications,

the deviation shall not exceed 10% of the indicated time value. This requirement shall be checked annually or upon a new mammography x-ray unit or a new tube installation.

5.11.5.7 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

5.11.5.7.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

5.11.5.7.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

5.11.5.7.3 Measuring Compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. The two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than .45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the tube manufacturer. Linearity shall also be checked annually or upon new x-ray tube installation.

5.11.5.8 Beam quality and half-value layer (HVL). For mammography systems operating at x-ray tube potentials of less than 50 kVp, the HVL in millimeters of aluminum of the useful beam shall be equal to or greater than the product of the measured tube potential in kilovolts multiplied by 0.01. The half-value layer shall be measured with the compression device in the beam and shall be measured at the same tube potential used in Appendix A of this Part, Mammography Dose Measurement Protocol and Appendix B of this Part, Mammography Phantom Image Evaluation. The HVL shall be checked annually and after repairs to the system have been made that could affect the filtration or upon new x-ray tube installation.

5.11.5.9 Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mAs shall not exceed 0.05.

5.11.5.10 Dosimetry. The average glandular dose delivered during a single craniocaudal view of a phantom simulating a standard breast shall not exceed 3.0 milligray (Gy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast. The average glandular dose shall be checked annually or upon new tube installation.

5.11.5.11 X-ray field/light field/image receptor/compression paddle alignment.

5.11.5.11.1 All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement is for both large and small cassettes sizes.

5.11.5.11.2 If a light field that passes through the x-ray beam limitation device is provided, it shall be aligned with the x-ray field so that the total of any misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.

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5.11.5.11.3 The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

5.11.5.12 Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

5.11.5.13 System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

5.11.5.14 Radiation output.

5.11.5.14.1 The system shall be capable of producing a minimum output of 4.5 Gy air kerma per second (513 mR per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions, shall be capable of producing a minimum output of 7.0 Gy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate

5.11.5.14.2 The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

5.11.5.15 Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

5.11.5.15.1 An override capability to allow maintenance of compression;

5.11.5.15.2 A continuous display of the override status; and

5.11.5.15.3 A manual emergency compression release that can be activated in the event of power or automatic release failure.

5.11.6 The quality assurance requirements of 4.2.16 and film processing requirements of 4.2.17.2 shall be met except where otherwise mentioned.

5.11.7 Quality control tests-other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer.

5.11.8 Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in RHB 5.11.1 through 5.11.7. In addition, at each examination location, before any examinations are conducted, the mobile mammography system shall be tested using the mammography phantom image evaluation to establish the adequacy of the image quality produced by the unit.

5.11.9 Use of test results.

5.11.9.1 After completion of the tests specified in RHB 5.11.1 through 5.11.8, the facility shall compare the test results to the corresponding specified action limits; or, for non-screen film modalities, to the manufacturer's recommended action limits; or for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

5.11.9.2 If the test results fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken and documented:

5.11.9.2.1 Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests described in RHB 5.11.1, 5.11.2, 5.11.4.1, 5.11.4.2, 5.11.4.3, 5.11.5.10, 5.11.6, 5.11.7, or 5.11.8.

5.11.9.2.2 Within thirty days of the test date for all other tests described in RHB 5.11.

RHB 5.12 Surveys.

5.12.1 At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests and numerical values to ensure that the facility meets the quality assurance requirements of the annual tests described in RHB 5.11.5 and RHB 5.11.6 or RHB 5.11.7; and the weekly phantom image quality test described in 5.11.2.

5.12.2 The results of all these tests conducted by the facility in accordance with RHB 5.11.1 through RHB 5.11.8, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.

5.12.3 The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

5.12.4 The survey report shall be sent to the facility within thirty days of the date of the survey.

5.12.5 The facility shall send a copy of the survey report to the Department within ten days of completion of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must be sent to the Department.

5.12.6 The survey report shall be dated and signed by the medical physicist performing and/or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

RHB 5.13 Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the applicable standards in RHB 5.8 and RHB 5.11. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or an individual under the direct supervision of a medical physicist.

RHB 5.14 Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every two years and each time the instrument is repaired. The instrument calibration must be traceable to

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a national standard and calibrated with an accuracy of plus or minus six percent (ninety-five percent confidence level) in the mammography energy range.

RHB 5.15 Additional Administrative Requirements. Each facility where mammography services are provided shall ensure the availability for each mammography patient:

5.15.1 Instructions on how to perform breast self-examination, and

5.15.2 Information that early detection of breast cancer is maximized through a combined approach, using monthly breast self-examination, a thorough physical examination performed by a physician, and mammography performed at recommended intervals; and

5.15.3 Information that mammography is the most accurate method for making an early detection of breast cancer, however, no diagnostic tool is 100% effective.

RHB 5.16 Facility Cleanliness

5.16.1 The facility shall establish and implement written procedures for maintaining darkroom, screen, and view box cleanliness.

5.16.2 The facility shall document that all cleaning procedures are performed at the frequencies specified in the written procedures.

RHB 5.17 Infection Control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

5.17.1 Comply with the manufacture recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

5.17.2 If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

RHB 5.18 Mammography procedures and techniques, for mammography patients with breast implants.

5.18.1 Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

5.18.2 Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.

RHB 5.19 Consumer Complaint Mechanism. Each facility shall:

5.19.1 Establish a written and documented system for collecting and resolving consumer complaints.

5.19.2 Maintain a record of each serious complaint received by the facility for at least three years after the date the complaint was received;

5.19.3 Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;

5.19.4 Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.

RHB 5.20 Clinical image quality. Clinical images produced by any certified facility shall continue to comply with the standards for clinical image quality established by that facility's accreditation body.

RHB 5.21 Mammography Medical Outcomes Audit. Each facility shall establish and maintain a mammography medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity and accuracy of the interpretation of mammograms.

5.21.1 General Requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

5.21.2 Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than twelve months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever is later. This audit analysis shall be completed within an additional twelve months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses shall be conducted at least once every twelve months.

5.21.3 Reviewing interpreting physician. Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every twelve months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If follow-up actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the follow-up.

RHB 5.22 Additional Mammography Review and Patient Notification.

5.22.1 If the Department believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the Department, for review by the accreditation body. The Department will determine whether the facility is in compliance with this Part and if not, whether there is a need to notify affected patients, their physicians, or the public that the liability, clarity, and accuracy of interpretation of mammograms has been compromised.

5.22.2 If the Department determines that the quality of mammography performed by a facility, whether or not certified under RHB 5.3, was so inconsistent with the quality standards established in this Part as to present a significant risk to individual or public health, the Department may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures and such other relevant information as the Department may require.

RHB 5.23 Revocation of Accreditation. If a facility's accreditation is revoked by an accreditation body, the Department may conduct an investigation into the reasons for the revocation. Following such investigation, the Department may suspend or revoke the facility's certificate and take whatever other action or combination of actions to protect public health, including requiring the establishment and implementation of a corrective plan of action that shall permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is suspended or revoked because it has lost its accreditation may not practice mammography.

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RHB 5.24 Suspension or Revocation of Certificates

5.24.1 Except as provided in 5.24.2, the Department may suspend or revoke a certificate if the Department finds that the owner, operator, or any employee of the facility:

5.24.1.1 Has been guilty of misrepresentation in obtaining the certificate;

5.24.1.2 Has failed to comply with the standards of RHB 5.2 through 5.22.

5.24.1.3 Has failed to comply with reasonable requests of the Department or the accreditation body for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of RHB 5.2 through RHB 5.22.

5.24.1.4 Has refused a reasonable request of a duly designated FDA inspector, Department inspector or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

5.24.1.5 Has violated or aided and abetted in the violation of any provision of this regulation;

5.24.1.6 Has failed to comply with prior sanctions imposed by the Department; or

5.24.1.7 Has failed to pay any required fees.

5.24.2 The Department may suspend the certificate of a facility if the Department makes a finding described in RHB 5.24.1 and also determines that:

5.24.2.1 The failure to comply with required standards present a serious risk to human health;

5.24.2.2 The refusal to permit inspection makes immediate suspension necessary; or

5.24.2.3 There is a reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

5.24.3 If the Department suspends a certificate in accordance with 5.24.2.

5.24.3.1 The facility may request a review from the Director of Health Regulation no later than thirty days from the effective date of this suspension;

5.24.3.2 The suspension shall remain in effect until the Department determines that:

5.24.3.2.1 Allegations of violations or misconduct were not substantiated;

5.24.3.2.2 Violations of required standards have been corrected to the Department's satisfaction; or

5.24.3.2.3 The facility's certificate is revoked in accordance with 5.24.4;

5.24.4 The Department may revoke the facility's certificate if the Department determines that the facility:

5.24.4.1 Is unwilling or unable to correct violations that were the basis for suspension; or

5.24.4.2 Has engaged in fraudulent activity to obtain or continue certification.

RHB 5.25 Mammography Units Used for Localization or Stereotactic Breast Biopsy Procedures

5.25.1 Personnel. The following requirements apply to all personnel involved in localization or biopsy procedures performed with mammography units:

5.25.1.1 Interpreting Physicians. The interpreting physician shall:

5.25.1.1.1 Be responsible for quality assurance activities including medical audit (tracking of number of biopsies done, cancers found, benign lesions, biopsies needing repeat, and complications).

5.25.1.1.2 Be responsible for oversight of all quality control.

5.25.1.1.3 Be responsible for the supervision of the radiologic technologist and the medical physicist.

5.25.1.1.4 Be responsible for post-biopsy management of the patient.

5.25.1.1.5 Documentation of compliance with this Part shall be provided to the Department upon request.

5.25.1.2 Radiologic Technologists.

5.25.1.2.1 The radiologic technologist shall be currently registered in good standing with the American Registry of Radiologic Technologists.

5.25.1.2.2 The technologist shall have previously received documented training specifically in stereotactic breast biopsy procedures and techniques along with positioning for stereotactic units. This training shall consist of 15 hours of continuing education in mammography every three years and three hours of Category A continuing education in stereotactic breast biopsy every three years.

5.25.1.2.3 Documentation of registration and training shall be provided to the Department upon request.

5.25.1.3 Medical Physicists. The medical physicist shall:

5.25.1.3.1 Be approved by the Department as a Class IX vendor as required in 2.6.6.9 and be certified in diagnostic radiological physics or radiological physics by either the American Board of Radiology (ABR) or The American Board Medical Physics (ABMP);

5.25.1.3.2 Meet the requirements of RHB 5.7.3.1.1, 5.7.3.1.2, and 5.7.3.1.3.

5.25.1.3.3 Have fifteen hours of continuing education in mammography physics every three years.

5.25.1.3.4 Have performed at least two stereotactic breast biopsy surveys per year and;

5.25.1.3.5 Have three hours of continuing education in stereotactic breast biopsy physics every three years.

5.25.2 Equipment. Mammography units used for stereotactic breast biopsy or localization procedures shall meet the requirements of RHB 5.8, 5.11.5.2, 5.11.5.3, and 5.11.5.8 with the exception of RHB 5.11.5.10. Digital output mammography systems that do not use screen-film image receptors are exempt from the requirements of RHB 5.8 of these regulations as they relate to screen-film image receptors.

5.25.3 Quality Assurance.

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5.25.3.1 Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity and accuracy of mammography localization or biopsy procedures performed at the facility.

5.25.3.2 Each facility shall have the services of a medical physicist available to survey mammography equipment and to oversee the equipment-related quality assurance practices of the facility.

5.25.3.3 The quality assurance program shall be in writing and shall have been developed by a medical physicist. The program shall include, but need not be limited to the following:

5.25.3.3.1 Specifications of the tests that are to be performed, including instructions to be employed in the performance of those tests; and

5.25.3.3.2 Specifications of the frequency at which tests are to be performed, the acceptable tolerance for each parameter measured and actions to be taken if tolerances are exceeded.

5.25.3.4 The medical physicist shall conduct a review of the quality assurance program each year. Such review shall include evaluation of the results of quality assurance testing and quality control tests as specified in the American College of Radiology's Stereotactic Breast Biopsy Accreditation Program Overview.

5.25.3.5 Each facility shall maintain written records of the radiation dose measurements and quality assurance testing performed, as required in this Part, for inspection by the Department for a period of at least one year, or until the next Department inspection, whichever is later. Such records shall include, but not be limited to, the following:

5.25.3.5.1 The date of the test and identification of the person performing the test;

5.25.3.5.2 Identification of the type of testing that was performed; and

5.25.3.5.3 Notification of whether the results of the testing were within the parameters established by the medical physicist.

5.25.3.6 The facility shall send a copy of the medical physicist's survey report to the Department within ten days of completion of corrective action required by the report. Documentation of corrective action, required as a result of the survey, must to be sent to the Department.

5.25.3.7 The survey report shall be dated and signed by the medical physicist performing and/or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

RHB 5.26 Shielding. All mammography facilities shall meet the shielding requirements specified in RHB 4.4.

RHB 5.27 Operating conditions. All mammography facilities shall meet the requirements of RHB 4.2.3.

RHB 5.28 Notification Requirements for Mobile Mammography Facilities Certified by Another Certifying Agency. Mobile mammography facilities that operate in South Carolina and are certified under MQSA by the FDA, or another State authorized by FDA to certify mammography facilities under MQSA, shall:

5.28.1 Notify the Department by telephone, facsimile, or letter of each date and location of operation of the mobile mammography facility in South Carolina prior to conducting such operation.

5.28.2 At all times while operating in South Carolina, have the following documentation available for review and inspection by the Department:

5.28.2.1 A copy of the mammography facility certificate issued by the FDA or another State, showing that the facility is currently certified.

5.28.2.2 A summary of the most recent physics survey of the mammography machine(s) and documentation of any corrective actions recommended by the medical physicist who performed the physics survey.

5.28.2.3 Documentation that personnel meet the qualifications of RHB 5.7.

RHB 5.29 Failure of Mobile Mammography Facilities Certified by Another Certifying Entity to Meet Requirements. The Department shall notify the certifying entity of the facts and circumstances and may take other actions as may be appropriate under the Atomic Energy and Radiation Control Act and regulations thereunder if the Department has reason to believe that the owner, operator, or any employee of a mobile facility certified by another certifying entity:

5.29.1 Has been guilty of misrepresentation in obtaining the certificate;

5.29.2 Has failed to comply with the standards of this Part;

5.29.3 Has failed to comply with reasonable requests of the Department for records, information, reports, or materials that the Department believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of this Part;

5.29.4 Has refused a reasonable request of a Department representative for permission to inspect the facility or the operations and pertinent records of the facility.

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Part V - Appendix A

Mammography Dose Measurement Protocol

The technique factors used for performing a mammography examination shall not permit the mean glandular absorbed dose to exceed the limits specified in RHB 5.11.5.10. Radiation measurements shall be performed with an integrating radiation measuring device that is appropriate to the high beam intensity and mammographic kilovoltage peak (kVp) used, and sufficiently sensitive to determine compliance with the criteria specified in RHB 5.14. The instrument shall have been calibrated as specified in RHB 5.14.

The mammography exam dose limits are based on an average compressed breast value of 4.2 centimeters having an average density (i.e., 50 percent adipose and 50 percent glandular).

Perform the following steps to determine the mean glandular dose to a nominal 4.2 centimeter compressed breast:

a) Measure and record the x-ray system's useful beam half value layer (HVL). (See RHB 5.11.5.8.) Any compression device normally in the useful beam during mammography procedures shall be required to be placed between the x-ray tube target and measuring device when determining the HVL. The useful beam shall be collimated to a size encompassing the detector.

NOTE: Filters used for the HVL evaluation should be placed as close to the target as practical. The HVL for screen-film mammography should not exceed the minimum acceptable HVL by more than 0.1 millimeter of aluminum equivalent.

b) Determine the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (see Appendix C of this Part) using the appropriate HVL, kVp and x-ray tube target-filter material.

NOTE: The kVp of screen-film mammography systems with molybdenum target-filter combinations should be accurately measured to determine the appropriate glandular dose to entrance exposure factor from Appendix C of this Part.

c) If the equipment has the capability for variable source to image receptor distance, set the craniocaudal source to image receptor distance (SID) for the image receptor system used.

d) Position in the useful beam any compression apparatus normally used.

NOTE: Some mammography systems have the capability of providing automatic adjustment of technique factors through feedback from the position of the compression device. On such systems, the compression device should be lowered to a position 4.2 centimeters above the breast support assembly (BSA). The device should then be removed, inverted and replaced to allow placement of the phantom and measuring device on the BSA below the compression device. If the compression device cannot be replaced in an inverted position, the device should be placed in the beam using auxiliary support.

e) Placement of the Radiation Measuring Device

1) For systems equipped with automatic exposure control (AEC):

A) Place a properly loaded film cassette in the cassette holder.

NOTE: The loaded cassette is placed in the cassette holder to simulate, as much as is possible, the conditions under which actual patient exposures are made. Following radiation measurements, the film should be discarded and the cassette reloaded with unexposed film.

B) Place a mammography phantom (see the definition for "Phantom" in RHB 9.168) on the breast support assembly (BSA). Align the phantom so that the edge of the phantom is aligned with the chest wall side of the BSA and the phantom is over the automatic exposure control device(s).

C) Place a radiation measuring device in the useful beam so the center axis of the device is parallel to the breast support assembly (BSA). The geometric center of the measuring device shall be positioned 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA and immediately adjacent to either side of the mammography phantom.

2) For systems not equipped with AEC, place a radiation measuring device in the useful beam so that the center axis of the device is parallel to the breast support assembly (BSA). The geometric center of the measuring device shall be positioned so that it is centered 4.5 centimeters above the BSA, 2.5 centimeters from the chest wall edge of the BSA and at the center line of the BSA. No part of the device's detector area shall be outside of the useful beam.

f) Collimate the x-ray field to the size normally used and assure that the area covered by the useful beam includes the detector area of the radiation measuring device and the mammography phantom if the equipment is equipped with automatic exposure.

g) Set the appropriate technique factors or automatic exposure controls normally used for a nominal 4.2 centimeter compressed breast.

h) Measure and record the exposure in air with the radiation measuring device.

i) Calculate the mean glandular dose for a 4.2 centimeter compressed breast by multiplying the measured exposure in millicoulombs per kilogram or in roentgens by the glandular dose to entrance exposure factor, which was determined using the procedure described in subsection (b) of this Appendix.

EXAMPLE: A mammography system is provided with a molybdenum target-filter combination, and the HVL and kVp are determined to be 0.3 and 30, respectively. Therefore, for a 4.2 centimeter compressed breast, the glandular dose to entrance exposure factor from the Mammography Dose Evaluation Table (Appendix C of this Part) would be 159 mrad. The measured roentgen output determined in subsection (h) of this Appendix is determined to be 1.8 R. Therefore, the mean glandular dose would be 1.8 R multiplied by 159 mrad/R. This results in a mean glandular dose measurement of 286 mrad. As such, the system would be in compliance with RHB 5.11.5.10.

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Part V - Appendix B

Mammography Phantom Image Evaluation

Mammography Phantom image evaluation shall be performed using the procedure below. The evaluation shall be performed weekly as a part of the quality assurance program. The evaluation shall be performed with the mammography phantom specified in RHB 9.172.

a) Equipment necessary for mammography phantom image evaluation includes a densitometer, the mammography phantom and mammographic cassette and film.

b) Load film in the mammographic cassette according to the manufacturer's instructions.

c) Place the properly loaded cassette in the cassette holder.

d) Place the mammography phantom on the breast support assembly (BSA) so that the edge of the phantom is aligned with the chest wall side of the BSA. Align the phantom so that the masses in the phantom are nearest the chest wall edge of the BSA and the fibers in the phantom are away from the chest wall edge of the BSA. If the mammography machine has the capability of automatic exposure control, place the phantom so that the phantom covers the phototimer sensor.

e) Position the compression device so that it is in contact with the phantom.

f) Select the technique factors used most frequently in the clinical setting for a 4.2 centimeter compressed breast and make an exposure of the phantom.

g) Process the film in the processor used for clinical mammography films.

h) Examine the processed image for areas of non-uniformity of optical density and for the presence of artifacts due to dirt, dust, grid lines or processing.

NOTE: If any of the problems noted above are evident on the processed image, the mammography machine film processor and film cassette(s) should be evaluated and the problem corrected. The phantom image evaluation should be repeated after the problem is corrected.

i) Measure and record the optical density of the film near the center of the phantom image. The optical density of the film at the center of the image of the phantom shall be at least 1.20 when exposed under a typical clinical condition.

j) Examine the phantom image and count and record the number of masses visualized. Repeat this procedure for the speck groups and the fibrils and record the number of objects visualized. There are a total of 16 imaging objects (5 masses, 5 speck groups and 6 fibrils) in the phantom. Evaluation criteria for objects visualized in the phantom image are in RHB 5.11.2.3. and RHB 5.11.2.4. As a minimum, the objects that must be visualized in the phantom image are:

1) The masses that are 0.75 millimeter or larger (a total of 3 masses);

2) The speck groups that are 0.32 millimeter or larger (a total of 3 speck groups);

3) The fibrils that are 0.75 millimeter or larger (a total of 4 fibrils).

NOTE: The phantom image should be compared with previous films, including the original phantom image, to determine if subtle changes are occurring from week to week.

Part V - Appendix C
Mammography Dose Evaluation Tables

These tables are used to determine the mean glandular dose in milligrays delivered by 25.9 mC/kg (or millirad) delivered by 1 R in air incident on a 4.2 centimeter thickness compressed breast of average density (50 percent adipose and 50 percent glandular tissue. Linear extrapolation or interpolation shall be made for any HVL not listed. To convert from entrance exposure in air in roentgens to mean glandular breast dose in millirads, multiply the entrance exposure by the factor shown in the table for the appropriate kVp and beam quality (HVL) combination.

GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS---50% ADIPOSE-50% GLANDULAR BREAST TISSUE---USING A Mo/Mo TARGET-FILTER COMBINATION*

HVL	X-ray Tube Voltage (kVp)											W/AI
	23	24	25	26	27	28	29	30	31	32	33	Target-Filter Combination
0.23	116											
0.24	121	124										
0.25	126	129	131									
0.26	130	133	135	138								
0.27	135	138	140	142	143							
0.28	140	142	144	146	147	149						
0.29	144	146	148	150	151	153	154					
0.30	149	151	153	155	156	157	158	159				170
0.31	154	156	157	159	160	161	162	163	164			175
0.32	158	160	162	163	164	166	167	168	168	170	171	180
0.33	163	165	166	168	169	170	171	173	173	174	175	185
0.34	168	170	171	172	173	174	175	176	177	178	179	190
0.35		174	175	176	177	178	179	180	181	182	183	194
0.36			179	181	182	183	184	185	185	186	187	199
0.37				185	186	187	188	189	190	191	191	204
0.38					190	191	192	193	194	195	195	208
0.39						196	197	198	198	199	200	213
0.40							201	202	203	204	204	217
0.41								206	207	208	208	221
0.42									211	212	212	225
0.43										215	216	230
0.44											220	234
0.45												238

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GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS ---50% ADIPOSE 50% GLANDULAR BREAST TISSUE ---USING A Mo/Rh TARGET-FILTER COMBINATION*

HVL	X-ray Tube Voltage (kVp)										
	25	26	27	28	29	30	31	32	33	34	35
0.28	149	151	154								
0.29	154	156	158	159							
0.30	158	160	162	162	163						
0.31	163	164	166	166	166	167	167				
0.32	167	169	171	171	171	171	172	172			
0.33	171	173	175	176	176	176	176	177			
0.34	176	178	179	179	180	180	180	181	181		
0.35	180	181	183	183	184	185	185	186	187		
0.36	185	186	187	187	188	188	189	190	191	191	
0.37	189	190	191	191	192	193	193	194	195	195	
0.38	193	194	196	196	197	197	197	198	199	199	200
0.39	198	199	200	200	201	201	202	202	203	203	204
0.40	202	203	204	204	205	205	206	207	208	208	208
0.41	206	207	208	208	209	209	210	211	212	212	212
0.42	211	211	212	212	213	213	214	215	216	216	217
0.43	215	216	217	217	218	218	219	219	220	220	221
0.44	220	220	221	221	222	222	223	223	224	224	225
0.45	224	224	225	225	226	226	227	227	228	228	229
0.46		228	229	229	230	231	231	232	233	233	234
0.47			233	233	234	235	235	236	237	237	238
0.48			238	238	239	240	240	241	241	242	242
0.49				242	243	243	244	244	245	245	246
0.50					247	247	248	248	249	250	251
0.51						251	252	253	254	254	255
0.52							257	257	258	258	259
0.53							261	261	262	263	264
0.54								265	266	267	268
0.55								269	270	271	272
0.56									275	276	276
0.57									279	280	281
0.58										284	285
0.59										288	289
0.60											293

GLANDULAR DOSE (IN mrad) FOR 1 ROENTGEN ENTRANCE EXPOSURE TO A 4.2-CM BREAST THICKNESS ---50% ADIPOSE 50% GLANDULAR BREAST TISSUE ---USING A Rh/Rh TARGET-FILTER COMBINATION*

X-ray Tube Voltage (kVp)											
HVL	25	26	27	28	29	30	31	32	33	34	35
0.28	150	155	159								
0.29	155	160	164	168							
0.30	160	164	168	172	176						
0.31	165	168	172	174	180	182					
0.32	169	173	177	181	184	186	188				
0.33	174	178	181	185	188	190	192				
0.34	179	183	186	190	193	195	196	199			
0.35	184	187	190	194	197	199	201	203			
0.36	189	192	195	198	201	204	205	207	209		
0.37	193	196	199	202	205	207	209	211	213		
0.38	198	201	204	207	209	211	213	215	217	219	221
0.39	203	206	208	211	214	216	217	219	221	223	224
0.40	208	211	213	216	218	220	221	223	224	226	228
0.41	213	215	217	220	222	224	225	227	228	230	232
0.42	218	220	222	224	226	228	229	231	232	234	236
0.43	222	224	226	228	230	232	233	235	236	238	240
0.44	227	229	231	233	235	237	238	239	240	242	243
0.45	232	234	235	237	239	241	242	243	244	246	247
0.46			239	241	243	245	246	247	248	250	251
0.47					247	249	250	251	252	254	255
0.48					251	253	254	255	256	258	259
0.49						257	258	259	260	261	262
0.50						261	262	263	264	265	266
0.51							266	267	268	269	270
0.52							270	271	272	273	274
0.53							275	276	276	277	278
0.54								279	280	280	281
0.55								283	284	284	285
0.56									288	288	289
0.57										292	293
0.58										296	297
0.59											300
0.60											304

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PART VI USE OF THERAPEUTIC EQUIPMENT

RHB 6.1 Scope. This part establishes requirements for use of therapeutic equipment by persons licensed to practice one or more of the health professions within the authority granted to them by statute or regulation. Therapeutic equipment in this part will be defined as any therapeutic machine capable of producing a useful beam of x-rays, or x-rays and charged particles with energies greater than 500 keV. Particle accelerators meeting this definition will be regulated under this part while all other particle accelerators will be regulated under Title C. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations. All provisions of this Part apply to therapeutic veterinary installations.

RHB 6.2 Shielding Requirements for all Therapeutic X-ray Equipment.

6.2.1 All facilities utilizing therapy equipment shall meet the shielding requirements specified in RHB 4.4.

RHB 6.3 General Provisions for All Therapeutic Equipment.

6.3.1 Radiation Safety Officer.

6.3.1.1 The registrant shall designate an individual who will be responsible for radiation protection for the therapeutic equipment. Such individual may be a radiological physicist, and shall:

6.3.1.1.1 Be qualified by training and experience concerning all hazards and precautions involved in operating the therapeutic equipment for which he is responsible.

6.3.1.1.2 Recommend a detailed program of radiation safety for effective compliance with the applicable requirements of these regulations.

6.3.1.1.3 Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the therapeutic equipment.

6.3.1.1.4 Make surveys and carry out other procedures as required by these regulations.

6.3.1.2 Each therapeutic machine shall be under the administrative control of the Radiation Safety Officer, who will be responsible for the safe operation of the equipment.

6.3.2 Procedures.

6.3.2.1 Written operating procedures as well as specified safety rules shall be established for each therapeutic unit facility and approved by the radiation safety officer.

6.3.2.1.1 Operating procedures. The written operating procedures to be implemented shall include the following:

6.3.2.1.1.1 Policies and procedures for pregnant workers; NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers;

6.3.2.1.1.2 Policies and procedures for personnel monitoring;

6.3.2.1.1.3 Policies and procedures for training new employees; and

6.3.2.1.1.4 Policies and procedures for identifying and reporting misadministrations, as defined by RHB 9.153.

6.3.2.1.1.5 Policies and procedures for quality assurance addressing annual equipment performance testing on radiation therapy simulators and CT scanners used for treatment planning.

6.3.2.1.2 Emergency Procedures. The emergency procedures shall include instructions for contacting the therapeutic radiological physicist when operational problems or emergencies occur and the actions that are to be taken until the physicist can be contacted.

6.3.2.2 Operators and maintenance personnel shall be familiar with and have available a copy of the written operating and emergency procedures. Documentation must be maintained indicating that the operator or maintenance person has read and agrees to adhere to the operating procedures.

6.3.3 Operator Requirements and Training.

6.3.3.1 The registrant shall assure that all therapeutic equipment under his control is operated only by a radiation therapist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association. For the purpose of this Part, a radiation therapist is defined as a person who applies radiation to humans for therapeutic purposes; performs treatment setups, including, but not limited to, patient positioning, setting of treatment parameters on the control panel, and verification of treatment accessories; or documents daily treatments for a patient's chart.

6.3.3.2 In-house modification, repairs, or preventative maintenance on therapeutic equipment components or safety interlocks may be performed only by or under the direct supervision of persons who have received at least the minimum training specified in RHB 6.3.3.12 and demonstrated competence specified in RHB 6.3.3.13.

6.3.3.3 No person other than a licensed practitioner or a radiation therapist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for therapeutic purposes.

6.3.3.4 No person shall employ or designate as a radiation therapist a person who does not hold a certificate issued by the South Carolina Radiation Quality Standards Association.

6.3.3.5 No person holding a certificate issued by the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for therapeutic purposes unless under the direction and supervision of a licensed practitioner and unless so directed by prescription of a licensed practitioner.

6.3.3.6 No person who is not certified by the South Carolina Radiation Quality Standards Association shall take, use, or exhibit the title of "limited practice radiographer," "radiographer," or "radiation therapist" or any other title, sign, display, or declaration that tends to lead the public to believe that the person is authorized to apply ionizing radiation on humans for therapeutic purposes.

6.3.3.7 A student enrolled in and attending a school or college of medicine, radiologic technology, radiation therapy, or a curriculum approved by the South Carolina Radiation Quality Standards Association, or a resident in an approved graduate education program of medicine may apply ionizing radiation to humans without a certificate from the South Carolina Radiation Quality Standards Association as long as the student or resident is under the supervision of a licensed practitioner or direct supervision of a certified radiation therapist appropriately trained to supervise the specific procedure.

6.3.3.8 The registrant shall display each operator's current certificate in public view, not obstructed by any barrier, equipment, or other object. The registrant may also post a notice to the public that South Carolina Radiation Quality Standards Association certificates are available for review upon request.

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6.3.3.9 The registrant shall ensure that each operator has received training specific to the equipment and procedures in use at his facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 6.3.2. Documentation of this training for each operator shall be made available for Departmental review.

6.3.3.10 All operators shall receive at least one month of on-the-job training before assuming operational responsibility.

6.3.3.11 The registrant shall maintain a record of all training for each operator. Such records shall be made available for Departmental inspection.

6.3.3.12 Training of in-house and test maintenance personnel shall include:

6.3.3.12.1 Fundamentals of Radiation Safety;

6.3.3.12.1.1 Characteristics of radiation.

6.3.3.12.1.2 Units of radiation dose.

6.3.3.12.1.3 Hazards of excessive exposure to radiation.

6.3.3.12.1.4 Levels of radiation from therapeutic equipment.

6.3.3.12.1.5 Methods used to prevent radiation exposure including shielding, interlocks, safety rules, and radiation monitoring equipment.

6.3.3.12.2 Use and care of personnel monitoring equipment employed at the facility.

6.3.3.12.3 Location and use of all operating controls.

6.3.3.12.4 Requirements of pertinent State Regulations.

6.3.3.12.5 Registrant's written operating and emergency procedures.

6.3.3.13 In-house personnel who are to perform or directly supervise modifications, tests or maintenance work shall demonstrate the following capabilities to the radiation safety officer:

6.3.3.13.1 Ability to read and understand electrical diagrams.

6.3.3.13.2 A thorough knowledge of the principles and operation of the therapeutic equipment.

6.3.3.13.3 A thorough knowledge of the safety interlock system.

6.3.3.13.4 Ability to understand, use, and check the operation of radiation survey instruments.

6.3.3.14 The registrant shall maintain a record of all training for in-house testing and maintenance personnel. Such records shall be made available for Departmental inspection.

6.3.4 Training for Therapeutic Radiation Machine Authorized Users.

6.3.4.1 For any therapeutic radiation machine covered in Part VI the registrant shall require the authorized user to be a licensed practitioner who;

6.3.4.1.1 Is certified in:

6.3.4.1.1.1 Radiation Oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or

6.3.4.1.1.2 Radiation oncology by the American Osteopathic Board of Radiology; or

6.3.4.1.1.3 Radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or

6.3.4.1.1.4 Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or;

6.3.4.1.2 Is in the active practice of therapeutic radiology and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

6.3.4.1.2.1 To satisfy the requirement for instruction, the classroom and laboratory training shall include radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of ionization radiation, and radiation biology.

6.3.4.1.2.2 To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include review of the full calibration measurements and periodic quality assurance checks, evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings, using administrative controls to prevent misadministrations, implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console, and checking and using radiation survey meters.

6.3.4.1.2.3 To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an authorized user. The supervised clinical experience shall include:

6.3.4.1.2.3.1 Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications;

6.3.4.1.2.3.2 Selecting proper dose and how it is to be administered;

6.3.4.1.2.3.3 Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients’ progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients’ reaction to radiation; and

6.3.4.1.2.3.4 Post-administration follow-up and review of case histories.

6.3.4.2 The registrant shall maintain a record of all training for each authorized user. Such records shall be made available for Departmental inspection.

6.3.5 Control.

6.3.5.1 The radiation safety officer shall maintain a current list of all personnel who are qualified to service the therapeutic equipment.

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6.3.5.2 No registrant shall permit a therapeutic unit to operate at any time with a safety interlock bypassed, except for necessary testing.

6.3.5.3 The accelerator shall not be used for treatment of patients unless the operator can maintain visual observation of the patient and audible communication with the patient.

6.3.5.4 No individual other than the patient shall be in the therapy room during irradiation.

6.3.6 Technique indicators. Instrumentation readouts and controls on the therapy control console must be clearly identified and easily discernable.

6.3.7 The accelerator is used in such a manner that patients, workers, and the general public are protected from radiation hazards and the provisions of Part III of these regulations are met.

6.3.8 No therapeutic machine shall be left unattended unless it is secured against unauthorized use.

RHB 6.4 Therapeutic X-ray Systems of Less than 1 MeV.

6.4.1 Equipment requirements.

6.4.1.1 Leakage radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the values specified at the distance stated for the classification of that x-ray system shown in Table 1.

TABLE 1. LEAKAGE LIMITS FOR THERAPEUTIC X-RAY SYSTEMS OF LESS THAN 1 MeV.

System	Leakage Limit	Measurement Location
Contact Therapy	100 mR/hr	5 cm from surface of tube housing
0-150 kVp (manufactured or installed prior to the effective date of these regulations)	1 R in 1 hr.	1 m from source
0-150 kVp (manufactured on or after the effective date of these regulations)	100 mR in 1 hr	1 m from source
151-500 kVp	1 R in 1 hr	1 m from source
500-999 kVp	0.1 percent of 1 R in 1 hr.	1 m from source useful beam or

6.4.1.2 Permanent Beam-Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

6.4.1.3 Removable and Adjustable Beam-Limiting Device.

6.4.1.3.1 Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kV and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

6.4.1.3.2 Adjustable beam-limiting devices shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kV and maximum treatment filter.

6.4.1.3.3 Adjustable beam-limiting devices installed after May 25, 2001, shall meet the requirements of RHB 6.4.1.3.

6.4.1.4 The filter system shall be so designed that:

6.4.1.4.1 The filters cannot be accidentally displaced at any possible tube orientation;

6.4.1.4.2 For equipment installed after the effective date of these regulations, an interlock system prevents irradiation if the proper filter is not in place;

6.4.1.4.3 The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 Roentgens (7.74 mC/kg) per hour under any operating conditions; and

6.4.1.4.4 Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

6.4.1.5 Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.

6.4.1.6 Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such markings shall be readily accessible for use during calibration procedures.

6.4.1.7 Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

6.4.1.8 Beam Monitor System. Systems of greater than 150 kVp manufactured after the effective date of these regulations shall be provided with a beam monitor system which:

6.4.1.8.1 Shall have the detector of the monitor system interlocked to prevent incorrect positioning;

6.4.1.8.2 Shall not allow irradiation until a preselected value of exposure has been made at the treatment control panel;

6.4.1.8.3 Shall independently terminate irradiation when the preselected exposure has been reached;

6.4.1.8.4 Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

6.4.1.8.5 Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;

6.4.1.8.6 Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and

6.4.1.8.7 Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

6.4.1.9 Timer.

6.4.1.9.1 A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector.

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6.4.1.9.2 The timer shall activate with the production of radiation and retain its reading after irradiation is interrupted. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

6.4.1.9.3 The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

6.4.1.9.4 The timer shall permit accurate presetting and determination of exposure times as short as 1 second.

6.4.1.9.5 The timer shall not permit an exposure if set at zero.

6.4.1.9.6 The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer factor to compensate for mechanical lag.

6.4.1.9.7 Timers shall be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

6.4.1.10 Control Panel Functions. The control panel, in addition to the displays required in other provisions of this Part, shall have:

6.4.1.10.1 An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

6.4.1.10.2 An indication of whether x-rays are being produced;

6.4.1.10.3 Means for indicating x-ray tube potential and current;

6.4.1.10.4 Means for terminating an exposure at any time

6.4.1.10.5 A locking device which will prevent unauthorized use of the x-ray system; and

6.4.1.10.6 For x-ray systems manufactured after May 25, 2001, a positive display of specific filters in the beam.

6.4.1.11 Multiple Tubes. When a control panel may energize more than one x-ray tube:

6.4.1.11.1 It shall be possible to activate only one x-ray tube at any time;

6.4.1.11.2 There shall be an indication at the control panel identifying which x-ray tube is activated; and

6.4.1.11.3 There shall be an indication at the tube housing assembly when that tube is energized.

6.4.1.12 Source to Skin Distance (SSD). There shall be means of determining initially the SSD to within 1 centimeter and of producing this measurement to within 2 millimeters thereafter.

6.4.1.13 Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

6.4.1.13.1 After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

6.4.1.13.2 An indication of shutter position shall appear on the control panel.

6.4.2 Facility Design Requirements for Therapy X-ray Systems Capable of Operating Above 50 kVp.

6.4.2.1 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

6.4.2.2 Viewing Systems.

6.4.2.2.1 Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

6.4.2.2.2 When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

6.4.2.2.3 Should both systems described in RHB 6.4.2.2.2 above fail or be inoperative, treatment shall not be performed with the unit until one of the systems is restored.

6.4.2.3 Barriers. With equipment operating at voltages above fifty (50) kVp, the required barriers shall be an integral part of the building.

6.4.2.4 Multiple Access. Treatment rooms to which access is possible through more than one entrance shall be provided with flashing warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on". Interlocks shall be provided such that all entrance doors must be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.4.3 Additional Requirements for X-ray Systems Capable of Operating Above 150 kVp.

6.4.3.1 All protective barriers shall be fixed except for entrance doors or beam interceptors.

6.4.3.2 The control panel shall be within a protective booth equipped with an interlocked door or located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room.

6.4.3.3 Interlocks shall be provided such that all entrance doors must be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.4.3.4 When any door referred to in RHB 6.4.3.3 is opened while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgen per hour.

6.4.3.5 A scram button or other emergency power cut-off switch shall be located and easily identifiable in all accessible high radiation areas.

6.4.3.6 All safety and warning devices, including interlocks, shall be tested and appropriately serviced after each 500 hours of operation or at intervals not to exceed six months, whichever comes first. Documentation shall be kept and available for review of all testing and servicing.

6.4.4 Surveys, Calibrations, and Spot Checks.

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6.4.4.1 Surveys.

6.4.4.1.1 All new facilities, and existing facilities not previously surveyed shall have a survey made by or under the direction of a qualified expert who is authorized by the Department to perform such surveys. Such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. A record shall be made of the therapeutic operating conditions and radiation levels measured at specific control points. One of these control points must be at the normal work station of the operator.

6.4.4.1.2 The registrant shall obtain a written report of the survey from the qualified expert. A copy of the initial report shall be transmitted by the registrant to the Department within 30 days of the first patient treatment following the survey. The registrant shall maintain all subsequent reports for inspection by the Department.

6.4.4.1.3 The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules or regulations.

6.4.4.1.4 The registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by these regulations. Each radiation survey instrument shall meet the requirements of RHB 1.4.4.

6.4.4.2 Calibrations. Calibrations of x-ray systems subject to the requirements of this Part shall meet the following requirements:

6.4.4.2.1 The calibration of an x-ray system shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output on output.

6.4.4.2.2 The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a radiological physicist who is physically present at the facility during such calibration.

6.4.4.2.3 Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall meet the requirements of RHB 1.4.4.

6.4.4.2.4 The calibration shall be such that the dose at a reference point in a water or tissue equivalent phantom can be calculated to within an uncertainty of 5 percent. For superficial units, free-in-air calibrations are acceptable.

6.4.4.2.5 The calibration of the x-ray system shall include, but not be limited to, the following determinations:

6.4.4.2.5.1 Verification that the x-ray system is operating in compliance with the design specifications;

6.4.4.2.5.2 Half-value layer for each kV setting and filter combination used;

6.4.4.2.5.3 The exposure rates as a function of field size, technique factors, filter, and treatment distance used; and

6.4.4.2.5.4 The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present which shall be within 5 millimeters for any field edge.

6.4.4.2.6 Records of calibrations shall be maintained by the registrant for 5 years after completion of the calibration. The records shall be available for review.

6.4.4.2.7 A copy of the most recent x-ray system calibration shall be available at or in the general area of the control panel.

6.4.4.2.8 A copy of the most recent x-ray system calibration shall be submitted to the Department upon request.

6.4.4.3 Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

6.4.4.3.1 The spot check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedures shall be submitted to the Department upon request.

6.4.4.3.2 If the radiological physicist does not perform the spot check measurement, the results of the spot check measurements shall be reviewed by the radiological physicist within 7 treatment days and a record made of the review.

6.4.4.3.3 The spot check procedures shall specify the frequency at which tests or measurements are to be performed. The spot check procedures shall specify that the spot check shall be performed during the calibration specified in RHB 6.4.4.2. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in RHB 6.4.4.2 shall be stated.

6.4.4.3.4 The written spot check procedures shall include special operating instructions which shall be carried out whenever a parameter in RHB 6.4.4.2 exceeds an acceptable tolerance.

6.4.4.3.5 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot check procedures, the system shall be recalibrated, as required in RHB 6.4.4.2.

6.4.4.3.6 Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for 2 years after completion of the spot check measurements. A copy of the most recent spot check shall be available at or in the area of the control panel.

6.4.4.3.7 Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of RHB 6.4.4.2.3 or which has been intercompared with a system meeting those requirements within the previous year.

6.4.4.4 Prohibited use. The x-ray system shall not be used in the administration of radiation therapy unless the requirements of RHB 6.4.4.2 and RHB 6.4.4.3 have been met.

RHB 6.5 X-ray and Electron Therapy Systems with Energies of 1 MeV and Above. These rules shall apply to facilities using therapy systems with energies 1 MeV and above. The records shall be maintained and available for review.

6.5.1 Leakage Radiation to the Patient Area. Equipment shall meet the following requirements:

6.5.1.1 For operating conditions producing maximum leakage radiation, the absorbed dose in rads (Grays) due to leakage radiation, including x-rays and electrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (Grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and plane surface. Measurements excluding those for neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. Measurements of the portion of the leakage

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radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.

6.5.1.2 For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in RHB 6.5.1.1 for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Department.

6.5.2 Beam-Limiting Devices. Adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than 2 percent of the useful photon beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be included in this requirement.

6.5.3 Filters.

6.5.3.1 Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge tray is damaged, the wedge transmission factor shall be redetermined.

6.5.3.2 If the absorbed dose rate data required by RHB 6.5.15 relates exclusively to operation with a field-flattening filter or beam scattering foil in place, such filter shall be removable only by the use of tools.

6.5.3.3 For equipment installed after May 25, 2001, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam scattering foils:

6.5.3.3.1 Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically.

6.5.3.3.2 An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

6.5.3.3.3 A display shall be provided at the treatment control panel showing filters in use.

6.5.3.3.4 An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

6.5.3.4 Attenuation of wedges and compensator devices must be checked before the device is placed into service. A visual inspection of the mechanical integrity of these accessories must be done monthly.

6.5.4 Beam Quality. The registrant shall determine data sufficient to assure that the following beam quality requirements in tissue equivalent material are met:

6.5.4.1 The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table 2. Linear interpolation shall be used for values not stated.

Table 2

Maximum Energy of Electron Beam in MeV	X-ray Absorbed Dose As a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

6.5.4.2 Compliance with RHB 6.5.4 shall be determined using:

6.5.4.2.1 A measurement within a tissue equivalent phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

6.5.4.2.2 The largest field size available which does not exceed 15 centimeters by 15 centimeters; and

6.5.4.2.3 A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

6.5.4.3 The measured ionization at the surface relative to maximum ionization along the central axis shall not exceed the limits stated in Table 3. Linear interpolation shall be used for values not stated.

Table 3

Maximum Photon Energy in MeV	Measured Ionization at surface relative to Maximum Ionization along central axis
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

6.5.4.4 Compliance with RHB 6.5.4.3 shall be determined by measurements made:

6.5.4.4.1 Within a tissue equivalent phantom using an instrument which will allow extrapolation to the surface absorbed dose;

6.5.4.4.2 Using a phantom whose size and placement meet the requirements of RHB 6.5.4.2;

6.5.4.4.3 After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam-flattening filters; and

6.5.4.4.4 Using the largest field size available which does not exceed 15 centimeters by 15 centimeters.

6.5.5 Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

6.5.5.1 Equipment manufactured after January 1, 1994, shall be provided with at least two independent radiation detectors. The detectors shall be incorporated into two independent dose monitoring systems.

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6.5.5.2 Equipment manufactured before January 1, 1994, shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

6.5.5.3 The detector and the system into which that detector is incorporated shall meet the following requirements:

6.5.5.3.1 Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

6.5.5.3.2 Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

6.5.5.3.3 Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

6.5.5.3.4 For new equipment, the design of the dose monitoring systems shall assure that: a) Malfunctioning of one system shall not affect the correct functioning of the secondary system; and b) Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

6.5.5.3.5 Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

6.5.5.3.5.1 Maintain a reading until intentionally reset to zero;

6.5.5.3.5.2 Have only one scale and no scale multiplying factors for each mode of operation; and

6.5.5.3.5.3 Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

6.5.5.3.6 In the event of power failure, the dose monitoring information required by RHB 6.5.5.3.5 displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

6.5.6 Beam Symmetry. In new equipment inherently capable of producing useful beams with unattenuated asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam-limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

6.5.7 Selection and Display of Dose Monitor Units.

6.5.7.1 Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

6.5.7.2 The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

6.5.7.3 After termination of irradiation, it shall be necessary to manually reset the dosimeter display to zero before subsequent treatment can be initiated.

6.5.7.4 For new equipment, after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

6.5.8 Termination of Irradiation by the Dose Monitoring System or Systems during Stationary Beam Therapy.

6.5.8.1 Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

6.5.8.2 If original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

6.5.8.3 For equipment manufactured after January 1, 1994, a secondary dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units, whichever is smaller, above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

6.5.8.4 For equipment manufactured after January 1, 1994, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

6.5.9 Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

6.5.10 Termination Switches. It shall be possible to terminate irradiation and equipment movements or go from any interruption condition to termination conditions at any time from the operator's position at the treatment control panel.

6.5.11 Timer.

6.5.11.1 A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

6.5.11.2 The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

6.5.11.3 For equipment manufactured after May 25, 2001, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

6.5.11.4 The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

6.5.12 Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

6.5.12.1 Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

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6.5.12.2 An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.

6.5.12.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations at the treatment control panel.

6.5.12.4 An interlock system shall be provided to prevent irradiation with x-ray except to obtain a port film when electron applicators are fitted.

6.5.12.5 An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

6.5.12.6 The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

6.5.13 Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

6.5.13.1 Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

6.5.13.2 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.5.13.3 The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

6.5.13.4 For new equipment, an interlock system utilizing monitoring of the bending magnet current shall be provided to terminate irradiation if the energy of the electrons striking the target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

6.5.14 Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

6.5.14.1 Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

6.5.14.2 An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

6.5.14.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.5.14.4 The mode of operation shall be displayed at the treatment control panel.

6.5.14.5 An interlock system shall be provided to terminate irradiation if movement of the gantry:

6.5.14.5.1 Occurs during stationary beam therapy; or

6.5.14.5.2 Stops during moving beam therapy unless such stoppage is a preplanned function.

6.5.14.6 Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement:

6.5.14.6.1 An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.

6.5.14.6.2 Where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

6.5.14.7 Where the dose monitor system terminates the irradiation in moving beam therapy, the termination of irradiation shall be as required in RHB 6.5.8.

6.5.15 Absorbed Dose Rate. A system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in RHB 6.5.5 may form part of this system. In addition:

6.5.15.1 The dose monitor rate shall be displayed at the treatment control panel.

6.5.15.2 If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameter utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be in a record maintained by the registrant.

6.5.16 Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

6.5.16.1 The x-ray target or the virtual source of x-rays; and

6.5.16.2 The electron window or the virtual source of electrons if the system has electron beam capabilities.

6.5.17 System Checking. Capabilities shall be provided so that all radiation safety interlocks can be checked for operation.

6.5.18 Facility and Shielding Requirements. In addition to RHB 6.2 of these rules, the following design requirements shall apply:

6.5.18.1 Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

6.5.18.2 Control Panel. The control panel shall be located outside the treatment room.

6.5.18.3 Viewing Systems.

6.5.18.3.1 Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the control panel.

6.5.18.3.2 When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

6.5.19 Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel independent of the particle accelerator. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of

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communication shall be used. When this is the case, a description of the alternate method shall be submitted to, and approved by the Department.

6.5.20 Room Entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all accessible doors to indicate when the useful beam is "on" and "off".

6.5.21 Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

RHB 6.6 Operational Requirements for X-ray and Electron Therapy Systems with Energies of 1 MeV and Above.

6.6.1 Radiological Physics Support. The services of a radiological physicist shall be utilized in facilities having therapy systems with energies of 1 MeV and above. The radiological physicist shall be responsible for:

6.6.1.1 Calibration;

6.6.1.2 Supervision and review of patient dosimetry;

6.6.1.3 Beam data acquisition and storage for computer dosimetry, and supervision of its use;

6.6.1.4 Quality assurance, including spot check review; and

6.6.1.5 Consultation with the radiation therapist in treatment planning, as needed.

6.6.1.6 The radiological physicist described in RHB 6.6.1 shall also be available and responsive to immediate problems or emergencies.

6.6.2 Surveys.

6.6.2.1 All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, the radiological physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

6.6.2.2 The registrant shall obtain a written report of the survey and a copy of the report shall be transmitted by the registrant to the Department within 30 days of the first patient treatment following the survey.

6.6.2.3 The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist, is in violation of applicable rules or regulations.

6.6.3 Calibrations.

6.6.3.1 The calibration of systems subject to RHB 6.5 shall be performed in accordance with an established calibration protocol acceptable to the Department before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The protocol used shall be a nationally accepted standard, such as one established by the American Association of Physicists in Medicine.

6.6.3.2 The calibration shall be performed by or under the direct supervision of the radiological physicist who is physically present at the facility during the calibration.

6.6.3.3 Calibration radiation measurements required by RHB 6.6.3 shall meet the requirements of RHB 1.4.4.

6.6.3.4 Calibrations shall be in sufficient detail that the dose at a reference point in tissue equivalent phantom may be calculated to within an uncertainty of 5 percent.

6.6.3.5 The calibration of the therapy unit shall include, but not be limited to, the following determinations:

6.6.3.5.1 Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, all patient positioning lights, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and collimator system, and beam flatness and symmetry at the specified depth.

6.6.3.5.2 The absorbed dose rate at various depths in a tissue equivalent phantom for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

6.6.3.5.3 The uniformity of the radiation field to include symmetry, flatness, and dependence on gantry angle.

6.6.3.5.4 Verification that existing isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

6.6.3.5.5 Verification of transmission factors for all accessories such as wedges, shadow trays, and/or universal beam modifying devices.

6.6.3.6 Records of calibration measurements under RHB 6.6.3.1 and dosimetry system calibrations under RHB 6.6.3.3 shall be maintained for 5 years after completion of the full calibration.

6.6.3.7 A copy of the latest calibrated absorbed dose rate measured pursuant to RHB 6.6.3.1 shall be available.

6.6.4 Spot Checks. Spot checks shall be performed on systems subject to RHB 6.5 during calibrations and at intervals established by the radiological physicist, not to exceed monthly, using a nationally accepted standard such as one established by the American College of Radiology, American Association of Physicists in Medicine, American College of Medical Physics, etc.

6.6.4.1 The spot check procedures shall be in writing and shall have been developed by the radiological physicist. A copy of the procedure shall be submitted to the Department upon request.

6.6.4.2 If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the radiological physicist within 7 treatment days.

6.6.4.3 The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

6.6.4.4 Spot checks shall be made at a depth beyond the calibration depth but no deeper than the 80% ionization depth.

6.6.4.5 Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.

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6.6.4.6 A parameter exceeding a tolerance set by the radiological physicist shall be corrected before the system is used for patient irradiation.

6.6.4.7 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated, as required in 6.6.3.

6.6.4.8 Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for a period of 3 years after completion of the spot check measurements.

6.6.4.9 Whenever a spot check requires a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of RHB 6.6.3.3 or which has been intercompared with a system meeting those requirements within the previous year.

6.6.5 Prohibited Use. The system shall not be used in the administration of radiation therapy unless the requirements of RHB 6.6.1 through RHB 6.6.4 have been met.

RHB 6.7 Misadministration Report Requirements of All Therapeutic X-ray Systems. All facilities utilizing therapeutic x-ray systems are subject to the misadministration reporting requirements in RHB 1.11.

PART VII
RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

RHB 7.1 Scope. This part establishes special requirements for analytical X-ray equipment. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.

RHB 7.2 Electron Microscopes.

Electron microscopes shall be exempt from the other requirements of Part VII except that they:

7.2.1 Shall be registered with the Department; and

7.2.2 Shall be installed, shielded, and operated in such a manner that no one shall be exposed beyond the limits defined in Section 3.4.1 of these regulations.

RHB 7.3 Hand-Held Analytical X-ray Equipment.

Hand-held analytical x-ray equipment shall be exempt from the other requirements of Part VII except that they:

7.3.1 Shall be registered with the Department;

7.3.2 Shall only be operated by personnel who have completed documented training as outlined in RHB 7.9;

7.3.3 Shall have an interlock system that prevents the operation of the unit unless the x-ray exit port is in contact with or in close proximity to the item being irradiated;

7.3.4 Shall be operated in accordance with the manufacturer's specifications;

7.3.5 Shall have operating procedures in accordance with RHB 7.10.

RHB 7.4 General Requirements for all Analytical X-ray Equipment.

7.4.1 Registration. All requirements of RHB 2.3 and 2.4 apply.

7.4.2 Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION- X-RAY EQUIPMENT", or words having similar intent.

7.4.3 Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol, and

7.4.3.1 A label bearing the words "Caution - Radiation - This Equipment Produces Radiation When Energized" or words having a similar intent shall be placed near any switch which energizes an x-ray tube.

7.4.3.2 A sign bearing the words "Caution- High Intensity X-ray Beam", or words having a similar intent on the x-ray source housing, shall be placed in the area immediately adjacent to each tube head. The sign shall be so located that it is clearly visible to any person operating, aligning, or adjusting the unit, or handling or changing a sample.

7.4.4 Warning Lights.

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7.4.4.1 An easily visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near any switch that energizes an X-ray tube and shall be illuminated only when the tube is energized.

7.4.4.2 Warning lights shall have fail-safe characteristics.

7.4.5 Safety Devices.

7.4.5.1 Any temporary alteration to safety devices, such as by-passing interlocks or removing shielding shall be:

7.4.5.1.1 Approved in advance by the radiation safety officer.

7.4.5.1.2 Specified in writing and posted near the x-ray tube housing.

7.4.5.1.3 Terminated as soon as possible.

7.4.5.1.4 Documented and the documentation maintained for inspection by the Department. This documentation shall contain: the nature of the alteration, and the signature and date of the individuals who made the alteration and who restored the unit to original condition.

7.4.5.2 Tests of all safety devices such as interlocks, shutters, and warning lights shall be conducted annually for all operable analytical x-ray equipment. Documentation of such tests shall be maintained for inspection by the Department.

7.4.5.3 The inspection and testing of safety devices shall not be a substitute for a radiation area survey.

7.4.5.4 Interlocks shall not be used to de-activate the x-ray tube, except in an emergency or during testing of the interlock system. After such shut-off, it shall be possible to restore the machine to full operation only from the control panel.

7.4.5.5 Unused ports on radiation source housings shall be secured in the closed position in a manner to prevent inadvertent opening.

7.4.6 Each x-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface does not exceed 2.5 milliRoentgen per hour.

7.4.7 Generator Cabinet. Each X-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance from its surface to 0.25 milliRoentgen per hour.

7.4.8 Radiation in excess of the limits specified in RHB 7.4.6 and RHB 7.4.7 shall be eliminated prior to using the analytical x-ray equipment.

7.4.9 Repair or Modification of X-ray Tube System. Except as specified in 7.3.5.1, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

RHB 7.5 Additional Requirements for Open Beam Configuration X-ray Equipment.

7.5.1 Safety Device. A device which prevents the entry of any portion of an individual's body into the primary beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-

beam configuration x-ray equipment. A registrant may apply to the Department for an exemption from the requirement of a safety device. Such application shall include:

7.5.1.1 A description of the various safety devices that have been evaluated;

7.5.1.2 The reason each of these devices cannot be used;

7.5.1.3 A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of the safety devices; and

7.5.1.4 The procedure for notifying proper persons in the event of an accident. This list shall include the names, addresses, and telephone numbers.

7.5.2 The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked to protect against unauthorized or accidental entry.

7.5.3 When not in use, equipment shall be secured in such a manner as to be inoperable by unauthorized persons.

7.5.4 Warning Devices. Open-beam configuration x-ray equipment shall be provided with a readily discernible indication of:

7.5.4.1 X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner, or

7.5.4.2 Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

7.5.5 Warning devices shall be labeled so that their purpose is easily identified.

7.5.6 Warning devices shall have fail-safe characteristics.

7.5.6.1 Where couplings exist, e.g., between the x-ray tube and the collimator of the diffractometer, etc., they shall prevent radiation from escaping the coupling.

7.5.6.2 Each port of the radiation source housing shall be provided with a beam shutter interlocked with the x-ray apparatus coupling, or collimator, in such a way that the port will be open only when the collimator or coupling is in place.

7.5.7 Operating Procedures. The registrant shall create and make available to x-ray operators written operating procedures. The procedures shall include, but not be limited to:

7.5.7.1 Policies and procedures for personnel monitoring.

7.5.7.2 Policies and procedures for controlling access to radiation areas.

7.5.7.3 Policies and procedures for locking and securing the x-ray unit.

7.5.7.4 Policies and procedures for pregnant employees.

7.5.7.5 Policies and procedures for training new employees.

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7.5.8 Operator training.

7.5.8.1 No person shall be permitted to operate, repair, modify, or maintain x-ray equipment unless such person has received instruction and demonstrated competence in:

7.5.8.1.1 Identification of radiation hazards associated with the use of the equipment;

7.5.8.1.2 Significance of the various radiation warning and safety devices incorporated into the equipment or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

7.5.8.1.3 Proper operation of the equipment per manufacturer's guidelines and registrant's written operating procedures;

7.5.8.1.4 Radiation survey instruments: operation, calibration, limitations, and survey techniques, if applicable;

7.5.8.1.5 Characteristics of ionizing radiation;

7.5.8.1.6 Methods of controlling radiation dose;

7.5.8.1.7 Units of radiation dose;

7.5.8.1.8 Personnel monitoring and the use of personnel monitoring equipment;

7.5.8.1.9 Symptoms of an acute localized exposure and;

7.5.8.1.10 Proper procedures for reporting an actual or suspected overexposure.

7.5.8.1.11 The regulations contained in this Part, and the applicable sections of Part III.

7.5.8.2 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

RHB 7.6 Additional Requirements for Enclosed Beam X-ray Equipment. To include stationary, mobile, and portable units.

7.6.1 The radiation source, sample, detector and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

7.6.2 The sample chamber closure shall be interlocked with the x-ray tube high voltage supply or a shutter in the primary beam so that no x-ray beam can enter the sample chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail-safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a properly functioning interlock.

RHB 7.7 Area Requirements for All Analytical X-ray Equipment.

7.7.1 Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in RHB 3.4. These levels shall be met at any specified tube rating.

7.7.2 Surveys, Tests and Inspections. Radiation surveys, as required by RHB 1.4 of all analytical x-ray systems to show compliance with RHB 7.7.1 shall be performed and records kept and available for review:

7.7.2.1 Upon installation of the equipment and at least once every twelve (12) months thereafter.

7.7.2.2 Following any change in the initial arrangement, number, or type of local components in the system.

7.7.2.3 Following any change in operating parameters.

7.7.2.4 Following any maintenance requiring the disassembly or removal of a local component of the system.

7.7.2.5 During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed.

7.7.2.6 Any time a visual inspection of the local components in the system reveals an abnormal condition.

7.7.2.7 Whenever monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.

7.7.3 Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the Department with 7.7.1 in some other manner. Upon approval by the Department, an area monitor or monitors may be used in place of an annual radiation survey. The area monitor shall be placed on the unit and changed on at least a quarterly basis. The results shall be documented and available for review. If an area monitor result shows a substantial increase over previous results, perform a documented investigation including a radiation area survey.

7.7.4 Tests and inspections of all safety devices shall be performed at least yearly to ensure their proper operation. The results shall be documented and available for review in accordance with RHB 1.10.2.4.

RHB 7.8 Radiation Survey Instruments.

All provisions of RHB 1.4.4 apply.

RHB 7.9 Minimum Personnel Radiation Safety Requirements For Radiation Safety Officers and Operators.

7.9.1 No registrant shall permit any individual to act as a radiation safety officer until such person:

7.9.1.1 Has been instructed in the subjects outlined in RHB 7.9.2 of this Part;

7.9.1.2 Has received copies of and instruction in: the regulations contained in this Part, Part IX, the applicable sections of Part III, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

7.9.1.3 Has demonstrated competence to use the X-ray machine, related handling tools, and survey instruments which will be employed in the assignment.

7.9.2 No person shall be permitted to operate, repair, modify, or maintain analytical x-ray equipment unless such person has received instruction and demonstrated competence in:

7.9.2.1 Identification of radiation hazards associated with the use of the equipment;

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7.9.2.2 Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

7.9.2.3 Proper operation of the equipment per manufacturer's guidelines and registrant's written operating procedures as specified in RHB 7.10;

7.9.2.4 Characteristics of ionizing radiation;

7.9.2.5 Personnel and/or area monitoring and the use of personnel and/or area monitoring equipment, if applicable.

7.9.3 Instruction and demonstration of competence shall be documented in writing and these records shall be available for review.

RHB 7.10 Operating Procedures

7.10.1 The registrant shall create and make available to x-ray operators written operating procedures. The procedures shall include, but not be limited to:

7.10.1.1 Policies and procedures for personnel and/or area monitoring;

7.10.1.2 Policies and procedures for pregnant employees;

7.10.1.3 Policies and procedures for training new employees;

7.10.1.4 Methods and occasions for conducting radiation surveys;

7.10.1.5 Methods for controlling access to radiographic areas;

7.10.1.6 Methods for locking and securing X-ray machines, when not in use or in storage;

7.10.1.7 Maintenance of records.

7.10.2 A copy of operator training provided as required by RHB 7.9 and a copy of operating procedures as required by RHB 7.10 shall be provided to the Department upon request.

RHB 7.11 Personnel Monitoring.

7.11.1 Personnel monitoring shall be required as outlined in RHB 3.12.

7.11.2 Finger or wrist dosimetric devices shall be provided to and shall be used by:

7.11.2.1 Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

7.11.2.2 Personnel maintaining analytical or research and development x-ray equipment if the maintenance procedures required the presence of a primary x-ray beam when any local component in the analytical or research and development x-ray system is disassembled or removed.

PART VIII

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL USES OF RADIOGRAPHIC SOURCES

RHB 8.1 Scope. The regulations in this part establish radiation safety requirements for industrial uses of X-ray machines. The requirements of this part are in addition to and not in substitution for the other requirements of these regulations.

RHB 8.2 Locking of X-ray Machines. Each x-ray machine shall be provided with a locking device designed to prevent unauthorized or accidental production of radiation, and shall be kept locked at all times except when under the direct surveillance of a radiographer, radiographer's assistant, a radiation safety officer, or an operator, as applicable.

RHB 8.3 Permanent Storage Precautions. Radiation machines shall be secured while in storage to prevent tampering or removal by unauthorized individuals.

RHB 8.4 Radiation Survey Instruments. All provisions of RHB 1.4.4 apply.

RHB 8.5 Labeling. There shall be a durable permanent label indicating the maximum operating current, kVp, the standard radiation symbol, and a caution notice which shall read as follows or similarly: "CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED." In addition, a label which reads, "CAUTION-RADIATION; THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" shall be located near or adjacent to each switch that controls the production of x-rays.

RHB 8.6 Registration and Posting Requirements.

8.6.1 Registration. Each facility shall meet the requirements of RHB 2.3 and 2.4 of these regulations.

8.6.2 Posting. Areas in which radiography is being performed shall be conspicuously posted as required by RHB 3.15 and 3.16.

RHB 8.7 Minimum Personnel Radiation Safety Requirements For Radiation Safety Officers and Operators.

8.7.1 No registrant shall permit any individual to act as a radiation safety officer until such person:

8.7.1.1 Has been instructed in the subjects outlined in RHB 8.11 of this Part;

8.7.1.2 Has received copies of and instruction in: the regulations contained in this Part, Part IX, the applicable sections of Part III, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

8.7.1.3 Has demonstrated competence to use the X-ray machine, related handling tools, and survey instruments which will be employed in the assignment.

8.7.2 No registrant shall permit any individual to act as an operator or radiographer until such person:

8.7.2.1 Has been instructed in the subjects outlined in RHB 8.11 of this Part;

8.7.2.2 Has received copies of and instruction in: Part IX, of these regulations, and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof; and

8.7.2.3 Has demonstrated competence to use, under the personal supervision of the Radiation Safety Officer, the X-ray machine, related handling tools, and survey instruments which will be employed in his assignment.

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8.7.2.4 The registrant shall have all training procedures and testing documented in writing, and available for the Department's review.

RHB 8.8 Operating and Emergency Procedures. The registrant shall have written operating and emergency procedures. These procedures shall include instruction in:

8.8.1 The handling and use of X-ray machines to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in Part III of these regulations;

8.8.2 Methods and occasions for conducting radiation surveys;

8.8.3 Methods for controlling access to radiographic areas;

8.8.4 Methods for locking and securing X-ray machines, when not in use or in storage;

8.8.5 Personnel monitoring and the use of personnel monitoring equipment; including steps that must be taken by radiography personnel in the event a pocket dosimeter is found to be off-scale;

8.8.6 The proper handling of exposed personnel;

8.8.7 Minimizing exposure of individuals in the event of an accident;

8.8.8 The procedure for notifying proper persons in the event of an accident. This shall include the listing of names, addresses, and telephone numbers; and

8.8.9 Maintenance of records.

RHB 8.9 Inspection and Maintenance. Each registrant shall ensure that checks for obvious defects in radiation machines are made at the beginning of each day of equipment use.

8.9.1 At least annually, each registrant shall inspect and repair components associated with radiation safety of the machines. Records of inspection and maintenance shall be maintained for the Department's inspection.

8.9.2 If any inspection conducted by the registrant reveals damage to the components affecting radiation safety, the radiation machine shall not be used and shall be labeled as defective until repaired.

RHB 8.10 Personnel Monitoring. No registrant shall permit any individual to act as a Radiation Safety Officer or as an operator unless, at all times during radiographic operations, each such person wears a film badge, thermoluminescent dosimeter (TLD), or other dosimeters approved by the Department. All provisions of Part III of these Regulations apply.

RHB 8.11 Minimum Subjects To Be Covered In Training Radiation Safety Officers and Radiographers.

8.11.1 Fundamentals of Radiation Safety:

8.11.1.1 Characteristics of ionizing radiation;

8.11.1.2 Units of radiation dose (rem or Sievert);

8.11.1.3 Hazards of exposure to radiation;

8.11.1.4 Levels of radiation from sources of radiation;

8.11.1.5 Methods of controlling radiation dose;

8.11.1.5.1 Working time;

8.11.1.5.2 Working distances; and

8.11.1.5.3 Shielding.

8.11.2 Radiation Detection Instrumentation to be Used:

8.11.2.1 Use of radiation survey instruments;

8.11.2.1.1 Operation;

8.11.2.1.2 Calibration; and

8.11.2.1.3 Limitations.

8.11.2.2 Survey techniques; and

8.11.2.3 Use of personnel monitoring equipment:

8.11.2.3.1 Film badges or other approved dosimeters; and

8.11.2.3.2 Pocket dosimeters or pocket chambers, if applicable.

8.11.3 Operation and control of X-ray machines.

8.11.4 The requirements of pertinent state regulations.

8.11.5 The registrant's written operating and emergency procedures.

RHB 8.12 Special Requirements for Certain Industrial Radiographic Techniques.

8.12.1 Cabinet Radiography.

8.12.1.1 Upon installation, a cabinet radiography unit shall not be operated until a physical radiation survey of the unit and areas adjacent to the unit has been performed. A radiation survey of the unit and area adjacent to the unit shall also be performed at least annually, and after any repair modification, or maintenance on the system.

8.12.1.2 Tests for proper operation of high radiation area control devices, alarm systems or interlocks must be conducted, at least annually, recorded, and maintained in accordance with RHB 8.9.

8.12.1.3 Radiation emitted from the cabinet x-ray unit shall not exceed 0.5 milliRoentgen per hour at any point five centimeters from the external surface.

8.12.1.4 A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

8.12.1.5 The insertion of any part of the human body through any port into the primary beam or through any aperture shall not be possible.

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8.12.1.6 Interlocks.

8.12.1.6.1 Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

8.12.1.6.2 Each access panel shall have at least one safety interlock.

8.12.1.6.3 Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with RHB 8.12.1.8.2 shall be necessary for resumption of x-ray generation.

8.12.1.6.4 Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

8.12.1.7 A ground fault, or an accidental electrical grounding of an electrical conductor, shall not result in the generation of x-rays.

8.12.1.8 Controls and indicators for all cabinet x-ray systems. For all systems to which this section is applicable, there shall be provided:

8.12.1.8.1 A key actuated control to insure that x-ray generation is not possible with the key removed.

8.12.1.8.2 A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

8.12.1.8.3 Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this regulation may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "X-RAY ON."

8.12.1.8.4 Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled "X-RAY ON."

8.12.1.9 Additional controls and indicators for cabinet x-ray systems designed to admit humans. For cabinet x-ray systems designed to admit humans, there shall also be provided:

8.12.1.9.1 A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

8.12.1.9.2 No means by which x-ray generation can be initiated from within the cabinet.

8.12.1.9.3 Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause the failure of both the audible and visible warning signals.

8.12.1.9.4 A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicator shall be activated for one-half second.

8.12.1.9.5 Signs indicating the meaning of the warning signals required by RHB 8.12.1.9.3 and 8.12.1.9.4 and containing instructions for the use of the control required by RHB 8.12.1.9.1. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.

8.12.1.10 Warning labels. There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED." There shall also be a permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement: "CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED--X-RAY HAZARD."

8.12.1.11 Additional requirements for x-ray baggage inspection systems. X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means to ensure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-rays.

8.12.1.11.1 During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

8.12.1.11.2 During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

8.12.1.12 Exemptions. To qualify for this exemption, registrant must provide documentation regarding the certified and/or certifiable status of each device.

8.12.1.12.1 Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this Part except for the following:

8.12.1.12.1.1 For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

8.12.1.12.1.1.1 No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this requirement shall be maintained for Departmental review.

8.12.1.12.1.1.2 Tests for proper operation of interlocks must be conducted and documented at intervals not to exceed six months. Records of these tests shall be maintained in accordance with RHB 1.10.2.4.

8.12.1.12.1.1.3 The registrant shall perform an evaluation of the radiation dose limits to determine compliance with Part III of this Regulation and 21 CFR 1020.40, Cabinet X-ray Systems, at intervals not exceed one year. Records of these evaluations shall be maintained in accordance with RHB 1.10.2.4.

8.12.1.12.1.2 Cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-ray Systems, and no modification shall be made to the system unless prior Departmental approval has been granted.

8.12.2 Shielded Room Radiography.

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8.12.2.1 Each registrant shall supply appropriate personnel monitoring equipment to, and shall require the use of such equipment by, every individual who operates, makes "set-ups," or performs maintenance on a radiation machine for shielded room radiography.

8.12.2.2 A physical radiation survey shall be conducted to determine that the X-ray machine is "off" prior to each entry into the shielded room. Such surveys shall be made with a radiation measuring instrument capable of measuring radiation of the energies and at the dose rates to be encountered, which is in good working order, and which has been properly calibrated within the preceding twelve months or following the last instrument servicing, whichever is later.

8.12.2.3 Each installation shall be provided with such primary barriers and secondary barriers as are necessary to assure compliance with RHB 3.4, and RHB 3.9.

8.12.2.4 Shielding. All provisions of RHB 4.4 apply.

8.12.3 Field Radiography.

8.12.3.1 Utilization Logs. Each registrant shall maintain current logs, which shall be kept available for inspection by the Department, showing for each X-ray machine the following information:

8.12.3.2 A description (or make and model number) of each X-ray machine;

8.12.3.3 The identity of the radiographer to whom assigned;

8.12.3.4 The plant or site where used and dates used; and

8.12.3.5 The dates each radiation machine is energized or used and number of exposures made.

8.12.3.6 Security. During each radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except a) where the high radiation area is equipped with a control device which turns the X-ray machine off upon unauthorized entry into the high radiation area or an alarm system which visibly or audibly signals the presence of a high radiation area, or b) where the high radiation area is locked to protect against unauthorized or accidental entry.

8.12.3.7 Radiation Surveys and Survey Records. No radiographic operation shall be conducted unless calibrated, operable radiation survey instrumentation is available and used at each site where radiographic exposures are made, as described in RHB 8.4.

8.12.3.7.1 A physical radiation survey shall be conducted to determine that the radiation machine is "off" prior to each entry into the radiographic exposure area.

8.12.3.7.2 Survey results and records of boundary locations shall be maintained and kept available for inspection by the Department.

8.12.3.8 Personnel Monitoring. In addition to the requirements of 8.10, each radiographer or radiographer's assistant shall wear a pocket dosimeter or pocket chamber along with a film badge during all radiographic operations. Pocket chambers or dosimeters shall be:

8.12.3.8.1 Capable of measuring doses from zero to at least 200 milliRoentgen;

8.12.3.8.2 Read and doses recorded daily; and

8.12.3.8.3 Recharged daily or at the start of each shift;

8.12.3.8.4 Reports received from the dosimeter processor and records of the pocket dosimeter and pocket chamber readings shall be maintained for inspection by the Department;

8.12.3.8.5 Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. Acceptable dosimeters shall read within plus or minus 30% of the true exposure calibration shall be maintained by the registrant for the Department's inspection.

8.12.4 Gauging Devices Radiography and Other Industrial Applications. The source shall be such that no radiation is emitted except by application of an electric current through an x-ray tube. Provisions shall be made to limit both the current through the tube and the voltage across the tube, so that radiation levels do not exceed the device classification under use conditions or through circuit component failures. In the event of fire or abnormal elevated temperatures, provisions shall be made to insure the high voltage is automatically disabled before loss of any integral shielding. This provision exempts x-ray tube sources from accident classification conditions.

8.12.4.1 A useful beam control system shall be provided in gauges whenever the useful beam is accessible and the radiation levels exceed 100 mrem/h (1 mSv/h) at 5 cm from any accessible surface or 5 mrem/h (.05 mSv/h) at 30 cm. The useful beam controls may include (but not be limited to) a moving shutter, a moving source, or a high voltage power supply.

8.12.4.2 A yellow or amber warning light with the radiation "High Voltage On" shall be located on the control panel and on or adjacent to the source housing and shall light only when power is applied to the x-ray tube high voltage circuit.

8.12.4.3 Radiation levels. The local components of an industrial x-ray system shall be located and arranged and shall include sufficient shielding or have access control such that no radiation in any area surrounding the local component group could result in a dose to an individual present therein in excess of the dose limits given in RHB 3.3.2. These levels shall be met at any specified tube rating.

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PART IX DEFINITIONS

As used in these regulations, the following definitions apply:

9.1 "Absorbed Dose" is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special units of absorbed dose are the rad or the gray.

9.2 "Accessible Surface" means the external surface of the enclosure or housing provided by the manufacturer.

9.3 "Accreditation body" or "body" means an entity that has been approved by FDA to accredit mammography facilities.

9.4 "Act" means Act No. 223, Atomic Energy and Radiation Control Act enacted by the 1967 Session South Carolina Legislature. [Section 13-7-40 *et seq.*, S.C. Code of Laws (1976, as amended)].

9.5 "Action limits" or "action levels" means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action shall be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

9.6 "Added filtration" means any filtration which is in addition to the inherent filtration.

9.7 "Adverse event" means an undesirable experience associated with mammography activities that include but are not limited to: poor image quality; failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and use of personnel that do not meet the requirements

9.8 "Adult" means an individual 18 or more years of age.

9.9 "Air kerma" means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (9keV), 1Gy=100rad.

9.10 "ALARA" (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in the Rules in this Chapter as is practical consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of sources of radiation in the public interest.

9.11 "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

9.12 "Analytical x-ray equipment" means any machine utilizing x-rays for examination of the microscopic structure, or elemental or chemical composition of materials. This includes x-ray equipment used for x-ray diffraction, fluorescence analysis, or spectroscopy.

9.13 "Analytical X-ray System" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

9.14 "Annually" means at intervals not to exceed 12 consecutive months.

9.15 "Applicator" means a structure which determines the extent of the treatment field at a given distance from the virtual source.

9.16 "Assembler" means any person engaged in the business of assembling, reassembling, replacing, installing, or reinstalling one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system, his employee, or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

9.17 "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

9.18 "Authorized representative" means an employee of the Department, or an individual outside the Department when the individual is specifically so designated by the Department.

9.19 "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (See also "Phototimer").

9.20 "Average Glandular dose" means, in mammography, the value in millirad for a given breast or phantom thickness which estimates the average absorbed dose to the glandular tissue extrapolated from free air exposures and based on fixed filter thickness and target material.

9.21 "Background radiation" means radiation from cosmic sources, naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include sources of radiation regulated by the agency.

9.22 "Barrier" (See "Protective Barrier").

9.23 "Beam Axis" means a line from the source through the centers of the x-ray fields.

9.24 "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

9.25 "Beam monitoring system" means a system designed to detect and measure the radiation present in the useful beam.

9.26 "Beam scattering foil" means a foil used in order to scatter a beam of electrons.

9.27 "Breast implant" means a prosthetic device implanted in the breast.

9.28 "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits as specified in Part III of these Regulations.

9.29 "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure which is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during x-ray production. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

9.30 "Calendar Quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January; and subsequent calendar quarters shall be such that no day is included in more than one calendar quarter or omitted from inclusion within a calendar quarter. No

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registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations, except at the beginning of a calendar year. For the purpose of Part V, "Calendar quarter" means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30 or October 1 through December 31.

9.31 "Calibration" means:

a) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

b) the strength of a source of radiation relative to a standard.

9.32 "Category I" means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society or an equivalent organization.

9.33 "C-Arm" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship.

9.34 "Central axis of the Beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

9.35 "Cephalometric" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

9.36 "Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

9.37 "Certification" means the process of approval of a facility by the Department to provide mammography services.

9.38 "Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

9.39 "Certified components" means components of x-ray systems which are subject to the Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968, promulgated under Public Law 90-602.

9.40 "Certified system" means any x-ray system which has one or more certified component(s).

9.41 "Changeable filters" means any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

9.42 "Change of Status" means transfer of ownership, change of address, or disposal of any X-ray system.

9.43 "Clinical image" means a mammogram.

9.44 "Coefficient of Variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$c = s/\bar{X} = 1/\bar{X} * \sum (X_i - \bar{X})^2 / n - 1$$

where:

s = Estimated standard deviation of the population.

\bar{X} = Mean value of observations in sample.

X_i = ith observation in sample.

n = Number of observations in sample.

9.45 "Collimator" means a device or mechanism by which the x-ray beam is restricted in size.

9.46 "Committed dose equivalent" means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

9.47 "Consumer" means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

9.48 "Continuing education unit or continuing education credit" means one contact hour of training.

9.49 "Contact hour" means an hour of training received through direct instruction.

9.50 "Controlled area" means an area outside of a restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.

9.51 "Coulomb per Kilogram" (C/kg) is the unit of exposure. One Roentgen is equal to 2.58 x 10⁻⁴ Coulomb per kilogram. Submultiples of this unit are the milliCoulomb per kilogram (mC/kg) and the microCoulomb per kilogram (uC/kg).

9.52 "CT" (See "Computed Tomography")

9.53 "CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 8.173.

9.54 "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

9.55 "Computed Tomography" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

9.56 "Contact Therapy System" means an x-ray system used for therapy with the x-ray tube port placed in contact with or within 5 centimeters of the surface being treated.

9.57 "Control Panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

9.58 "Cooling Curve" means the graphical relationship between heat units stored and cooling time.

9.59 "Dead-man Switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

9.60 "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

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9.61 "Deep-dose equivalent" (H_d), which applies to external whole-body exposure, is the equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

9.62 "Department" means the South Carolina Department of Health and Environmental Control.

9.63 "Detector" (See "Radiation detector")

9.64 "Diagnostic mammography" means mammography performed on a patient with:

- (a) Clinical signs, symptoms or physical findings suggestive of breast cancer;
- (b) An abnormal or questionable screening mammogram;
- (c) A history of breast cancer with breast conservation surgery regardless of absence of clinical breast signs, symptoms or physical findings; or
- (d) Augmented breast regardless of absence of clinical breast signs, symptoms or physical findings.

9.65 "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

9.66 "Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

9.67 "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

9.68 "Diaphragm" means a device or mechanism by which the x-ray beam is restricted in size.

9.69 "Direct instruction" means face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations or reviews student performance; or the administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

9.70 "Direct scattered radiation" means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered Radiation").

9.71 "Direct supervision", in Part V, means that:

During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or

During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

9.72 "Dose" is a generic term which means absorbed dose, dose equivalent, effective dose equivalent, or total effective dose equivalent as defined in these regulations.

9.73 "Dose Equivalent" (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent at the rem and sievert (Sv).

9.74 "Dose limits" (See Limits)

9.75 "Dose monitoring system" means a system of devices for the detection, measurement, and display of quantities of radiation.

9.76 "Dose monitor unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

9.77 "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

9.78 "Effective dose equivalent" (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \sum W_T H_T$).

9.79 "Embryo/fetus" means the developing human organism from conception until the time of birth.

9.80 "Entrance or access point" means any location through which an individual could gain access to radiation areas or to a source of radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

9.81 "Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

9.82 "ESE" means the exposure at skin entrance where the center of the useful beam enters the patient.

9.83 "Equipment" (See "X-ray system").

9.84 "Established operating level" means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

9.85 "Exposure" is the amount of ionization per unit mass of air due to x-rays. It is the quotient of dQ by dm where " dQ " is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass " dm " are completely stopped in air. The special units of exposure are the Roentgen (R), or the coulomb per kilogram.

9.86 "Exposure rate" means the exposure per unit of time, such as R/min and mR/h.

9.87 "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

9.88 "Extremities" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

9.89 "Eye dose equivalent" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2)

9.90 "Facility" means the location at which one or more x-ray machines are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

9.91 "Facility" or "mammography installation" means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician or other facility that conducts mammography activities, including operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram and maintaining viewing conditions for that interpretation.

9.92 "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

9.93 "FDA" means the Food and Drug Administration.

9.94 "Field emission equipment" means equipment which uses an x-ray tube in which an electron emission from the cathode is due solely to the action of an electric field.

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9.95 "Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.

9.96 "Field Radiography" means the examination of the macroscopic structure of materials by nondestructive methods of utilizing sources of radiation in a non-fixed or non-permanent location.

9.97 "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the central axis of the useful beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

9.98 "Filter" means material placed in the useful beam to preferentially absorb selected radiation.

9.99 "First allowable time" means the earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body.

9.100 "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

9.101 "Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

9.102 "Fog test" means an evaluation of increased density and reduced contrast on film which has not been exposed to the radiation field. This is usually done by processing unexposed film and measuring the density.

9.103 "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

9.104 "Gauge" means a mechanism designed and manufactured for the purpose of determining or controlling thickness, density, level, interface location, or qualitative or quantitative chemical composition. It may include components such as radiation shields and useful beam controls incorporated into the gauge in order to meet the requirements or specifications of this regulation.

9.105 "General purpose radiographic x-ray system" means any radiographic x-ray which, by design, is not limited to radiographic examination of specific anatomical regions.

9.106 "Gonadal shield" means a protective barrier for the testes or ovaries.

9.107 "The "Gray" is the unit of absorbed dose. It is equal to 1 joule per kilogram. One rad is equal to 1×10^{-2} Gray. Submultiples included in this document are the milliGray (Gy) and the microGray (uGy).

9.108 "Half-value layer (HVL)" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

9.109 "Healing arts" means any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

9.110 "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed

practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

9.111 "Health Professions" means the professional persons authorized by the laws of the State to use x-rays in the diagnosis or treatment of human or animal disease.

9.112 "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

9.113 "High radiation area" means any area, accessible to individuals, in which there exists radiation at such levels that the whole body could receive in any one hour, a dose in excess of 0.1 rem (mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

9.114 "HVL" (See "Half-value layer").

9.115 "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

9.116 "Image receptor" means any device, such as radiographic film, which transforms incident photons either into a visible image or into another form which can be made into a visible image by further transformations.

9.117 "Image receptor support" means, for mammographic systems, that part of the system designed to support the image receptor during mammography.

9.118 "Individual" means any human being.

9.119 "Individual monitoring" means:

(a) the assessment of dose equivalent by the use of devices designed to be worn by an individual; or

(b) the assessment of dose equivalent by the use of survey data.

9.120 "Individual Monitoring Devices" or "individual monitoring equipment" means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), and pocket ionization chambers.

9.121 "Industrial x-ray equipment" means any machine utilizing x-rays for examination of the macroscopic structure of materials. This includes x-ray equipment used for cabinet radiography, shielded room radiography, field radiography, and gauges.

9.122 "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

9.123 "Inoperative" means any x-ray machine or device that is temporarily or permanently rendered incapable of producing x-rays.

9.124 "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Department.

9.125 "Interim regulations" means the regulations entitled "Requirements for Accrediting Bodies of Mammography facilities" (58 FR 67558-67565) and "Quality Standards and Certification Requirements for Mammography Facilities"(58 FR 67565-67572), published by FDA on December 21, 1993, and amended on

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September 30, 1994 (59 FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994 and April 28, 1999.

9.126 "Interlock" means a device for precluding access to a high radiation area by automatically reducing the exposure rate upon entry by personnel.

9.127 "Interpreting physician" means a licensed physician who interprets mammograms and who meets the requirements of Section 5.7.1 and 5.25.1.1.

9.128 "Irradiation" means the exposure of matter to ionizing radiation.

9.129 "Isocenter" means the intersection of the collimator axis of rotation and the gantry axis of rotation.

9.130 "Kilovolts peak" (See "Peak tube potential").

9.131 "kV" means kilovolts.

9.132 "kVp" (See "Peak tube potential").

9.133 "Lead interpreting physician" means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of Sections 5.9, 5.10.1, 5.10.2, 5.10.4, 5.10.5, 5.10.6 and 5.10.7 of this Part. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

9.134 "Leakage radiation (non-diagnostic)" means all radiation coming from within the tube housing complex except the useful beam(s).

9.135 "Leakage radiation (diagnostic)" means radiation emanating from the diagnostic source assembly except for:

- 1) the useful beam, and
- 2) radiation produced when the exposure switch or timer is not activated.

9.136 "Leakage technique factors" means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3) For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

9.137 "Licensed practitioner" means an individual with professional specialization who has met the criteria as outlined by the South Carolina Department of Labor, Licensing, and Regulation.

9.138 "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

9.139 "Limits" or "Dose Limits" means the permissible upper bounds of radiation doses.

9.140 "Linear attenuation coefficient" or "μ" means the quotient of dN/N divided by dl when dN/N is the fraction of uncharged ionizing radiation that experience interactions in traversing a distance dl in a specified material.

9.141 "Line voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation.

Percent line-voltage regulation = $100 (V_n - V_l) / V_l$ where
 V_n = No load line potential and
 V_l = Load line potential.

9.142 "mA" means milliAmpere.

9.143 "Mammogram" means a radiographic image produced through mammography.

9.144 "Mammographic modality" means a technology for radiography of the breast. Examples are screen-film mammography and digital mammography.

9.145 "Mammography" means radiography of the breast.

9.146 "Mammography equipment evaluation" means an onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in this Part.

9.147 "Mammography medical outcomes audit" means a systematic collection of mammography results and the comparison of those results with outcomes data.

9.148 "Mammography unit" or "units" means an assemblage of components for the production of x-rays for use during mammography, including, at a minimum, an x-ray generator, an x-ray control, a tube housing assembly, a beam limiting device and the supporting structures for these components.

9.149 "mAs" means milliAmpere second.

9.150 "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

9.151 "Mean optical density" means the average of the optical densities (OD) measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

9.152 "Medical device" means an instrument, tool, machine, test kit, or implant that is used to prevent, diagnose, or treat disease or other medical conditions.

9.153 "Medical physicist", for the purpose of Part V, means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications set forth in RHB 5.7.3.

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9.154 "Member of the public" means an individual in a controlled or unrestricted area; however, an individual is not a member of the public during any period in which the individual receives an occupational dose.

9.155 "Minor" means an individual less than 18 years of age.

9.156 "Misadministration" means the administration of:

9.156.1 Radiation to the wrong patient, wrong treatment site, or wrong mode of treatment;

9.156.2 Performance of a diagnostic or therapeutic procedure other than that ordered by the prescribing physician.

9.156.3 A therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 20 percent.

9.156.4 When the treatment consists of three or fewer fractions, a therapeutic radiation dose from a source such that errors in the source calibration, time of exposure, or treatment geometry result in a calculated total treatment dose differing from the total prescribed treatment dose by more than 10 percent.

9.156.5 When the calculated weekly treatment dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose.

9.157 "Mobile x-ray equipment" (See "X-ray equipment").

9.158 "Monitoring", "radiation monitoring" or "radiation protection monitoring" means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

9.159 "MQSA" means the federal Mammography Quality Standards Act of 1992.

9.160 "Multi-reading" means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

9.161 "Nonstochastic effect" means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of nonstochastic effect (also called a deterministic effect).

9.162 "Moving beam therapy" means radiation therapy with relative displacement of the useful beam or the patient during irradiation. It includes arc therapy, skip therapy, conformational therapy, and rotational therapy.

9.163 "Normal treatment distance" means:

1) For electron irradiation, the distance from the scattering foil or exit window of the electron beam to the surface along the central axis of the useful beam, or from the virtual source to the surface along the central axis of the useful beam as specified by the manufacturer.

2) For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be specified by the manufacturer.

9.164 "Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to radiation, whether in the possession of the registrant or other person. Occupational dose does not include dose received from background radiation,

as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the general public.

9.165 "Open beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

9.166 "Operating Conditions" means circumstances required to maintain a radiation protection program sufficient to ensure compliance with the provisions of this Regulation. Conditions include, but are not limited to, patient holding, pregnant workers, use of shielding and barriers, pregnant patients, use of personnel monitoring devices, employee training, and quality assurance methods.

9.167 "Operating procedures" means detailed written instructions including, but not limited to, use of the x-ray equipment, use of shielding and barriers, quality assurance methods, occasions and methods for conducting area surveys, use of personnel monitoring devices, and alignment, calibration, or preventative maintenance of x-ray equipment. Routine and emergency radiation safety considerations are part of these procedures. Emergency procedures shall include methods of notifying proper persons in the event of an emergency, to include the listing of names, addresses and phone numbers.

9.168 "Operative" means any x-ray machine or device that is capable of producing x-rays.

9.169 "Out of State Facility" means any person proposing to bring an x-ray machine into the State for any temporary use.

9.170 "Patient" means an individual or animal subjected to healing arts examination, diagnosis, or treatment, including a mammography evaluation.

9.171 "PBL" (See "Positive Beam Limitation").

9.172 "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

9.173 "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 the foregoing, other than entities over which a federal government agency has exclusive jurisdiction.

9.174 "Personnel monitoring equipment" means devices designed to be carried or worn by an individual for the purpose of measuring the dose which an individual receives (e.g., film badges, pocket chambers, pocket dosimeters).

9.175 "Phantom" in Part VI, means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of the tissue.

9.176 "Phantom" in Part V, means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer. This definition does not apply to phantoms used for Quality Assurance testing of stereotactic biopsy units. It is equivalent to a nominal 4.2 centimeter compressed breast of average density (i.e., 50 percent adipose and 50 percent glandular tissue) and shall contain the following objects:

1) Spherical masses, composed of phenolic plastic with thicknesses of: 2.00, 1.00, 0.75, 0.50 and 0.25 millimeter;

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2) Specks, composed of aluminum oxide, with diameters of: 0.54, 0.40, 0.32, 0.24 and 0.16 millimeter

3) Fibers composed of nylon, with thicknesses of: 1.56, 1.12, 0.89, 0.75, 0.54, and 0.40 millimeter.

9.177 "Phantom image" means a radiographic image of a phantom.

9.178 "Phototimer" means a method for controlling radiation exposure to image receptors by measuring the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated (See "Automatic exposure control").

9.179 "Physical science" means physics, chemistry, radiation science (including medical physics and health physics) and engineering.

9.180 "PID" (See "Position indicating device").

9.181 "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

9.182 "Portable x-ray equipment" (See "X-ray equipment").

9.183 "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

9.184 "Positive Beam Limitation" means the automatic or semiautomatic adjustment of an x-ray beam to the selected image receptor size, whereby exposures cannot be made without such adjustments.

9.185 "Positive mammogram" means a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

9.186 "Primary beam" means ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

9.187 "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been acquired.

9.188 "Primary protective barrier" (See "Protective barrier").

9.189 "Protective apron" means an apron made of radiation absorbing material used to reduce radiation exposure.

9.190 "Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, to protect anyone other than the patient from radiation exposure.

2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

9.191 "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

9.192 "Provisional certificate" means the provisional certificate described in RHB 5.3.3.

9.193 "Public dose" means the dose received by a member of the public from exposure to radiation by a registrant, or to another source of radiation either within a registrant's controlled area or in unrestricted areas. It does not include occupational dose or doses received from background radiation, as a patient from medical practices, or from voluntary participation in medical research programs.

9.194 "Qualified expert" means an individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

9.195 "Qualified instructor" means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists or medical physicists who meet the requirements of Section 5.7 and 5.25.1 of this Part would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the requirements of this Part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

9.196 "Quality Assurance" is a program designed to produce high quality radiographs at minimal cost and minimal patient exposure.

9.197 "Quality Control" is the routine measurement of image quality and the performance of the diagnostic x-ray imaging system, from x-ray beam output to the viewing of radiographs, and the continual adjustment of that performance to an optimal and consistent level.

9.198 "Quality control technologist" means an individual meeting the requirements of RHB 5.7.2 who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

9.199 "Quality Factor" (Q) means the modifying factor that is used to derive dose equivalent from absorbed dose. Quality factors are provided in the definition of rem.

9.200 The "rad" is a measure of the absorbed dose of any radiation to body tissue in terms of the energy absorbed per unit mass of the tissue. One rad is the absorbed dose corresponding to 100 ergs per gram of tissue. (One millirad {mrad} = 0.001 rad.)

9.201 "Radiation" means ionizing radiation, including gamma rays, x-rays, alpha particles, beta particles, high speed electrons, neutrons, high speed protons, and other atomic particles, but not sound or radio waves, or visible, infrared, or ultraviolet light.

9.202 "Radiation area" means any area accessible to individuals in which there exists radiation at such levels that the whole body could receive in any one hour, a dose in excess of 5 millirem (.05 mSv) at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

9.203 "Radiation detector" means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

9.204 "Radiation dose" means dose.

9.205 "Radiation Installation" is any location or facility where radiation machines are used.

9.206 "Radiation Safety Officer" means one who has the knowledge and responsibility to apply appropriate radiation protection regulations, and is approved in writing by the registrant.

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9.207 "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

9.208 "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

9.209 "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises field radiography operations, and who is responsible to the registrant for assuring compliance with the requirements of these regulations.

9.210 "Radiographer's Assistant" means any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in field radiography.

9.211 "Radiographic imaging system" means any system whereby a permanent or temporary image is recorded on an image receptor by the action of ionizing radiation.

9.212 "Radiological physicist" means an individual who is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma ray physics; or certified by the American Board of Medical Physicists in radiation oncology physics, or have the equivalent training experience as approved, or have the following minimum training and experience:

9.212.1 A Master's or a Doctoral degree in Physics, Biophysics, Radiological Physics, or Health Physics or Medical Physics; one year full-time training in therapeutic radiological physics;

9.212.2 One year full-time experience in a therapeutic facility where the individual's duties involve calibration and spot checks of a medical accelerator, and includes personal calibration and spot check of at least one machine.

9.213 "Radiologic technologist", in Part V, means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and when performing mammography without direct supervision, also meets the requirements set forth in RHB 5.7.2.

9.214 "Rating" means the operating limits as specified by the component manufacturer.

9.215 "Recording" means producing a permanent form of an image resulting from x-ray photons.

9.216 "Registrant" means any person who is registered with the Department or is legally obligated to register with the Department pursuant to the Act and these regulations.

9.217 "Registration" means registering with the Department in accordance with these regulations and the Act.

9.218 "Rem" is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert). The quality factors for converting absorbed dose to dose equivalent are as follows:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent*
X-, gamma, or beta radiation	1	1 a Unit Dose Equivalent*
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

*Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

9.219 "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady step midscale reading.

9.220 "Restricted area" (controlled area) means any area, access to which is controlled by the registrant for purposes of protection of individuals from exposure to radiation. A "restricted area" shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

9.221 "Roentgen" (R) is the special unit of exposure. One Roentgen equals 2.58×10^{-4} Coulombs/kilogram of air. (See exposure.)

9.222 "Safety device" means a device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path.

9.223 "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

9.224 "Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system or between successive scans measured along the direction of such displacement.

9.225 "Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

9.226 "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

9.227 "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

9.228 "Screening mammography" means mammography performed on an asymptomatic patient to detect the presence of breast cancer at an early stage.

9.229 "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary system.

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- 9.230 "Secondary protective barrier" (See "Protective barrier").
- 9.231 "Serious adverse event" means an adverse advent that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.
- 9.232 "Serious complaint" means a report of a serious adverse event.
- 9.233 "Shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material.
- 9.234 "Shallow-dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2) averaged over an area of 1 square centimeter.
- 9.235 "Shielded room radiography" means industrial radiography using radiation machines, which is conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets conditions for an unrestricted area and the only access to which is through openings which are interlocked so that the radiation machine will not operate unless all openings are securely closed.
- 9.236 "Shutter" means a device attached to the tube housing assembly which can totally intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.
- 9.237 "SID" (see Source to Image Receptor Distance).
- 9.238 "Sievert (Sv)" is the unit of dose equivalent. The dose equivalent in Sieverts is equal to the absorbed dose in grays multiplied by the quality factor. ($1 \text{ Sv} = 100 \text{ rems}$). Submultiples included in this document are the milliSievert (mSv) and the microSievert (uSv).
- 9.239 "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the registrant.
- 9.240 "Source" means the focal spot of the x-ray tube.
- 9.241 "Source to image receptor distance (SID)" means the distance from the source to the center of the input surface of the image receptor.
- 9.242 "Source of radiation" means any device or equipment emitting or capable of producing x-ray radiation.
- 9.243 "Special procedures" means the application of special x-ray equipment and specialized techniques to obtain required diagnostic information. This usually provides enhanced detail of a given anatomical structure but with reduced visualization of others. Special procedures include, but are not limited to, angiography, cardiac catheterization, myelogram, and surgery.
- 9.244 "Special purpose x-ray system" means any radiographic x-ray system which is limited, by design, to radiographic examinations of specified anatomical regions. Special purpose x-ray systems include, but are not limited to, mammography units, dedicated chest units, cystography units, and head and skull units.
- 9.245 "Spot check" means a procedure which is performed to assure that a previous calibration continues to be valid.
- 9.246 "Spot film" means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

9.247 "Spot film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

9.248 "SSD" means the distance between the source and the skin entrance plane of the patient.

9.249 "Standard breast" means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

9.250 "Stationary x-ray equipment" (See "X-ray equipment").

9.251 "Stochastic effects" means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects (also called a probabilistic effect).

9.252 "Stray radiation" means the sum of leakage and scattered radiation.

9.253 "Supervision" means the delegating of the task of applying radiation pursuant to this part by persons, not licensed in the healing arts or veterinary medicine, who provide services under the practitioner's control. The licensed practitioner assumes full responsibility for these tasks and must assure that the tasks will be administered correctly.

9.254 "Survey" means an evaluation of the use, of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to tests, physical examination, and measurements of levels of radiation.

9.255 "Survey" in Part V, means an onsite physics consultation and evaluation of a facility's quality assurance program performed by a medical physicist.

9.256 "Target" means that part of a radiation head which by design intercepts a beam of accelerated particles with subsequent emission of other radiation.

9.257 "Technique factors" means the following conditions of operations:

- 1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;
- 2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
- 3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
- 4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and
- 5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

9.258 "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

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9.259 "Test" means a method for determining the characteristics or condition of sources of radiation or components thereof.

9.260 "Therapeutic-type-protective tube housing" (1) For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the source does not exceed one Roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential. (2) For x-ray therapy equipment capable of operation at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that leakage radiation at a distance of one meter from the source does not exceed an exposure of one Roentgen in an hour or 0.1 percent of the useful beam dose rate at one meter at its maximum rated continuous current for the maximum rated accelerating potential.

9.261 "Time cycle" means the film development time.

9.262 "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

9.263 "Total Effective Dose Equivalent" (TEDE) means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

9.264 "Traceable to a national standard" means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within plus or minus 3 percent of the national standard in the mammography energy range.

9.265 "Tube" means an x-ray tube, unless otherwise specified.

9.266 "Tube housing-apparatus complex" means those parts of an analytical x-ray device in which x-rays are produced and utilized for a useful purpose. This includes the x-ray tube housing, shutter or port assemblies, collimators, cameras, goniometers, and electronic radiation detectors.

9.267 "Tube housing assembly" means the tube housing with tube installed. It includes high voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

9.268 "Unrestricted area" (uncontrolled area) means any area to which access is not controlled by the registrant for purposes of protection of individuals from exposure to radiation, and any area used for residential quarters.

9.269 "Vendor" means a person who is engaged in the business of selling, leasing, installing, or offering to sell, lease, or install x-ray machines or machine components or is engaged in the business of furnishing or offering to furnish x-ray machine services, which includes, but is not limited to, reinstalling, reassembling, leasing, servicing, maintenance, calibration, and repair of x-ray equipment, facility and shielding design, radiation surveys, instrument calibration, personnel dosimetry, processor cleaning and maintenance, and health physics consultations.

9.270 "Very high radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

9.271 "Virtual source" means a point from which radiation appears to originate.

9.272 "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

9.273 "Worker" means an individual engaged in work under a license or registration issued by the agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

9.274 "X-ray equipment" means an x-ray system, subsystem, or component thereof.

9.274.1 Mobile means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

9.274.2 Portable means X-ray equipment designed to be hand carried.

9.274.3 Stationary means X-ray equipment designed which is installed in a fixed location.

9.274.4 Transportable means X-ray equipment installed in a vehicle or trailer.

9.275 "X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube housing assembly, a beam limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

9.276 "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

9.277 "X-ray subsystem" means any combination of two or more components of an x-ray system.

9.278 "X-ray tube" means any electron tube which is designed to be used primarily for the production of x-rays.

9.279 "Year" means the period of time beginning in January used to determine compliance with the provisions of this part. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

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PART X NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS: INSPECTIONS

RHB 10.1 Purpose and Scope. This Part establishes requirements for notices, instructions, and reports by registrants to individuals employed by them, and options available to such individuals in connection with Department inspections of registrants to ascertain compliance with the provisions of the Act and regulations issued thereunder regarding radiological working conditions. The regulations in this Part apply to all persons who receive, possess, use, own, or transfer radiation producing equipment registered by the Department pursuant to the regulation in Part II.

RHB 10.2 Posting of Notices to Workers.

10.2.1 Each registrant shall post current copies of the following documents: 1) the regulations in this Part and in Part III; 2) "Notice to Employees" Form SC-RHA-20; 3) any notice of violation involving radiological working conditions; or order issued pursuant to Part I and any response from the registrant.

10.2.2 If posting of a document is not practicable, the registrant may post a notice which describes the document and states where it may be examined.

10.2.3 Documents, notices of forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work associated with the X-ray equipment to observe them on the way to or from any equipment location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

10.2.4 Department documents posted pursuant to RHB10.2.3, of this section shall be posted within five (5) working days after receipt of the documents from the Department; the registrant's response, if any, shall be posted within five (5) working days after dispatch from the registrant. Such document shall remain posted for a minimum of five (5) working days or until action correcting the violation has been completed, whichever is later.

RHB 10.3 Instructions to Workers. All individuals working in or frequenting any portion of a restricted area shall be kept informed of the use of x-ray equipment or of radiation in portions of the unrestricted area; shall be instructed in the health protection problems associated with exposure to such x-ray equipment or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Department regulations for the protection of personnel from radiation occurring in such areas; shall be instructed of their responsibility to report promptly to the registrant any conditions which may lead to or cause a violation of Department regulations or unnecessary exposure to radiation; shall be instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation; and shall be advised as to the radiation exposure requests which workers may request pursuant to RHB 10.4. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

RHB 10.4 Notification and Reports to Individuals.

10.4.1 Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radiation exposure to the body of an individual shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Department regulations, orders, or inspections. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the registrant, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement: "This report is furnished to you under the provisions of the South Carolina Department of Health and Environmental Control's Radiation Control Regulations. You should preserve this report for future reference."

10.4.2 At the request of any worker, each registrant shall advise such worker annually of the worker's exposure to radiation as shown in records maintained by the registrant pursuant to RHB 3.22.

10.4.3 At the request of the worker formerly engaged in work controlled by the registrant, each registrant shall furnish to the worker a report of the workers' exposure to radiation. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the registrant, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the workers' activities involved exposure to radiation from x-ray producing equipment registered by the Department; and shall include the dates and locations of work under the registrant in which the worker participated during this period.

10.4.4 When a registrant is required pursuant to RHB 3.25 or 3.26 to report to the Department any exposure of an individual to radiation, the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Department.

RHB 10.5 Presence of Registrants and Workers During Inspections.

10.5.1 Each registrant shall afford to the Department, at all reasonable times, opportunity to inspect machines, activities, facilities, premises, and records pursuant to these regulations.

10.5.2 During an inspection, Department inspectors may consult privately with workers as specified in RHB 10.6. The registrant may accompany Department inspectors during other phases of an inspection.

10.5.3 If, at any time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of the physical working conditions.

10.5.4 Each workers' representative shall be routinely engaged in work under control of the registrant and shall have received instructions as specified in RHB 10.3. With approval of the registrant, the workers' representative may be an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative shall be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

10.5.5 Different representatives of registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection.

10.5.6 Notwithstanding the other provisions of this section, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for the area shall be an individual previously authorized by the registrant to enter that area.

RHB 10.6 Consultation with Workers During Inspection.

10.6.1 Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to the extent of an effective and thorough inspection.

10.6.2 During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the Act, or these regulations, or any unnecessary exposure of an individual to radiation from x-ray producing equipment under the registrant's control. Any such notice in writing shall comply with the requirements of RHB 10.7.1.

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10.6.3 The provisions of RHB 10.6.2 of this section shall not be interpreted as authorization to disregard instructions pursuant to RHB 10.3

RHB 10.7 Request by Workers for Inspections.

10.7.1 Any worker or representative of workers who believes that a violation of the Act, or these regulations exists or has occurred in work under a registrant with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. Any such notice shall be in writing and shall set forth the specific grounds for the notice. A copy shall be provided to the registrant by the Department no later than at the time of inspection.

10.7.2 If, upon receipt of such notice, the Director of Health Regulation or the Chief of the Bureau of Radiological Health determines that the complaint meets the requirements set forth in RHB 10.7.1 of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in this complaint.

10.7.3 No registrant shall discharge or in any manner discriminate against any worker because such worker has filed any compliant or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of the worker or others of any option afforded by this Part.

RHB 10.8 Inspections not Warranted. Informal Review.

10.8.1 If the Chief of the Bureau of Radiological Health determines, with respect to a complaint under RHB10.7 that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Bureau Chief shall notify the complainant, if identified, in writing of such determination. The complainant, if identified, may obtain a review of such determination by submitting a written statement of position with the Director of Health Regulation, who will provide the registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position with the Bureau of Radiological Health who will provide the complainant with a copy of such statements by certified mail. Upon the request of the complainant, the Bureau of Radiological Health may hold an informal conference in which the complainant and the registrant may orally present their views. An informal conference may also be held at the request of the registrant, but disclosure of the identity of the complainant will be made only following receipt written authorization from the complainant. After considering all written or oral views present, the Director of Health Regulation shall affirm, modify, or reverse the determination of the Chief of the Bureau of Radiological Health and furnish the complainant and the registrant a written notification of the decision and the reason therefore.

10.8.2 If the Chief of the Bureau of Radiological Health determines that an inspection is not warranted because the requirements of RHB 10.7.1 have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of RHB 10.7.1.

RHB 10.9 Right to inspect and investigate. The Department of Health and Environmental Control is the state agency responsible for the control and regulation of radiation sources. Section 13-7-40(A), S.C. Code of Laws (1976, as amended). By statute, the Department is authorized to enter, at all reasonable times, private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of its regulations. Section 13-7-40(A), S.C. Code of Laws (1976, as amended). Because the Department is authorized by law to enter and inspect property in order to determine compliance with Department regulations, such entry and inspection falls under the health oversight activities exception of Health Insurance Portability and Accountability Act (HIPAA). Therefore, where protected health information is necessary for determining

compliance with Department regulations, protected health information may be used and disclosed to the Department without the subject's authorization under HIPAA.

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PART XI REGIONAL CALIBRATION LABORATORY

RHB 11.1 Scope. This part establishes operating requirements and fees for the South Carolina Regional Calibration Laboratory (SCRCL).

RHB 11.2 Operations.

11.2.1 The SCRCL shall maintain a current accreditation status as directed by the Conference of Radiation Control Program Directors.

11.2.2 The SCRCL shall perform accredited calibration procedures that will be traceable to the National Institute of Standards and Technology.

11.2.2.1 The SCRCL shall perform yearly proficiency tests under the guidance of, and in coordination with, the National Institute of Standards of Technology.

11.2.3 The SCRCL shall maintain current written operating procedures. The policies of the operating procedures will be followed for all instruments entrusted to the SCRCL for calibration.

11.2.4 Each instrument received shall be surveyed for contamination. Contaminated instruments will not be calibrated at the South Carolina Regional Calibration Laboratory.

11.2.5 Each Geiger-Mueller, Ion Chamber and R Meter will be calibrated at two (2) points on each scale.

RHB 11.3 Fees.

11.3.1 A fee shall be charged for each instrument and probe calibrated at the SCRCL. The following table shall be used by the Department to determine calibration fees:

Type of Instrument	Fees
Geiger-Mueller (GM)	\$75
Ion Chamber	
First mode	\$75
Second mode	\$18.75
R Meter	\$50
MDH 1015 or 1515	
One probe-five calibration points	\$250
Additional probe-five calibration points	\$106.25
MDH 2025	
One probe- five calibration points	\$106.25
Additional probe-five calibration points	\$75
Dosimeter test - analog and digital	\$18.75 Per mode of operation
Replacement Carbon Zinc Batteries	
15 volts (NEDA 220)	Market price plus tax

22.5 volts (NEDA 221)	
22.5 volts (NEDA 215)	
30 volts (NEDA 210)	
67.5 volts (NEDA 416)	
300 volts (NEDA 722)	
Replacement desiccant pellets	Market price plus tax
Minimum handling fee, any instrument-no calibration	\$18.75

11.3.2 Shipping and insurance charges will be added to calibration fees for instruments requiring mail services. Charges will be the same as the cost to the Department.

11.3.3 An invoice for calibrations and other services will be issued to the person or organization requesting the calibration. All fees are due upon receipt of the invoice.

Fiscal Impact Statement:

There will be no increased costs to the State or its political subdivisions with the implementation of these amendments. This program is partially funded by the collection of fees from the regulated community as mandated by the Atomic Energy and Radiation Control Act. The Act requires the cost of running the program to be recovered through the collection of fees.

Statement of Need and Reasonableness:

This statement of need and reasonableness was determined by staff analysis pursuant to S.C. Code Section 1-23-115(C)(1)-(3) and (9)-(11).

DESCRIPTION OF REGULATION: R.61-64, X-Rays (Title B).

Purpose: The amendment of R.61-64 is to update the regulation pertaining to x-ray devices and facilities that utilize x-ray equipment.

Legal Authority: R.61-64, X-Rays (Title B), is authorized by 1976 Code Section 13-7-45 et seq.

Plan for Implementation: Upon approval from the S.C. General Assembly and publication as a final regulation in the South Carolina State Register, a copy of R.61-64 that includes these amendments, will be available electronically on the Department’s Laws and Regulations website and subsequently in the Code of Regulations of the S.C. Code of Laws. Printed copies will be available for a fee from the Department’s Freedom of Information Office. Staff will educate the regulated community on the provisions of the Act and the requirements of the regulation.

DETERMINATION OF NEED AND REASONABLENESS OF THE REGULATION BASED ON ALL FACTORS HEREIN AND EXPECTED BENEFITS:

These revisions are needed in order to update the existing regulation and to bring the inspection frequencies more in line with the national standards. R.61-64 was last revised on June 26, 2009. The changes will clarify the requirements of facilities that utilize x-ray devices. The language changes will clarify many Sections and Parts of the regulation. This update will promote greater health and safety to the public, delete requirements that are no longer applicable, and make stylistic and grammatical changes for clarity. In addition the regulations increase the registration fees to allow for the hiring of six additional inspectors. The fee increase will provide funding for

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the hiring of additional inspectors to increase the frequency of inspections. The last fee increase was in June 2003.

The changes are reasonable due to the fact that they will bring the requirements more in line with the national suggested state regulations.

DETERMINATION OF COST AND BENEFITS:

The program implementing R.61-64 is partially funded by a collection of fees from the regulated community as mandated by the Atomic Energy and Radiation Control Act. This Act requires the fees collected from the regulated community to be sufficient to not only protect the public health, safety, and environment, but to also recover costs incurred by the Department through regulation. In order to subsidize hiring of six additional inspectors to increase frequency of inspections, the regulation increases registration fees by \$31.

See Fiscal Impact Statement above for cost to the State and its political subdivisions.

UNCERTAINTIES OF ESTIMATES:

There are no known uncertainties of estimates.

EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH:

There are no anticipated effects on the environment. The amendments seek to have a positive effect upon the public health of the citizens of the state. The revision of R.61-64 will clarify the entire regulation and allow for more inspections due to increased Department personnel.

DETRIMENTAL EFFECTS ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE REGULATION IS NOT IMPLEMENTED:

There are no anticipated detrimental effects on the environment if these changes are not implemented. The Department does not anticipate a detrimental effect to public health of the citizens. Conversely, there is an anticipated positive effect from the added requirements and clarifications.

Statement of Rationale:

The revisions herein are intended to update the R.61-64 based on Departmental recommendations, national standards, and practices to better promote safety to facilities that utilize x-ray producing equipment. The language changes will add clarity with respect to specificity, organization, and intent. The regulation increases registration fees to allow for the hiring of six additional inspectors.

Document No. 4602
DEPARTMENT OF LABOR, LICENSING AND REGULATION
BUILDING CODES COUNCIL
 CHAPTER 8

Statutory Authority: 1976 Code Sections 6-8-20, 6-9-40, 6-9-63(E), and 40-1-70

- 8-800. International Building Code.
- 8-804. IBC Section 1014.2. Egress through intervening spaces.
- 8-805. IBC Section Appendix H Signs.
- 8-900 International Fire Code.
- 8-910. IFC Section 2307.5.3 Vehicle impact protection.
- 8-911. IFC Section 2307.6 Private fueling of motor vehicles.
- 8-1002 IFGC Section 401.10 Third-party testing and certification.
- 8-1005. IFGC Section 412.7.3 Vehicle impact protection.
- 8-1006. IFGC Section 412.8 Private fueling of motor vehicles.
- 8-1100. National Electrical Code.
- 8-1101. NEC Article 210.12(B) Arc-Fault Circuit-Interrupter Protection.
- 8-1200. International Residential Code.
- 8-1202. IRC Figure R302.1 Exterior walls.
- 8-1203. IRC Section R302.2 Townhouses.
- 8-1204. IRC Section R302.5.1 Opening protection.
- 8-1205. IRC Section R303.4 Mechanical ventilation.
- 8-1206. IRC Figure R307.2 Minimum Fixture Clearances.
- 8-1207. IRC Section R311.7.5.1 Risers.
- 8-1208. IRC Section R312.1.1 Where required.
- 8-1209. IRC Section R312.2 Window fall protection.
- 8-1210. IRC Section R313.1 Townhouse Automatic Fire Sprinkler Systems.
- 8-1211. IRC Section R313.2. One and two-family dwellings automatic fire sprinkler systems.
- 8-1212. IRC Section R317.1.1 Field treatment.
- 8-1213. IRC Section R404.1.9.2 Masonry piers supporting floor girders.
- 8-1214. IRC Section R502.11.4 Truss design drawings.
- 8-1215. IRC Section R703.8 Flashing.
- 8-1216. IRC Chapter 11 Energy Efficiency.
- 8-1217. IRC Section M1411.5 Insulation of refrigerant piping.
- 8-1218. IRC Section M1411.6 Locking access port caps.
- 8-1219. IRC Section M1502.3 Duct termination.
- 8-1220. IRC Section M1502.4.4 Duct length.
- 8-1221. IRC Section G2418.2 Design and Installation.
- 8-1222. IRC Section P2503.6 Shower Liner Test.
- 8-1223. IRC Section P2904.1 General.
- 8-1224. IRC Section E3901.12 HVAC outlet.
- 8-1225. IRC Section Appendix H Patio Covers.

Synopsis:

The South Carolina Building Codes Council proposes to amend its regulations by adopting with modifications, the mandatory codes shown in 2015 Edition of the International Building Code; 2015 Edition of the International Residential Code; 2015 Edition of the International Fire Code; 2015 Edition of the International Fuel Gas Code; 2014 Edition of the National Electrical Code. Additionally, adopting without modification the 2015 Edition of the International Plumbing Code and 2015 Edition of the International Mechanical Code as published. Additionally, amending its regulations by adopting permissive codes as shown in 2015 Edition of the International Property Maintenance Code; 2015 Edition of the International Existing Building Code; 2015

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Edition of the International Swimming Pool and Spa Code; and 2015 Edition of the International Performance Code for Buildings and Facilities.

A Notice of Drafting was published in the *State Register* on August 28, 2015.

Instructions:

Replace the regulations as shown below. All other sections remain unchanged.

Text:

CHAPTER 8

BUILDING CODES COUNCIL

ARTICLE 8

INTERNATIONAL BUILDING CODE

8-800. International Building Code.

NOTE-This article is based upon the International Building Code, 2015 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, except for the modifications referenced below. This code is identical to the 2015 Edition of the International Building Code except for the following modifications:

8-804. IBC Section 903.2.9 Group S-1.

An automatic sprinkler system shall be provided throughout all buildings containing a Group S-1 occupancy where one of the following conditions exists:

1. A Group S-1 fire area exceeds 12,000 square feet (1115 m²).
2. A Group S-1 fire area is located more than three stories above grade plane.
3. The combined area of all Group S-1 fire areas on all floors, including any mezzanines, exceeds 24,000 square feet (2230 m²).
4. A Group S-1 fire area used for the storage of commercial motor vehicles where the fire area exceeds 5,000 square feet (464 m²).
5. A Group S-1 occupancy used for the storage of upholstered furniture or mattresses where the fire area exceeds 2,500 square feet (232 m²).

8-805. IBC Section 1009.4 Elevators.

In order to be considered part of an accessible means of egress, an elevator shall comply with the emergency operation and signaling device requirements of Section 2.27 of ASME A17.1. Standby power shall be provided in accordance with Chapter 27 and Section 3003. The elevator shall be accessed from an area of refuge complying with Section 1009.6. Elevators shall also comply with 3008 Occupant Evacuation Elevators.

Exceptions:

1. Areas of refuge are not required at the elevator in open parking garages.
2. Areas of refuge are not required in buildings and facilities equipped throughout with an automatic sprinkler system installed in accordance with Section 903.3.1.1 or 903.3.1.2.
3. Areas of refuge are not required at elevators not required to be located in a shaft in accordance with Section 712.
4. Areas of refuge are not required at elevators serving smoke-protected assembly seating areas complying with Section 1029.6.2.
5. Areas of refuge are not required for elevators accessed from a refuge area in conjunction with a horizontal exit.

8-806. IBC Section 1014.2. Egress through intervening spaces.

Means of egress shall consist of continuous and unobstructed paths of travel to the exterior of a building. Means of egress shall not be permitted through kitchens, closets, restrooms and similar areas nor through adjacent tenant spaces.

Exception: Means of egress shall be permitted through a kitchen area serving adjoining rooms constituting part of the same dwelling unit or guest room.

When unusually hazardous conditions exist, the building official may require additional means of egress to assure the safety of the occupants.

8-807. IBC Section Appendix H Signs.

Adopt Appendix H.

ARTICLE 9

INTERNATIONAL FIRE CODE

8-900. International Fire Code.

NOTE-This article is based upon the International Fire Code, 2015 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, except for the modifications referenced below.

This code is identical to the 2015 Edition of the International Fire Code except for the following modifications:

8-910. IFC Section 2307.6.4 Vehicle impact protection.

Exception: An alternative method may be used that meets the intent of this section with the approval of the AHJ.

8-911. IFC Section 2308.4 Private fueling of motor vehicles.

Self-service LP-gas dispensing systems, including key, code and card lock dispensing systems, shall not be open to the public. In addition to the requirements of Sections 2305 and 2306.7, self-service LP-gas dispensing systems shall be in accordance with the following:

1. The system shall be provided with an emergency shutoff switch located within 100 feet (30 480 mm) of, but not less than 20 feet (6096 mm) from dispensers.

2. The owner of the LP-gas motor fuel-dispensing facility shall provide for the safe operation of the system and the training of users.

ARTICLE 10

INTERNATIONAL FUEL GAS CODE

8-1000. International Fuel Gas Code.

NOTE-This article is based upon the International Fuel Gas Code, 2015 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, except for the modifications referenced below.

This code is identical to the 2015 Edition of the International Fuel Gas Code except for the following modifications:

8-1005. IFGC Section 412.8.3 Vehicle impact protection.

Exception: An alternative method may be used that meets the intent of this section with the approval of the AHJ.

8-1006. IFGC Section 412.9 Private fueling of motor vehicles.

Self-service LP-gas dispensing systems, including key, code and card lock dispensing systems, shall not be open to the public. In addition to the requirements of the International Fire Code, self-service LP-gas dispensing systems shall be provided with an emergency shutoff switch located within 100 feet (30 480 mm) of, but not

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less than 20 feet (6096 mm) from, dispensers and the owner of the dispensing facility shall ensure the safe operation of the system and the training of users.

ARTICLE 11

NATIONAL ELECTRICAL CODE

8-1100. National Electrical Code.

NOTE-This article is based upon the National Electrical Code, 2014 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, except for the modifications referenced below.

This code is identical to the 2014 Edition of the National Electrical Code except for the following modifications:

8-1101. NEC Article 90.2(B)(5) Scope.

b. Are located in legally established easements, rights-of-way, or by other agreements either designated by or recognized by public service commissions, utility commissions, or other regulatory agencies having jurisdiction for such installations, or

8-1102. NEC Article 210.12(B) Arc-Fault Circuit-Interrupter Protection.

(c) A circuit serving no outlets within the bedroom except the smoke detector shall not be protected by an arc-fault protector.

ARTICLE 12

INTERNATIONAL RESIDENTIAL CODE

8-1200. International Residential Code.

2012 International Residential Code Modification Summary

(Statutory Authority: 1976 Code Section 6-9-40)

NOTE-This article is based upon the International Residential Code, 2015 Edition, in accordance with the statutory amendments to acts governing the Building Codes Council, except for the modifications referenced below.

This code is identical to the 2015 Edition of the International Residential Code except for the following modifications:

8-1202. IRC Figure R301.2.1.1 Regions Where Wind Design Is Required.

Buildings shall be assigned a wind design category in accordance with figure R301.2(4)(B) until probabilistic hazard maps, funded by the S.C. General Assembly, can be presented by the author, Dr. Timothy Mayes, and the findings reviewed, addressed and, if justified, adopted as a modification by the S.C. Building Codes Council.

8-1203. IRC Section R301.2.2.1 Determination of Seismic Design Category.

Buildings shall be assigned a seismic design category in accordance with R301.2(2) until probabilistic hazard maps, funded by the S.C. General Assembly, can be presented by the author, Dr. Timothy Mayes, and the findings reviewed, addressed and, if justified, adopted as a modification by the S.C. Building Codes Council.

8-1204. IRC Figure R302.1 Exterior walls.

Exception 6. a. The minimum fire separation distance for improvement constructed on a lot shown on: [i] a recorded bonded or final subdivision plat, or [ii] a sketch plan, site plan, plan of phased development or preliminary plat approved by the local governing authority which was recorded or approved prior to the implementation of IRC 2012 which shows or describes lesser setbacks than the fire separation distances provided in Table R302.1(1) shall be equal to the lesser setbacks, but in no event less than 3 feet.

b. The minimum fire separation distance for improvements constructed on a lot where the local governing authority has prior to the implementation of IRC 2012: [i] accepted exactions or issued conditions, [ii] granted a special exception, [iii] entered into a development agreement, [iv] approved a variance, [v] approved a

planned development district, or [vi] otherwise approved a specific development plan which contemplated or provided for setbacks less than the fire separation distances provided in Table R302.1(1) shall be equal to the lesser setback, but in no event less than 3 feet.

8-1205. IRC Section R302.5.1 Opening protection.

Openings from a private garage directly into a room used for sleeping purposes shall not be permitted. Other openings between the garage and residence shall be equipped with solid wood doors not less than 1 3/8 inches (35 mm) in thickness, solid or honeycomb core steel doors not less than 1 3/8 inches (35 mm) thick, or 20-minute fire-rated doors.

8-1206. Section R.302.13 Fire Protection of Floors.

Floor assemblies that are not required elsewhere in this code to be fire-resistance rated, shall be provided with a 1/2-inch (12.7 mm) gypsum wallboard membrane, 5/8-inch (16 mm) wood structural panel membrane, or equivalent on the underside of the floor framing member. Penetrations or openings for ducts, vents, electrical outlets, lighting, devices, luminaires, wires, speakers, drainage, piping and similar openings or penetrations shall be permitted.

Exceptions:

1. Floor assemblies located directly over a space protected by an automatic sprinkler system in accordance with Section P2904, NFPA 13D, or other approved equivalent sprinkler system.
2. Floor assemblies located directly over a crawl space.
3. Portions of floor assemblies shall be permitted to be unprotected where complying with the following:
 - 3.1. The aggregate area of the unprotected portions does not exceed 80 square feet (7.4 m²) per story.
 - 3.2. Fireblocking in accordance with Section R302.11.1 is installed along the perimeter of the unprotected portion to separate the unprotected portion from the remainder of the floor assembly.
4. Wood floor assemblies using dimension lumber or structural composite lumber equal to or greater than 2-inch by 10-inch (50.8 mm by 254 mm) nominal dimension, or other approved floor assemblies demonstrating equivalent fire performance.

8-1207. IRC Section R303.4 Mechanical ventilation.

The Building Codes Council does not adopt IRC Section R303.4.

8-1208. IRC Figure R307.1 Minimum Fixture Clearances.

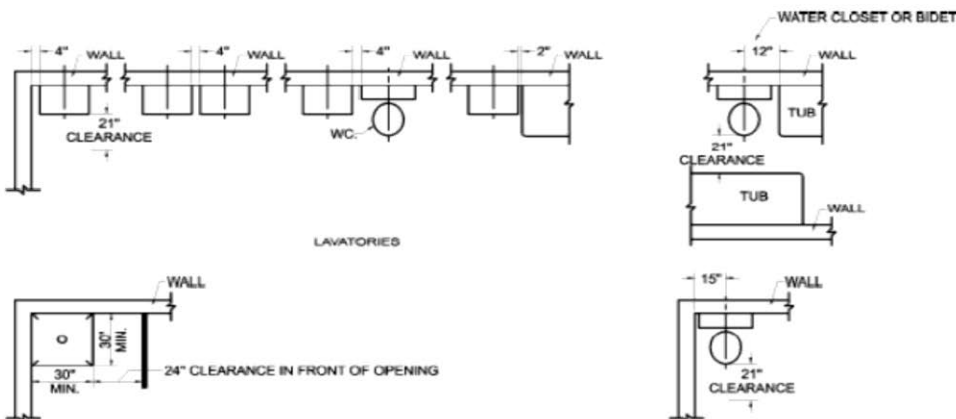


Figure 307.1
Minimum Fixture Clearances

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8-1209. IRC Section R311.7.5.1 Risers.

The maximum riser height shall be 7³/₄ inches (196 mm). The maximum riser height for masonry stairs shall be 8 inches (203 mm). The riser shall be measured vertically between leading edges of the adjacent treads. The greatest riser height within any flight of stairs shall not exceed the smallest by more than 3/8 inch (9.5 mm). Risers shall be vertical or sloped from the underside of the nosing of the tread above at an angle not more than 30 degrees (0.51 rad) from the vertical. Open risers are permitted provided that the opening between treads does not permit the passage of a 4-inch-diameter (102 mm) sphere.

Exception: The opening between adjacent treads is not limited on stairs with a total rise of 30 inches (762 mm) or less.

8-1210. IRC Section R312.1.1 Where required.

Guards shall be located along open-sided walking surfaces of all decks, porches, balconies, stairs, ramps and landings that are located more than 30 inches measured vertically to the floor or grade below and at any point where a downward slope exceeds 3V:12H within 36 inches (914 mm) horizontally to the edge of the open side. Insect screening shall not be considered as a guard.

8-1212. IRC Section R313 Automatic Fire Sprinkler Systems.

R313.1 Townhouse automatic fire sprinkler systems. An automatic residential fire sprinkler system shall not be required to be installed in *townhouses* when constructed in accordance with R302.2.

Exception: An automatic residential fire sprinkler system shall not be required where *additions* or *alterations* are made to existing *townhouses* that do not have an automatic residential fire sprinkler system installed.

R313.1.1 Design and installation. Automatic residential fire sprinkler systems when installed for *townhouses* shall be designed and installed in accordance with Section P2904 or NFPA 13D.

R313.2 One- and two-family dwellings automatic fire systems. An automatic residential fire sprinkler system shall not be required to be installed in one- and two-family *dwellings*.

Exception: An automatic residential fire sprinkler system shall not be required for *additions* or *alterations* to existing buildings that are not already provided with an automatic residential sprinkler system.

R313.2.1 Design and installation. Automatic residential fire sprinkler systems when installed shall be designed and installed in accordance with Section P2904 or NFPA 13D.

8-1213. IRC Section R317.1.1 Field treatment.

Field-cut ends, notches and drilled holes of preservative-treated wood shall be treated in the field in accordance with AWPAC M4 or in accordance with the preservative-treated wood product manufacturer's recommendations.

8-1214. IRC Section R319.1 Address ID.

Buildings shall be provided with *approved* address identification. The address identification shall be legible and placed in a position that is visible from the street or road fronting the property. Address identification characters shall contrast with their background. Address numbers shall be Arabic numbers or alphabetical letters. Numbers shall not be spelled out. Each character shall be not less than 4 inches (102 mm) in height with a stroke width of not less than 0.5 inch (12.7 mm). Where access is by means of a private road and the building address cannot be viewed from the public way, a monument, pole or other sign or means shall be used to identify the structure. Address identification shall be maintained.

8-1215. IRC Section R326.1 Swimming Pools, Spas, and hot tubs.

Entire section deleted without substitution.

8-1216. IRC Section R404.1.9.2 Masonry piers supporting floor girders.

Masonry piers supporting wood beams and girders sized in accordance with Tables R602.7(1) and R602.7(2) shall be permitted in accordance with this section. Piers supporting girders for interior bearing walls shall be filled solidly with grout or type M or S mortar and shall have a minimum nominal dimension of 8 inches (203 mm) and a maximum height not exceeding 10 times the nominal thickness from the top of footing to bottom of

sill plate or girder. Piers supporting beams and girders for exterior bearing walls shall be filled solidly with grout or type M or S mortar; shall contain a minimum of one #4 (13 mm) dowel mid-depth; and shall have a minimum nominal dimension of 8 inches (203 mm) and a maximum height of 4 times the nominal thickness from top of footing to bottom of sill plate or girder unless it can be shown by accepted engineering practice that there is sufficient foundation wall along the foundation line to resist the imposed lateral loads, in which case the maximum height shall not exceed 10 times the nominal thickness. Girders and sill plates shall be anchored to the pier or footing in accordance with Section R403.1.6 or Figure R404.1.5(1). Floor girder bearing shall be in accordance with Section R502.6.

8-1217. IRC Section R408.4 Access.

Access shall be provided to all under-floor spaces. Access openings through the floor shall be a minimum of 18 inches by 24 inches (457 mm by 610 mm). Openings through a perimeter wall shall be not less than 16 inches by 24 inches (407 mm by 610 mm). Where any portion of the through-wall access is below *grade*, an areaway not less than 16 inches by 24 inches (407 mm by 610 mm) shall be provided. The bottom of the areaway shall be below the threshold of the access opening. See Section M1305.1.4 for access requirements where mechanical *equipment* located under floors.

8-1218. IRC Section R502.11.4 Truss design.

Truss design drawings. Truss design drawings, prepared in compliance with Section R502.11.1, shall be provided to the building official at the time of inspection. Truss design drawings shall be provided with the shipment of trusses delivered to the job site. Truss design drawings shall include at a minimum the information specified as follows:

8-1219. IRC Section R506.2.3 Vapor Retarder.

A 6-mil (0.006 inch; 152 μ m) polyethylene or *approved* vapor retarder with joints lapped not less than 6 inches (152 mm) shall be placed between the concrete floor slab and the base course or the prepared subgrade where no base course exists.

Exception: The vapor retarder is not required for the following:

1. Utility buildings and other unheated *accessory structures*.
2. For unheated storage rooms having an area of less than 70 square feet (6.5 m²) and carports.
3. Driveways, walks, patios and other flatwork not likely to be enclosed and heated at a later date.
4. Where *approved* by the *building official*, based on local site conditions.

8-1220. IRC Section R606.7 Piers.

The unsupported height of masonry piers shall not exceed 10 times their least dimension. Where structural clay tile or hollow concrete masonry units are used for isolated piers to support beams and girders, the cellular spaces shall be filled solidly with grout or Type M or S mortar, except that unfilled hollow piers shall be permitted to be used if their unsupported height is not more than four times their least dimension. Where hollow masonry units are solidly filled with grout or Type M or S mortar, the allowable compressive stress shall be permitted to be increased as provided in Table R606.9.

8-1221. IRC Section R703.4 Flashing.

R703.4 Flashing. Flashing shall be provided in accordance with this section and shall be installed at all of the following locations:

1. Exterior window and door openings.
2. At the intersection of chimneys or other masonry construction with frame or stucco walls, with projecting lips on both sides under stucco copings.
3. Under and at the ends of masonry, wood or metal copings and sills.
4. Continuously above all projecting wood trim.
5. Where exterior porches, decks or stairs attach to a wall or floor assembly of wood frame construction.
6. At wall and roof intersections.
7. At built-in gutters.

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R703.4.1 Flashing Materials. Approved flashing materials shall be corrosion-resistant. Self adhered membranes used as flashing shall comply with AAMA 711. Pan flashing shall comply with Section R703.4.2. Installation of flashing materials shall be in accordance with Section R703.8.3.

R703.4.2 Pan Flashing. Pan flashing installed at the sill of exterior window and door openings shall comply with this section. Pan flashing shall be corrosion-resistant and shall be permitted to be pre-manufactured, fabricated, formed or applied at the job site. Self-adhered membranes complying with AAMA 711 shall be permitted to be used as pan flashing. Pan flashing shall be sealed or sloped in such a manner as to direct water to the surface of the exterior wall finish or to the water-resistive barrier for subsequent drainage.

R703.4.3 Flashing Installation. Flashing installation shall be in accordance with this section and the flashing manufacturer's installation instructions. Flashing shall be applied shingle fashion in a manner to prevent entry of water into the wall cavity or penetration of the water to the building structural framing components. Flashing shall extend to the surface of the exterior wall finish.

R703.4.3.1 Flashing Installation at Exterior Windows and Doors. Flashing at exterior windows and doors shall be applied shingle fashion and shall extend to the surface of the exterior wall finish or to the water resistive-barrier for drainage. Installation of flashing materials shall be in accordance with one or more of the following methods:

1. The fenestration manufacturer's installation and flashing instructions.
2. The flashing manufacturer's installation instructions.
3. Flashing details or other methods approved by the building official.
4. As detailed by a registered design professional.

8-1222. IRC Section R802.10.1 Wood Truss Design.

Truss design drawings, prepared in conformance to Section R502.11.1 shall be provided to the building official at the time of their inspection. Truss design drawings shall be provided with the shipment of trusses delivered to the job site. Truss design drawings shall include, at a minimum, the following information:

8-1223. IRC Section R905.2.8.5 Drip Edge.

A drip edge shall be provided at eaves and rake edges of asphalt shingle roofs where required by the manufacturer.

8-1224. IRC Section M1411.6 Insulation of refrigerant piping.

Piping and fittings for refrigerant vapor (suction) lines shall be insulated with insulation have a thermal resistivity of at least R 2.5 hr. ft² F/Btu and having external surface permeance not exceeding 0.05 perm [2.87 ng/(s m² Pa)] when tested in accordance with ASTM E 96.

8-1225. IRC Chapter 11 Energy Efficiency.

The Building Codes Council does not adopt IRC Chapter 11.

8-1226. IRC Section M1411.8 Locking access port caps.

The Building Codes Council does not adopt IRC Section M1411.8.

8-1227. IRC Section M1502.3 Duct termination.

Exhaust ducts shall terminate on the outside of the building. Exhaust duct terminations shall be in accordance with the dryer manufacturer's installation instructions. Exhaust duct terminations shall be equipped with a backdraft damper. Screens shall not be installed at the duct termination.

8-1228. IRC Section M1502.4.5 Duct length.

The maximum length of a clothes dryer exhaust duct shall not exceed 35 feet (10668 mm) from the dryer location to the wall or roof termination.

8-1229. IRC Section M1503.4 Makeup air required.

Exhaust hood systems capable of exhausting more than 400 cubic feet per minute (0.19m³/s) shall be mechanically or naturally provided with makeup air at a rate approximately equal to the exhaust air rate more

than 400 cubic feet per minute. Such makeup air systems shall be equipped with not less than one damper. Each damper shall be a gravity damper or an electrically operated damper that automatically opens when the exhaust system operates. Dampers shall be accessible for inspection, service, repair and replacement without removing permanent construction or any other ducts not connected to the damper being inspected, serviced, repaired or replaced.

8-1230. IRC Section M1601.4.1 Joints, seams and connections.

Longitudinal and transverse joints, seams and connections in metallic and nonmetallic ducts shall be constructed as specified in SMACNA HVAC *Duct Construction Standards—Metal and Flexible* and NAIMA *Fibrous Glass Duct Construction Standards*. Joints, longitudinal and transverse seams, and connections in ductwork shall be securely fastened and sealed with welds, gaskets, mastics (adhesives), mastic-plus-embedded-fabric systems, liquid sealants or tapes.

Tapes and mastics used to seal fibrous glass ductwork shall be *listed* and *labeled* in accordance with UL 181A and shall be marked “181A-P” for pressure-sensitive tape, “181 A-M” for mastic or “181 A-H” for heat-sensitive tape. Tapes and mastics used to seal metallic and flexible air ducts and flexible air connectors shall comply with UL 181B and shall be marked “181 B-FX” for pressure-sensitive tape or “181 BM” for mastic. Duct connections to flanges of air distribution system equipment shall be sealed and mechanically fastened. Mechanical fasteners for use with flexible nonmetallic air ducts shall comply with UL 181B and shall be marked 181B-C. Crimp joints for round metallic ducts shall have a contact lap of not less than 1 inch (25 mm) and shall be mechanically fastened by means of not less than three sheet-metal screws or rivets equally spaced around the joint. Closure systems used to seal all ductwork shall be installed in accordance with the manufacturers’ instructions.

Exceptions:

1. Spray polyurethane foam shall be permitted to be applied without additional joint seals.
2. Where a duct connection is made that is partially inaccessible, three screws or rivets shall be equally spaced on the exposed portion of the joint so as to prevent a hinge effect.
3. For ducts having a static pressure classification of less than 2 inches of water column (500 Pa), additional closure systems shall not be required for continuously welded joints and seams and locking-type joints.

8-1231. IRC Section G2418.2 Design and Installation.

Piping shall be supported with pipe hooks, pipe straps, bands, brackets, hangers, or building structural components suitable for the size of piping, of adequate strength and quality, and located at intervals so as to prevent or damp out excessive vibration.

8-1232. IRC Section P2503.6 Shower Liner Test.

Where shower floors and receptors are made water tight by the application of materials required by Section P2709.2, the completed liner installation shall be tested. Shower liner shall be tested to the lesser of the depth of threshold or 2” and shall be operated at normal pressure for a test period of not less than 15 minutes, and there shall be no evidence of leakage.

8-1233. IRC Section P2603.5 Freezing.

In localities having a winter design temperature of 32°F (0°C) or lower as shown in Table R301.2(1) of this code, a water pipe shall not be installed outside of a building, in exterior walls, in *attics* or crawl spaces, or in any other place subjected to freezing temperature unless adequate provision is made to protect it from freezing by insulation or heat or both. Water service pipe shall be installed not less than 12 inches (305 mm) deep and not less than 6 inches (152 mm) below the frost line.

8-1234. IRC Section P2903.10 Hose Bibb.

This section is deleted without substitution.

8-1235. IRC Section P2904.1 General.

The design and installation of residential fire sprinkler systems shall be in accordance with NFPA 13D or Section P2904 which shall be considered equivalent to NFPA 13D. Partial residential sprinkler systems shall be

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permitted to be installed only in buildings not required to be equipped with a residential sprinkler system. Section P2904 shall apply to stand-alone and multipurpose wet-pipe sprinkler systems that do not include the use of antifreeze. A multipurpose fire sprinkler system shall provide domestic water to both fire sprinklers and plumbing fixtures. A stand-alone sprinkler system shall be separate and independent from the water distribution system. A backflow preventer shall not be required to separate a stand-alone sprinkler system from the water distribution system. Any individual offering to contract for the design, installation, testing, and/or maintenance of a residential multipurpose fire sprinkler systems, as referred in Section P2904, must be certified and licensed through the South Carolina Contractors Licensing Board.

8-1236. IRC Section E3802.4 In unfinished basements and crawl spaces.

Where type NM or SE cable is run at angles with joists in unfinished basements, cable assemblies containing two or more conductors of sizes 6 AWG and larger and assemblies containing three or more conductors of sizes 8 AWG and larger shall not require additional protection where attached directly to the bottom of the joists. Smaller cables shall be run either through bored holes in joists or on running boards. Type NM or SE cable installed on the wall of an unfinished basement shall be permitted to be installed in a listed conduit or tubing or shall be protected in accordance with Table E3802.1. Conduit or tubing shall be provided with a suitable insulating bushing or adapter at the point where the cable enters the raceway. The sheath of the Type NM or SE cable shall extend through the conduit or tubing and into the outlet or device box not less than 1/4 inch (6.4 mm). The cable shall be secured within 12 inches (305 mm) of the point where the cable enters the conduit or tubing. Metal conduit, tubing, and metal outlet boxes shall be connected to an equipment grounding conductor complying with Section E3908.13. [334.15(C)]

8-1237. IRC Section Appendix H Patio Covers.

The Building Codes Council does adopt IRC Section Appendix H.

8-1238. Appendix J Existing Buildings.

The Building Codes Council does adopt IRC Section Appendix J.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will amend regulations by adopting with modifications, the mandatory codes shown in 2015 Edition of the International Building Code; 2015 Edition of the International Residential Code; 2015 Edition of the International Fire Code; 2015 Edition of the International Fuel Gas Code; 2014 Edition of the National Electrical Code. Additionally, adopting without modification the 2015 Edition of the International Plumbing Code and 2015 Edition of the International Mechanical Code as published. Additionally, amending its regulations by adopting permissive codes as shown in 2015 Edition of the International Property Maintenance Code; 2015 Edition of the International Existing Building Code; 2015 Edition of the International Swimming Pool and Spa Code; and 2015 Edition of the International Performance Code for Buildings and Facilities.

Document No. 4617
DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL
 CHAPTER 71

Statutory Authority: 1976 Code Sections 23-9-60, 23-9-550, 23-35-45, and 23-36-80

71-8302. Explosives.

Synopsis:

The Office of State Fire Marshal proposes to eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

A Notice of Drafting was published in the *State Register* on September 25, 2015.

Instructions:

Regulation 71-8302 is amended as shown below.

Text:

SUBARTICLE 3
 EXPLOSIVES

71-8302. Explosives.

(Statutory Authority: 1976 Code Sections 23-9-40(b), 23-9-60, 23-36-10 et seq.)

71-8302.1. General.

A. The purpose of this regulation is to provide reasonable safety and protection to the public, public property, private property, and operators from the manufacture, transportation, handling, use, and storage of explosives in South Carolina.

B. This regulation shall apply to the manufacture, transportation, handling, use, and storage of explosives in South Carolina.

C. This regulation does not apply to the sale or storage of fireworks as regulated by the Board of Pyrotechnic Safety.

71-8302.2. Codes and Standards.

A. All references to codes and standards found in these regulations refer to the editions adopted in R.71-8300.2 and are modified by the following regulations as shown below.

B. The building code shall define occupancy classifications referenced in these regulations.

71-8302.3. Licensing and Permitting Fees.

A. All applications for licenses, tests, or permits must be accompanied by the appropriate fees.

B. The OSFM is responsible for all administrative activities of the licensing program. The SFM shall employ and supervise personnel necessary to effectuate the provisions of this article and shall establish fees sufficient but not excessive to cover expenses, including direct and indirect costs to the State for the operation of this licensing program. Fees may be adjusted not more than once each two years, using the method set out in S.C. Code Ann. Section 40-1-50(D), 1976, as amended.

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C. Fees shall be established for the following:

1. Application
2. Background Check
3. Testing
4. Licensing
5. Permitting
6. Inspection
7. Renewal

D. All fees are due at time of application.

E. Submission requirements for Blasting Permit application

1. Applications for Blasting Permits shall be submitted to the OSFM for approval at least 48 hours before the start of blasting operations.

2. Applications submitted less than 48 hours before the start of blasting operations may be subject to a \$200.00 special processing fee.

3. Blasting Permit applications shall include the properly completed form and shall be accompanied by all information listed on the Blasting Permit application form when applying to the OSFM for a Blasting Permit.

F. All fees paid to the OSFM are nonrefundable.

71-8302.4. Licenses and Permits.

A. Classification of Licenses and Permits

	Class	Category	Blasting Permitted
1.	A	Unlimited	All types of blasting
2.	B	General	All phases of blasting operations in quarries, aboveground open pit mines, and aboveground construction
3.	C	General	All phases of blasting operations in underground mines, shafts, tunnels, and drifts
4.	D	Demolition	All phases of blasting in demolition projects
5.	E	Seismic	All phases of blasting in seismic prospecting
6.	G	Special	Special blasting as described on the permit

B. Licenses

1. No person shall be granted a license who has not successfully completed a written examination administered by the OSFM covering the applicable codes, state laws and regulations for the license classification for which they are applying.

2. Any applicant who fails the written examination is allowed one (1) re-test after a minimum seven (7) day waiting period. Any applicant who fails the re-test shall wait at least six (6) months before reapplying.

3. Licenses are not transferable.

4. The OSFM may accept determination of relief from disability incurred by reason of a criminal conviction that has been granted by the Director of the Bureau of Alcohol, Tobacco, Firearm and Explosives, U. S. Department of Justice, Washington, D.C., pursuant to Section 555.142, Subpart H, Title 27, Code of Federal Regulations and Title 18 United States Code, Chapter 40, Section 845(b).

5. New applicants for licensing shall:

a. Submit an application for a new license.

b. Submit a completed fingerprint card with his or her application. The OSFM will conduct a criminal background check as part of the licensing application process.

c. Provide the appropriate Federal licenses to handle and use explosives or explosive materials. Applicants must provide a copy of applicable Federal licenses with their application.

d. Provide proof of public liability insurance for an amount not less than one million dollars (\$1,000,000). The coverage company must be an insurer which is either licensed by the DOI in this State or approved by the DOI as a nonadmitted surplus lines carrier for risks located in this State. In the event the liability insurance is canceled, suspended, or nonrenewed, the insurer shall give immediate notice to the OSFM.

6. Each applicant for renewal shall each year:
 - a. Submit an application for renewal.
 - b. Submit a completed fingerprint card with his or her application. The OSFM will conduct a criminal background check as part of the licensing application process.
 - c. Provide a copy of their current Federal licenses for handling and using explosives or explosive material with their renewal application.
 - d. Attend at least four (4) hours of continuing education acceptable to the OSFM. Certificates of training or other proof of training attendance must be provided when requested by the OSFM.
 - e. Provide proof of insurance. The coverage company must be an insurer which is either licensed by the DOI in this State or approved by the DOI as a nonadmitted surplus lines carrier for risks located in this State. In the event the liability insurance is canceled, suspended, or nonrenewed, the insurer shall give immediate notice to the OSFM.
 - f. An expired license shall not be renewed. A new license shall be obtained by complying with all requirements and procedures for an original license.

C. Blasting Permits

1. Blasting Permit application forms shall be available on the OSFM website and shall contain the information deemed appropriate by the OSFM. At a minimum, the application form shall include:
 - a. Applicant name and contact information;
 - b. Blaster name, license, and contact information;
 - c. Blast site information including location, purpose of blasting, and fire department responsible for responding to the site;
 - d. Anticipated date and time range of blasting operations;
 - e. Information on separation distances detailing the actual distances to the nearest gas lines, power transmission lines, public roads, and structures;
 - f. The type(s) of explosive used;
 - g. Information on quantities of explosive used including the estimated amount of explosives for the duration of the permit, amount per shot, and amount per charge; and,
 - h. Information regarding whether a seismograph will be used.
2. Blasting Permit application forms shall list all information required to be submitted with the form per R.71-8302.3.E. This list shall include at least the following:
 - a. Current certificate of insurance;
 - b. Directions to the blast site;
 - c. Site plan of the blast site showing measured distances to adjacent buildings, streets, utilities, wells, and other facilities that have been superimposed on officially published maps, electronic satellite imagery, or another means of showing the site area and its vicinity that OSFM determines to be acceptable;
 - d. Blasting plan that addresses proposed blasting procedures, quantity of material to be removed by blasting, number of blasts to be detonated, quantity and type of explosives to be used, maximum amount of explosives per delay, the maximum number of holes per delay, and the proposed placement of seismographs; and
 - e. Safety plan that addresses on-site storage, traffic control, barricading, signage plan, and adverse weather operation plan.
3. No permit will be granted without submission of a complete Blasting Permit application form and payment of application fee.
4. No variations from the terms of the blasting permit are allowed without authorization from the OSFM.

D. Magazine Permits

1. Magazine Permit Application Forms shall contain the information deemed appropriate by the OSFM.
2. Magazine Permit Application Forms shall be available on the OSFM website.
3. Magazine permits expire at 12:01 AM on January 1 of each licensing cycle. Any magazine permit not renewed by December 31 may incur a late fee of \$100.00 (each).
4. Magazine permits shall be visible on the exterior of all magazines. Defaced or destroyed permits will be reported to the OSFM when discovered. The OSFM may, at their discretion, charge the administrative costs of replacing the magazine permit.
5. Each magazine shall be inspected and approved by the OSFM before use.

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71-8302.5. Records.

A. Licensed blasters shall keep records of each blast. The Blaster's Log shall contain the following minimum data:

1. Name of company or contractor;
2. Location, date, and time of blast;
3. Name, signature, and license number of blaster in charge of blast;
4. Type of material blasted;
5. Number of holes, burden and spacing;
6. Diameter and depth of holes;
7. Types of explosives used;
8. Total amount of explosives used;
9. Maximum amount of explosives per delay period of 8 milliseconds or greater;
10. Method of firing and type of circuit;
11. Direction and distance in feet to nearest dwelling house, public building, school, church, commercial or institutional building neither owned nor leased by the person conducting the blasting;
12. Weather conditions;
13. Type and height or length of stemming;
14. Whether mats or other protections were used;
15. Type of delay electric blasting caps used and delay periods used;
16. Exact location of seismograph, if used, and the distance of seismograph from blast as indicated accurately by the person taking the seismograph reading;
17. Seismograph records, where required including:
 - a. Name of person and firm analyzing the seismograph record; and
 - b. Seismograph reading;
18. Maximum number of holes per delay period of eight milliseconds or greater.

B. Blasters will provide a blast report on forms approved by the OSFM and submit these forms within three working days of the blast when deemed necessary by the OSFM.

C. Blasting records shall be retained by the licensed blaster and available for inspection by SFM during normal work hours at their place of business. These blast records shall include as a minimum for each blast:

1. Blasting Permit;
2. Seismograph reports when used;
3. Blaster's Record/log;
4. Pre-Blast Survey (if applicable).

D. Magazine log shall be available for inspection by OSFM upon request during normal work hours or hours of operation of the magazine.

71-8302.6. Blasting Safety and Operations.

A. The contractor, operator, and the blaster are responsible for the conduct of blasting operations on any site.

B. These regulations do not relieve the contractor, operator, blaster or other persons of their responsibility and liability under any other laws.

C. The OSFM may require the use of a seismograph on any blasting operation where damage to personal property has or may occur.

D. A Seismograph shall be used on all blasting operations: (1) within 1500 feet of a building, (2) where the scaled distances shown in NFPA 495 are not followed, or (3) when directed by the OSFM.

E. Operators must notify the OSFM within 24 hours of any fires or thefts involving explosives. The operators shall provide the OSFM with a copy of the report filed with the police department or the incident report from the fire department. Operators must also provide the OSFM Office with a copy of ATF Form 5400.5.

F. The operator shall have their license in their possession when handling, possessing or using explosive materials and shall show their license when asked by any AHJ.

G. A copy of the blasting permit shall be kept at the firing station.

H. This section shall be followed for firing the blast:

1. A warning signal shall be given before every blast. Warning signals shall comply with the following:
 - a. Warning signal is a one (1) minute series of long horn or siren blasts five (5) minutes before the blast signal.
 - b. Blast signal is a series of short horn or siren blasts one (1) minute before the shot.
 - c. All clear signal is a prolonged horn or siren blast following the inspection of the blast area.
2. The signal shall be made from an air horn, siren or other device, and must be loud enough to be clearly heard in all areas that could be affected by the blast or flyrock from the blast. The signal must be distinctive and unique so that it cannot be confused with any other signaling system that might occur on the site. A vehicle horn shall not be used as a signaling system.

71-8302.7. Explosives and Investigations.

All costs incurred by the OSFM for investigations involving explosives or blasting operations shall be reimbursed to the State by the individual or company involved in the investigation. Such reimbursements will only apply when the individual or company has been found in violation of the South Carolina Explosives Control Act (S.C. Code Ann. 23-36-10, et seq., 1976, as amended) or these Regulations.

71-8302.8. Variances.

A. This section provides licensees the opportunity to request variances of the regulations under specific conditions.

1. The OSFM may grant variances when it can be demonstrated the variance improves safety or provides an equivalent level of safety as provided in the regulations and adopted codes.
2. Such a variance may be modified or revoked by the OSFM.
3. When applicable, these variances must also be approved by the U.S. Bureau of Alcohol, Tobacco, Firearms and Explosives.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

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Document No. 4618

DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL
CHAPTER 71

Statutory Authority: 1976 Code Sections 23-9-60, 23-9-550, 23-35-45, and 23-36-80

71-8300. Fire Prevention and Life Safety.

Synopsis:

The Office of State Fire Marshal proposes to eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

A Notice of Drafting was published in the *State Register* on September 25, 2015.

Instructions:

Regulation 71-8300 is amended as shown below.

Text:

SUBARTICLE 1
FIRE PREVENTION AND LIFE SAFETY

71-8300. Fire Prevention and Life Safety.

(Statutory Authority: 1976 Code Sections 23-9-60, 39-41-260, 40-82-70)

71-8300.1. General.

A. Title. These regulations shall be known as the State Fire Marshal's Rules and Regulations.

B. Intent.

1. The purpose of these regulations is:

a. to safeguard to a reasonable degree, life and property from fire, explosion, dangerous conditions, natural disasters, acts of terrorism, and other hazards associated with the construction, alteration, repair, use, and occupancy of buildings, structures, or premises, and

b. to provide safety to fire fighters and emergency responders during emergency situations.

2. These regulations shall be the minimum standards required for fire prevention and life safety in South Carolina for all buildings and structures and shall not be waived.

C. Applicability.

1. These regulations shall apply to state, county, municipal, and private buildings, structures, or premises unless excluded by these regulations or state statute.

2. All buildings, structures, or premises shall be constructed, altered, or repaired in conformance with these regulations.

3. All equipment or systems in a building, structure, or premise shall be constructed, installed, altered, or repaired in conformance with these regulations.

4. These regulations become effective immediately upon the publication as final regulations in the South Carolina State Register.

5. These regulations shall not conflict with any state statute, code, or ordinance adopted pursuant to S.C. Code Ann. Section 6-9-5 et. seq., 1976, as amended, by any municipality or political subdivision. In the event of a conflict, such statute, code, or ordinance shall apply.

6. These regulations shall not apply to:

a. Buildings constructed, or occupied exclusively as one and two-family dwellings, unless amended by these or other state regulations. Conversion of such buildings to another use that is not regulated under the IRC but is regulated under the IBC is considered a change of occupancy, and such buildings must comply with the applicable provisions of the IBC for such a change of use.

D. Existing Buildings.

1. Unless addressed by requirements in these regulations, adopted codes, or state statutes that are indicated to be applicable to them, existing buildings, structures, or premises shall be permitted to continue in operation under the code applicable at the time when the buildings, structures, or premises were constructed.

2. Alterations, repairs, additions, and rehabilitation to an existing building, structure, or premise shall fully comply with the current codes.

3. Change of use or occupancy of an existing building shall comply with the current code requirements for change of occupancy classification.

E. Acronyms and Definitions: The following references apply throughout these regulations. Words not defined in these regulations shall have the meaning stated in the referenced codes and standards adopted by these regulations.

1. "AHJ" means Authority Having Jurisdiction, which is the SFM, or his agents, or any local fire official covered by S.C. Code Ann. Section 23-9-30, 1976, as amended.

2. "ATF" means the United States Department of Justice, Bureau of Alcohol, Tobacco, Firearms and Explosives.

3. "Bulk hydrogen compressed gas system" means an assembly of equipment that consists of, but is not limited to, storage containers, pressure regulators, pressure relief devices, compressors, manifolds, and piping with a storage capacity of more than 400 cubic feet (approximately 3000 gal.) of compressed hydrogen gas (or 5000 scf), including unconnected reserves on hand at the site, and terminates at the source valve.

4. "Bulk liquefied hydrogen gas system" means an assembly of equipment that consists of, but is not limited to, storage containers, pressure regulators, pressure relief devices, vaporizers, liquid pumps, compressors manifolds, and piping, with a storage capacity of more than 39.7 gal. of liquidized hydrogen, including unconnected reserves on hand at the site, and terminates at the source valve.

5. "Citation" means a summons to appear before the OSFM because of a violation of any part or all of this regulation and may carry a monetary fine of up to \$2,000 per violation.

6. "Consumer Fireworks" means any small device designed to produce visible effects by combustion and which must comply with the construction, chemical composition, and labeling regulations of the U.S. Consumer Product Safety Commission, as set forth in Title 16, Code of Federal Regulations, parts 1500 and 1507. Some small devices designed to produce audible effects are included, such as whistling devices, ground devices containing fifty (50) mg or less of explosive materials, and aerial devices containing 130 mg or less of explosive materials. Consumer fireworks are classified as fireworks UN0336 and UN0337 by the USDOT at 49 CFR 172.101. This term does not include fused setpieces containing components which together exceed 50 mg of salute powder. Consumer fireworks are further defined as those classified by the USDOT hazard classification 1.4g. These fireworks were formerly known as "Class C Fireworks."

7. "Container" means all vessels including, but not limited to tanks, cylinders, or pressure vessels used for the storage of hydrogen.

8. "Display Fireworks" means large fireworks designed primarily to produce visible or audible effects by combustion, deflagration, or detonation. This term includes, but is not limited to, salutes containing more than two (2) grains (130 mg) of explosive materials, aerial shells containing more than 40 grams of pyrotechnic compositions, and other display pieces which exceed the limits of explosive materials for classification as "Consumer Fireworks." Display fireworks are classified as fireworks UN0333, UN0334, or UN0335 by the USDOT at 49 CFR 172.101. This term also includes fused setpieces containing components which together exceed fifty (50) mg of salute powder. Display fireworks are further defined as those classified by the USDOT as hazard classification 1.3g. These fireworks were formerly known as "Class B Fireworks."

9. "DOI" means the Department of Insurance.

10. "Engineered hydrogen systems" means systems or equipment that is custom designed for a particular application.

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11. "Existing Building" means a building, structure, or premise for which preliminary or final drawings have been approved by the appropriate agency as provided in these regulations, in buildings where construction has begun, or those occupied on or before the date of adoption of these regulations.

12. "Fire Prevention" means any activity to prevent fire before fire occurs.

13. "Fireworks" means any composition or device designed to produce a visible or an audible effect by combustion, deflagration, or detonation, and which meets the definition of "consumer fireworks" or "display fireworks" as defined by this section.

14. "Firm" means any person, partnership, corporation, association, or governmental entity.

15. "Fixed Fire Extinguishing System" means a pre-engineered fire extinguishing system.

16. "Hydrogen" is an element of the periodic table which, at room temperature and pressure, but can be compressed and/or refrigerated into a liquefied state.

17. "Hydrogen facility" is a fueling station or a fuel cell site that will store or dispense hydrogen for use as a transportation fuel, motor fuel, or in a fuel cell.

18. "Hydrogen generation system" means a packaged, factory matched, or site constructed hydrogen gas generation appliance or system such as (a) an electrolyzer that uses electrochemical reactions to electrolyze water to produce hydrogen gas; (b) a reformer that converts hydrocarbon fuel to a hydrogen-rich stream of composition and condition suitable for a type of device using the hydrogen. It does not include hydrogen generated as a byproduct of a waste treatment process.

19. "IBC" means the International Building Code.

20. "ICC" means the International Code Council.

21. "IFC" means the International Fire Code.

22. "IFGC" means the International Fuel Gas Code.

23. "IRC" means the International Residential Code.

24. "LP-Gas" means Liquefied Petroleum Gas as defined in 40-82-20.

25. "Motion Picture" means, for the purposes of this item, any audiovisual work with a series of related images either on film, tape, or other embodiment, where the images shown in succession impart an impression of motion together with accompanying sound, if any, which is produced, adapted, or altered for exploitation as entertainment, advertising, promotional, industrial, or educational media.

26. "MSDS(s)" means Material Safety Data Sheet(s).

27. "NFPA" means the National Fire Protection Association.

28. "OSFM" means the Office of State Fire Marshal, Division of Fire and Life Safety, Department of Labor, Licensing and Regulation.

29. "Person" means an individual, partnership, or corporation;

30. "Portable Fire Extinguisher" means a portable device containing extinguishing agent that can be expelled under pressure for the purpose of suppressing or extinguishing a fire.

31. "Pre-engineered hydrogen system" means a system or device that has been designed with the intention of mass production and sales to the public, which uses or produces hydrogen in its function.

32. "Proximate Audience" means any indoor use of pyrotechnics and the use of pyrotechnics before an audience located closer than the distances allowed by NFPA 1123.

33. "Public Firework Display" means a presentation of Display or Consumer Fireworks for a public gathering.

34. "Pyrotechnics" means any composition or device designed to produce visible or audible effects for entertainment purposes by combustion, deflagration, or detonation.

35. "S.C." means South Carolina.

36. "Servicing" includes maintenance, recharging, or hydrostatic testing of a Portable Fire Extinguisher or a Fixed Fire Extinguishing System.

37. "SFM" means the State Fire Marshal or his agent.

38. "Theatrical Pyrotechnics" means pyrotechnic devices for professional use in the entertainment industry similar to consumer fireworks in chemical composition and construction but not intended for consumer use.

39. "USDOT" means U.S. Department of Transportation.

71-8300.2. Codes and Standards.

A. All references to codes and standards found in these regulations refer to the editions specified in the IFC unless otherwise stated in these regulations or adopted by state statutes.

B. The requirements of the IFC, International Fire Code, (as adopted pursuant to S.C. Code Ann. Section 6-9-5, et. seq., 1976, as amended) shall constitute the minimum standards for fire prevention and life safety protection for construction, occupancy, and use of all buildings, structures, and premises within the scope of these regulations except as modified by these regulations. In addition, to the extent to which they can be applied without conflicting with other state regulations or state statutes, the following sections of Chapter 1 of the IFC shall apply:

1. Scope and General Requirements (Section 101). "The State of South Carolina" shall be used for the Name of Jurisdiction.

2. Applicability (Section 102)

3. Liability (Section 103.4)

4. General Authority and Responsibilities (Section 104)

5. Maintenance (Section 107)

6. Unsafe Buildings (Section 110)

C. The requirements of NFPA 10, Standard for Portable Fire Extinguishers, shall be used as referenced within the adopted ICC codes for the installation, servicing, maintenance, recharging, repairing, and hydrostatic testing of all portable fire extinguishers.

D. The requirements of the following NFPA standards shall be used as referenced within the adopted ICC codes for the design, installation, testing and maintenance of fixed fire extinguishing systems in South Carolina except as modified by these regulations.

1. NFPA 11, Standard for Low-, Medium-, and High-Expansion Foam

2. NFPA 12, Standard on Carbon Dioxide Extinguishing Systems

3. NFPA 12A, Standard on Halon 1301 Fire Extinguishing Systems

4. NFPA 17, Standard for Dry Chemical Extinguishing Systems

5. NFPA 17A, Standard for Wet Chemical Extinguishing Systems

6. NFPA 750, Standard on Water Mist Fire Protection Systems

7. NFPA 2001, Standard on Clean Agent Fire Extinguishing Systems

8. NFPA 2010, Standard for Fixed Aerosol Fire Extinguishing Systems

E. The requirements of the following NFPA standards shall be used as referenced within the adopted ICC codes for the design, installation, testing, and maintenance of water-based extinguishing systems in South Carolina except as modified by these regulations.

1. NFPA 13, Standard for the Installation of Sprinkler Systems

2. NFPA 13D, Standard for the Installation of Sprinkler Systems in One- and Two-Family Dwellings and Manufactured Homes

3. NFPA 13R, Standard for the Installation of Sprinkler Systems in Low-Rise Residential Occupancies

4. NFPA 14, Standard for the Installation of Standpipe and Hose Systems

5. NFPA 15, Standard for Water Spray Fixed Systems for Fire Protection

6. NFPA 16, Standard for the Installation of Foam-Water Sprinkler and Foam-Water Spray Systems

7. NFPA 18, Standard on Wetting Agents

8. NFPA 20, Standard for the Installation of Stationary Pumps for Fire Protection

9. NFPA 22, Standard for Water Tanks for Private Fire Protection

10. NFPA 24, Standard for the Installation of Private Fire Service Mains and Their Appurtenances

11. NFPA 25, Standard for the Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems

12. NFPA 214, Standard on Water-Cooling Towers

F. The requirements of NFPA 30, Flammable and Combustible Liquids Code, shall be used as referenced within the adopted ICC codes for the storing and handling of flammable and combustible liquids in South Carolina except as modified by these regulations.

G. The requirements of NFPA 30A, Code for Motor Fuel Dispensing Facilities and Repair Garages, shall be used as referenced within the adopted ICC codes for the storing, handling, and dispensing of flammable and

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combustible liquids at service stations, farms, and isolated sites in South Carolina except as modified by these regulations.

H. The requirements of NFPA 52, Vehicular Gaseous Fuel Systems Code, shall be used as referenced within the adopted ICC codes for storing, handling, and dispensing vehicular alternative fuels in South Carolina except as modified by these regulations.

I. The requirements of NFPA 54, National Fuel Gas Code, shall be used as referenced within the adopted ICC codes for design, materials, components, fabrication, assembly, installation, testing, inspection, operation, and maintenance installation of fuel gas piping systems, appliances, equipment, and related accessories, installation, combustion, and ventilation air and venting in South Carolina except as modified by these regulations.

J. The requirements of NFPA 58, Liquefied Petroleum Gas Code, shall be used as referenced within the adopted ICC codes for the design, construction, location, installation and operation of equipment for storing, handling, transporting by tank truck or tank trailer, and use of LP-Gases and the odorization of such gases in South Carolina except as modified by these regulations.

K. The requirements of NFPA 59, Utility LP-Gas Plant Code, shall be used as referenced within the adopted ICC codes for the design, construction, location, installation, operation, and maintenance of refrigerated and non-refrigerated utility gas plants to the point where LP-Gas or an LP-Gas and air mixture is introduced into the utility distribution system in South Carolina except as modified by these regulations.

L. The requirements of NFPA 70, National Electrical Code, shall be used as referenced within the adopted ICC codes for fire prevention and life safety from hazards of electricity in South Carolina except as modified by these regulations.

M. The requirements of NFPA 72, National Fire Alarm and Signaling Code, shall be used as referenced within the adopted ICC codes for the design, installation, testing, and maintenance of fire alarm systems in South Carolina except as modified by these regulations.

N. The requirements of NFPA 96, Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations, shall be used as referenced within the adopted ICC codes for ventilation control and fire protection of commercial cooking operations in South Carolina except as modified by these regulations.

O. The requirements of NFPA 99, Health Care Facilities Code, shall be used as referenced within the adopted ICC codes for flammable and non-flammable medical gasses used in health care and other facilities intended for inhalation or sedation, but not limited to, analgesia systems for dentistry, podiatry, veterinary, and similar uses in South Carolina except as modified by these regulations.

P. The requirements of NFPA 101, Life Safety Code, shall be used as referenced within the adopted ICC codes for fire prevention and life safety in South Carolina when evaluating alternative methods of fire and life safety per R. 71-8300.10 except as modified by these regulations.

Q. The requirements of the NFPA 102, Standard for Grandstands, Folding and Telescopic Seating, Tents, and Membrane Structures, shall be used as referenced within the adopted ICC codes for fire prevention and life safety for all tents and membrane structures normally used in South Carolina except as modified by these regulations.

R. The requirements of NFPA 160, Standard for the Use of Flame Effects Before an Audience, including Annexes B and C, shall be used as referenced within the adopted ICC codes for all flame effects use in proximate audience pyrotechnics displays or motion picture special effects in South Carolina except as modified by these regulations.

S. The requirements of NFPA 407, Standard for Aircraft Fuel Servicing, shall be used as referenced within the adopted ICC codes for the storing, handling, and dispensing of flammable and combustible liquids at private aircraft fueling facilities in South Carolina except as modified by these regulations.

T. The requirements of NFPA 409, Standard on Aircraft Hangars, shall be used as referenced within the adopted ICC codes for the design construction, occupancy, and use of aircraft hangars in South Carolina except as modified by these regulations.

U. The requirements of NFPA 495, Explosive Materials Code, shall be used as referenced within the adopted ICC codes for the manufacture, transportation, use and storage for all explosives in South Carolina, except as modified herein.

V. The requirements of NFPA 1122, Code for Model Rocketry, shall be used as referenced within the adopted ICC codes for model rocketry associated with public firework displays or proximate audience pyrotechnic displays or motion picture special effects in South Carolina except as modified by these regulations.

W. The requirements of NFPA 1123, Code for Fireworks Display, including Annex A and E, shall be used as referenced within the adopted ICC codes for all firework displays in South Carolina except as modified by these regulations.

X. The requirements of NFPA 1124, Code for the Manufacture, Transportation, Storage, and Retail Sales of Fireworks and Pyrotechnic Articles, shall be used as referenced within the adopted ICC codes for transportation, storage, and use of all display fireworks and pyrotechnic articles used for proximate audience pyrotechnic displays or motion picture special effects in South Carolina except as modified by these regulations.

Y. The requirements of NFPA 1126, Standard for the Use of Pyrotechnics Before a Proximate Audience, including Annexes A, B, and D, shall be used as referenced within the adopted ICC codes for all proximate audience displays in South Carolina except as modified by these regulations.

Z. The requirements of NFPA 1127, Code for High Power Rocketry, shall be used as referenced within the adopted ICC codes for all high power rockets used for proximate audience pyrotechnic displays or motion picture special effects in South Carolina except as modified by these regulations.

AA. The requirements of NFPA 1142, Standard on Water Supplies for Suburban and Rural Fire Fighting, shall be used as referenced within the adopted ICC codes for water supplies for rural fire fighting in South Carolina except as modified by these regulations.

BB. The OSFM shall post and maintain a list of the currently adopted editions of the codes and standards listed above on the OSFM website.

CC. The codes and standards listed in R.71-8300.2 that are adopted by the OSFM shall be accessible for viewing at no cost to the public through the OSFM website.

71-8300.3. Alternate Materials and Alternate Methods of Construction.

A. The requirements of these regulations are not intended to prevent the use of any material or method of construction not specifically prescribed by the regulations, adopted codes, or standards enforced by the OSFM. The SFM has the authority to accept alternative methods of compliance within the intent of these regulations, after finding that the materials and method of work offered is for the purpose intended, at least the equivalent of that prescribed in these regulations in quality, strength, effectiveness, fire resistance, durability, and safety. The SFM shall require submission of sufficient evidence or proof to substantiate any claim made regarding use of alternative materials and methods.

B. Compliance with applicable standards of the National Fire Protection Association, or other nationally recognized fire safety standards, may be used for consideration of alternative methods if found suitable by the SFM.

71-8300.4. Construction Documents and Shop Drawings.

A. Construction documents and/or shop drawings, as appropriate, must be submitted to the OSFM for the following:

1. Fire sprinkler systems per S.C. Code Ann. Section 40-10-260.
2. LP-Gas systems per R.71-8304.
3. Hydrogen facilities per S.C. Code Ann. Section 23-9-510 et seq.
4. Facilities that the OSFM is contractually obligated to review.

B. Construction documents. Construction documents and shop drawings shall be in accordance with this section.

1. Submittals. Construction documents and supporting data shall be submitted in one complete set with each application for a review and in such form and detail as required by the OSFM reviewer to be able to determine compliance.

2. The construction documents and shop drawings shall be prepared by the appropriate registered design professional(s) or other LLR licensee as required by statute or regulation.

a. Practice of architecture as defined in S.C. Code Ann. Section 40-3-20 requires a licensed architect unless exempt per S.C. Code Ann. Section 40-3-290.

b. Practice of engineering as defined in S.C. Code Ann. Section 40-22-20 requires a licensed engineer unless exempt per S.C. Code Ann. Section 40-22-280.

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c. Fire sprinkler system documentation shall be prepared in accordance with the specific provisions in S.C. Code Ann. Sections 40-10-250 and 40-10-260.

3. The OSFM is authorized to not require the submission of construction documents and supporting data if:

a. they are not required to be prepared by a registered design professional, and

b. it is found that the nature of the work applied for is such that review of construction documents is not necessary to obtain compliance with this code.

4. Examination of documents. OSFM shall examine or cause to be examined the submitted construction documents and shall ascertain by such examinations whether the work indicated and described is in accordance with the applicable requirements.

5. Information on construction documents. Construction documents shall be drawn to scale upon suitable material. Electronic media documents are allowed to be submitted when approved by the OSFM. Construction documents shall be of sufficient clarity to indicate the location, nature and extent of the work proposed and show in detail that it will conform to the provisions of these regulations and other relevant laws, rules and regulations as determined by the OSFM.

a. Fire protection system shop drawings. Shop drawings for fire protection system(s) reviewed by OSFM shall be submitted to indicate compliance with these regulations and the referenced codes and standards, and shall be approved prior to the start of installation. Shop drawings shall contain all information as required by the applicable statutes, regulations, adopted codes and referenced installation standards.

b. Information on construction documents shall be specific, and the technical codes shall not be cited in whole or in part, nor shall the term “legal” or its equivalent to be used as a substitute for specific information.

c. All drawings shall bear a title block with complete, legible information indicating at a minimum where applicable: project name, project address, drawing author, drawing title, drawing number, original drawing date, all subsequent drawing revision dates, sequential drawing revision numbers, company name, and company mailing address.

6. Applicant responsibility. It shall be the responsibility of the applicant to ensure that the construction documents include all of the fire protection requirements and the shop drawings are complete and in compliance with the applicable statutes, regulations, codes and standards.

7. Approved documents. Construction documents approved by the OSFM are approved with the intent that such construction documents comply in all respects with this code. Review and approval by the OSFM shall not relieve the applicant of the responsibility of compliance with this code.

a. Phased approval. The OSFM is authorized to issue approval for the construction of part of a structure, system or operation before the construction documents for the whole structure, system or operation have been submitted, provided that adequate information and detailed statements have been filed complying with pertinent requirements of this code. The holder of such approval for parts of a structure, system or operation shall proceed at the holder’s own risk with the building operation and without assurance that approval for the entire structure, system or operation will be granted.

b. Compliance with code. The issuance or granting of approval shall not be construed to be an approval of any violation of any of the provisions of these regulations. Approvals presuming to give authority to violate or cancel the provisions of these regulations shall not be valid. The issuance of approval based on construction documents and other data shall not prevent an AHJ from requiring the correction of errors in the construction documents and other data. Any addition to or alteration of approved construction documents shall be approved in advance by the AHJ, as evidenced by the issuance of a new or amended approval.

8. Corrected documents. Where field conditions necessitate any substantial change from the approved construction documents, the AHJ shall have the authority to require the corrected construction documents to be submitted for approval.

9. Revocation. The OSFM is authorized to revoke approval issued under the provisions of these regulations when it is found by inspection or otherwise that there has been a false statement or misrepresentation as to the material facts in the application or construction documents or shop drawings on which the permit or approval was based including, but not limited to, any one of the following:

a. The permit or approval is used for a location or establishment other than that for which it was issued.

b. The permit or approval is used for a condition or activity other than that listed in the permit.

c. Conditions and limitations set forth in the permit or approval have been violated.

- d. There have been any false statements or misrepresentations as to the material fact in the application for permit or plans submitted or a condition of the permit.
- e. The permit or approval is used by a different person or firm than the name for which it was issued.
- f. Failure, refusal, or neglect to comply with orders or notices duly served in accordance with the provisions of this regulation within the time provided therein.
- g. The permit or approval was issued in error or in violation of a statute, regulation, code, or standard.

71-8300.5. Incident Reporting.

A. Purpose. These provisions are intended to help the State and its local governmental entities to develop fire reporting and analysis capability for their own uses, to obtain data that can be used to more accurately assess and subsequently combat the fire problem at the State or local level, and to support the efforts of the National Fire Data Center in the United States Fire Administration (USFA) to gather and analyze information on the magnitude of the nation's fire problem, as well as its detailed characteristics and trends.

B. The local fire chief or his designee shall furnish to the OSFM the following information:

- 1. Fire fatalities from fires occurring within the fire department's jurisdiction, shall be reported directly to the OSFM immediately.
- 2. Firefighter line-of-duty deaths shall be reported directly to the OSFM immediately.
- 3. By the 15th day of each month, information concerning all incidents responded to by the fire department during the preceding month shall be reported. This information shall be reported by a method and in a format approved by the OSFM. The National Fire Incident Reporting System (NFIRS) shall serve as the minimum standard reporting method and format for these monthly reports.

C. These reports are privileged against liability unless the report is made with actual malice.

71-8300.6. Fire Investigations.

A. Purpose.

1. The intent of this section is to assist OSFM in improving its ability to provide fire prevention and fire education efforts and data; and, to support OSFM licensing and permitting functions.

2. It is not the intent of this section for OSFM to perform criminal investigation functions which overlap the authority and responsibility of police and other enforcement agencies.

B. The OSFM shall have the authority to investigate the cause, origin, and circumstances of any fire, explosion or other hazardous condition.

C. Information that could be related to trade secrets or processes shall not be made part of the public record, except as directed by a court of law.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

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Document No. 4619

**DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL
CHAPTER 71**

Statutory Authority: 1976 Code Sections 23-9-60, 23-9-550, 23-35-45, and 23-36-80

71-8301. Fire Prevention and Life Safety for Special Occupancies

Synopsis:

The Office of State Fire Marshal proposes to eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

A Notice of Drafting was published in the *State Register* on September 25, 2015.

Instructions:

Regulation 71-8301 is amended as shown below.

Text:

**SUBARTICLE 2
FIRE PREVENTION AND LIFE SAFETY FOR SPECIAL OCCUPANCIES**

71-8301. Fire Prevention and Life Safety for Special Occupancies.
(Statutory Authority: 1976 Code Section 23-9-60)

71-8301.1. General.

- A. The purpose of this Subarticle is to provide specific requirements for certain occupancies.
- B. This regulation shall apply to:
 - 1. New and existing foster homes.
 - 2. New and existing schools inspected by the OSFM.
- C. The Department of Social Services shall provide a list of registered in-home childcare facilities to the OSFM annually.

71-8301.2. Codes and Standards.

- A. All references to codes and standards found in these regulations refer to the editions adopted in R.71-8300.2 and are modified by the following regulations as shown below.
- B. The building code shall define occupancy classifications referenced in these regulations.

71-8301.3. Requirements for Special Occupancies.

- A. All Foster Home Facilities
 - 1. Foster homes providing care, maintenance, and supervision for no more than six (6) children, including the natural or adopted children of the foster parent; shall comply with the following:
 - a. Must be a facility designed and constructed with the intent to be used as a dwelling per applicable statutes and regulations.

b. At least one (1) portable fire extinguisher with a minimum classification of 2A:10BC shall be installed near cooking areas. The fire extinguishers shall be installed and maintained in accordance with the manufacturer's instructions.

c. Each facility housing foster children shall maintain means of egress as required by original construction.

d. All heating devices must be selected, used, and installed per the manufacturer's recommendations and the listing conditions set by an approved testing laboratory.

e. Unvented gas heaters shall have an operating oxygen depletion device, an operating safety shutoff device, and shall be located or guarded to prevent burn injuries.

f. Fireplaces shall be equipped with fire screens, partitions, or other means to protect clients from burns.

g. A fire escape plan describing what actions are to be taken by the family in the event of a fire must be developed and posted.

h. A fire escape drill shall be conducted every three (3) months.

i. Records of the drills shall be maintained on the premises for three (3) years. The records shall give the date, time, and weather conditions during the drill, number evacuated, description, and evaluation of the fire drill. Fire drills shall include complete evacuation of all persons from the building.

j. A fire escape drill shall be conducted within twenty-four (24) hours of the arrival of each new foster child.

k. Portable unvented fuel-fired heating equipment shall be prohibited in all foster homes.

l. An approved carbon monoxide alarm shall be installed and maintained outside of each separate sleeping area in the immediate vicinity of the bedroom in dwelling units within which fuel fired appliances are installed and in dwelling units that have attached garages.

m. Each sleeping room must have an operable door that closes and latches to provide compartmentation that protects occupants in case of a fire event.

n. The dwelling shall be free of dangers that constitute an obvious fire hazard, such as faulty electrical cords, overloaded electrical sockets, or an accumulation of papers, paint, or other flammable material stored in the dwelling.

o. Facilities serving as a foster home shall have approved address numbers placed in a position that is plainly legible and visible from the street. Address number shall be a minimum of 4 inches high with a minimum stroke width of 0.5 inch and shall contrast with their background.

p. Listed smoke alarms shall be installed in accordance with the manufacturer's installation instructions and in the following locations:

(i) On the ceiling or wall outside of each separate sleeping area in the immediate vicinity of bedrooms; and

(ii) In each room used for sleeping purposes; and

(iii) In each habitable story within a dwelling.

q. Listed smoke alarms shall be powered from:

(i) the electrical system of the dwelling as the primary power source and a battery as a secondary power source;

(ii) a battery rated for a 10-year life, provided the smoke alarm is listed for use with a 10-year battery; or

(iii) battery power that is part of a listed wireless interconnected smoke alarm unit.

r. All sleeping rooms below the fourth story shall have emergency escape and rescue openings that open from the inside.

s. Such emergency escape and rescue openings shall be sized and configured in accordance with the applicable code requirements.

2. Foster homes that do not comply with Section A.1.s. above, shall have one of the following:

a. Listed smoke alarms required to be installed by Section A.1.p. above shall be interconnected in such a manner that the activation of one alarm will activate all of the alarms in the dwelling unit. Physical interconnection of smoke alarms shall not be required where listed wireless alarms are installed and all alarms sound upon activation of one alarm; or

b. A residential fire sprinkler system in accordance with the applicable statutes, regulations, and adopted codes.

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B. Inspection of School Facilities

1. The OSFM shall work in conjunction with local resident fire marshals to ensure regular fire and life safety inspections are conducted of all public schools that are subject to these regulations. The OSFM shall work in conjunction with the Department of Education's Office of School Facilities to ensure a fire and life safety inspection of each new school is conducted prior to occupancy and to ensure that additions to schools and school alterations are also inspected.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

Document No. 4620

DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL
CHAPTER 71

Statutory Authority: 1976 Code Sections 23-9-60, 23-9-550, 23-35-45, and 23-36-80

71-8305. Fireworks and Pyrotechnics.

Synopsis:

The Office of State Fire Marshal proposes to eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

A Notice of Drafting was published in the *State Register* on September 25, 2015.

Instructions:

Regulation 71-8305 is amended as shown below.

Text:

SUBARTICLE 6
FIREWORKS AND PYROTECHNICS

71-8305. Fireworks and Pyrotechnics.

(Statutory Authority: 1976 Codes Sections 23-9-10 et seq. and 23-35-45 et seq.)

71-8305.1. General.

A. The purpose of this regulation is to provide reasonable safety and protection to the public, public property, private property, performers, display operators, and emergency responders from the hazards associated with the handling, use, transportation, and storage of pyrotechnics and fireworks.

B. This regulation shall apply to:

1. The handling and use of fireworks intended for public fireworks display;
 2. The construction, handling and use of fireworks equipment intended for public fireworks display;
 3. The general conduct and operation of public firework displays;
 4. The transportation and storage of fireworks for public fireworks display;
 5. The transportation and use of consumer fireworks;
 6. The construction, handling, and use of pyrotechnics intended for proximate audience displays; special effects for motion picture, theatrical, and television productions;
 7. The construction, handling, and use of flame effects intended for proximate audience displays, or special effects for motion picture, theatrical, and television productions;
 8. The construction, handling, and use of rockets intended for proximate audience displays, or special effects for motion picture, theatrical, and television productions; and
 9. The general conduct and operation of proximate audience displays.
- C. This regulation shall not apply to:
1. The manufacture, sale, or storage of fireworks as governed by the SC Department of Labor Licensing and Regulation, State Board of Pyrotechnic Safety;
 2. The transportation, handling, and/or use of fireworks by the SFM, his employees, or any commissioned law enforcement officers acting within their official capacities;
 3. Fireworks deregulated by the USDOT;
 4. Weapons used in enactments, when there is no projectile;
 5. Artillery field pieces used as salutes with no projectile; and
 6. The outdoor use of model rockets within the scope of NFPA 1122.

71-8305.2. Codes and Standards.

- A. All references to codes and standards found in these regulations refer to the editions adopted in R.71-8300.2 and are modified by the following regulations as shown below.
- B. The building code shall define occupancy classifications referenced in these regulations.

71-8305.3. Licensing and Permitting Fees.

- A. All fees are due at time of application for licenses, tests, or permitting.
- B. Permit applications are due in the OSFM fifteen business days before the performance date. Fees may be doubled for an application received less than fifteen days before the performance date.
- C. The OSFM is responsible for all administrative activities of the licensing and permitting program. The SFM shall employ and supervise personnel necessary to effectuate the provisions of this article and shall establish fees sufficient but not excessive to cover expenses, including direct and indirect costs to the State for the operation of this licensing program.
- D. Fees shall be established for the following:
 1. Application
 2. Background Check
 3. Testing
 4. Licensing
 5. Permitting
 6. Inspection
 7. Renewal
- E. All fees are due at time of application for licenses, background checks, testing, permits, inspection or renewal.
- F. All fees paid to the OSFM are nonrefundable.

71-8305.4. Qualifications of Operators.

- A. All Operators.

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1. No person shall be granted a license who has not successfully completed a written examination administered by the OSFM. The exam will cover the applicable codes, state laws, and regulations and the additional requirements listed below for the specific class of license for which they are applying.

2. Any applicant who fails the written examination is allowed one re-test after a minimum seven-day waiting period. Any applicant who fails the re-test shall wait at least six months before reapplying.

3. Applicants shall submit a completed fingerprint card with their application. The OSFM will conduct a criminal background check as part of the licensing application process.

4. Operators using explosives or explosive materials must have the appropriate Federal licenses. Operators shall provide a copy of applicable Federal licenses.

5. Licenses must be renewed biennially on the day of expiration shown on the license.

6. Every two years, each licensed operator shall be required to attend training offered by the OSFM or attend pre-approved training providing a total of eight (8) hours of continuing education during the licensing cycle.

7. The OSFM may revoke, suspend, or deny a license because of, but not limited to:

a. Failure to comply with any order written by the OSFM;

b. Conviction of (1) a felony, (2) a crime of violence, or (3) any crime punishable by a term of imprisonment exceeding two years; or

c. Advocating or knowingly belonging to any organization or group which advocates violent overthrow of or violent action against the federal, state, local government, or its citizens; or

d. Having or contracting physical or mental illness or conditions that in the judgment of the OSFM would make use or possession of fireworks, pyrotechnics, or explosive materials hazardous to the licensee or the public; or

e. Violating the terms of the license or essential changes in the conditions under which the license was issued without prior approval of the OSFM;

f. Violating the state laws or regulations governing Public Fireworks Displays or Proximate Audience Pyrotechnics; or

g. Giving false information or making a misrepresentation to obtain a license.

B. Public Display Operators.

1. Applications for licensing must provide a notarized statement from a South Carolina licensed display operator that the applicant has actively participated in the set-up and operation of at least six (6) fireworks displays while holding a valid pyrotechnic operator trainee license, and the statement must indicate for each display the date, the site, and the name and license number of the supervising operator.

2. The person in charge of the Public Fireworks Display shall be licensed by the OSFM.

C. Proximate Audience Display Operators.

1. Applications for licensing must provide a notarized statement from a South Carolina licensed display operator or company that the applicant has actively participated in the set-up and operation of at least six (6) proximate audience performances while holding a valid pyrotechnic operator trainee license, and using the types of pyrotechnics for the license classification the applicant is seeking, and the statement must indicate for each display the date, the site, and the name and license number of the supervising operator. Only the OSFM may accept an alternative number of displays for this requirement based on the applicant's experience.

2. Licenses for pyrotechnic operators authorize and place the responsibility for the handling, supervision, and discharge of the fireworks or pyrotechnic device permitted by their license classification. The operator is responsible for the training of his or her assistants in the safe handling, supervision, and discharge of the fireworks or pyrotechnic devices permitted by their license classification.

a. "Pyrotechnic Operator - Unrestricted" may conduct and take charge of all activity in connection with the use of explosives or explosive materials, rockets, flame effects, Display Fireworks, binary system pyrotechnics, Consumer Fireworks, Theatrical Pyrotechnics, Novelties, and other special effects permitted by the OSFM for a proximate audience display, commercial entertainment, or special effects in motion picture, theatrical, and television productions.

b. "Pyrotechnic Operator - Commercial Outdoor" may conduct and take charge of all activity in connection with the use of flame effects, Display Fireworks, binary system pyrotechnics, Consumer Fireworks, Theatrical Pyrotechnics, and Novelties permitted by the OSFM for a proximate audience display and commercial entertainment.

c. "Pyrotechnic Operator - Rockets" may conduct and is restricted to all activities in connection with research, experiments, production, transportation, fuel loading, and launching of all types of experimental, solid fuel, and high power rockets. Only individuals or companies holding valid import, export, or wholesale licenses may import, export, or wholesale experimental high-powered motors.

d. "Pyrotechnic Operator - Motion Picture Special Effects" may conduct and take charge of all activity in connection with the use of explosives or explosive materials, flame effects, Display Fireworks, binary system pyrotechnics, Consumer Fireworks, Theatrical Pyrotechnics, and Novelties, and other special effects permitted by the OSFM for the sole purpose of motion picture, television, theatrical or operatic productions.

e. "Pyrotechnic Operator - Commercial Indoor" may conduct and take charge of all activity in connection with the use of binary system pyrotechnics, Theatrical Pyrotechnics, and Novelties permitted by the OSFM in stage or theatrical productions only.

f. "Pyrotechnic Operator - Trainee" must function under the direct supervision and control of a pyrotechnic operator for the license classification that he/she is seeking a license.

71-8305.5. Display Permits.

A. All Displays.

1. Any person who desires to hold a Public Fireworks Display or a Proximate Audience Display must obtain a permit from the OSFM before the display.

2. Permits shall be valid for up to one calendar period prescribed or until any condition of the permit application changes. The OSFM shall make final determination of a change of condition in the permit.

3. All permit forms will be made available on the OSFM website.

4. The OSFM may revoke, suspend, or deny a permit because of, but not limited to:

a. The display operator does not possess the correct license classification for the display; or

b. Not complying with any order written by the OSFM; or

c. Violating the terms of the permit or essential changes in the conditions under which the permit was issued without prior approval of the OSFM; or

d. Giving false information or making a misrepresentation to obtain a permit.

5. The following additional information must be provided with the permit application:

a. A list of the number, type, and size of fireworks or effects being discharged;

b. A Diagram of display site including measurements;

c. Directions to the site; and

d. A Copy of certificate of insurance.

6. The AHJ providing fire suppression equipment and personnel for the Public Fireworks Display must sign the permit form to acknowledge their awareness of the proposed display.

7. Permits must be posted at the display site.

8. A "Request to Modify an Existing Pyrotechnic Display Permit" form must be submitted for approval of requested changes in the conditions or terms under which a permit was previously issued.

B. Public Fireworks Display Permits.

1. The sponsor of the display shall forward a copy of the permit to the OSFM along with the items required in these regulations fifteen business days before the display. The permit becomes valid when co-signed by the OSFM.

2. The validated permit will be distributed as follows:

a. The OSFM shall retain the original;

b. A copy to the sponsor;

c. A copy to the supplier, which will authorize shipment of the fireworks;

d. A copy to the AHJ providing the fire suppression equipment and personnel for the display;

e. A copy posted at the display site.

3. All pyrotechnics shall be purchased from a pyrotechnic manufacturer or distributor licensed by the Board of Pyrotechnic Safety. A licensed Public Display Operator shall be present and supervise firing of all public fireworks displays.

4. The fireworks supplier shall carry a minimum of \$1,000,000 of Public Liability Insurance. The policy must list as an additional insured the display sponsor as well as the State of South Carolina, and its agents. The

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coverage company must be an insurer which is either licensed by the DOI in this State or approved by the DOI as a nonadmitted surplus lines carrier for risks located in this State. In the event the liability insurance is canceled, suspended, or nonrenewed, the insurer shall give immediate notice to the OSFM.

C. Proximate Audience Display Permits.

1. Public Liability Insurance in the amount of \$1,000,000 shall be provided by the permittee. The permittee shall furnish a certificate of insurance in this amount with their application. The permittee shall list the State of South Carolina and its agents as additional insured.

2. Public Liability Insurance in the amount of \$1,000,000 shall be provided by any permittee involved with motion picture productions. Motion picture companies employing this person(s) shall list the State of South Carolina and its agents as additional insured.

3. The coverage company must be an insurer which is either licensed by the DOI in this State or approved by the DOI as a nonadmitted surplus lines carrier for risks located in this State. In the event the liability insurance is canceled, suspended, or nonrenewed, the insurer shall give immediate notice to the OSFM.

71-8305.6. General Operational Requirements of Displays.

A. All Displays.

1. The operator shall have their license in their possession when conducting a display and shall exhibit their license on request of any AHJ.

2. All displays must have a person in charge that holds the proper license issued by the OSFM for the type of display being conducted.

3. The SFM or any approved AHJ may enforce these laws and regulations.

4. Magazine log shall be available for inspection during normal work hours, 1 hour before, and 1 hour after each performance.

5. Operators must notify the OSFM within 24 hours of any fires or thefts involving fireworks. The operators shall provide the OSFM with a copy of the report filed with the police department or the incident report from the fire department. Operators must also provide the OSFM with a copy of ATF Form 5400.5.

6. Any person who violates any provision of these laws and regulations will purchase the appropriate permit, pay the appropriate license fee, if any are required, and be subject to the following penalty provisions:

a. S.C. Code Ann. Section 23-36-170, 1976, as amended.

b. S.C. Code Ann. Section 23-35-150, 1976, as amended.

7. Confiscation, storage, or disposal of fireworks, pyrotechnic and explosive materials used for proximate audience or public firework displays by the SFM shall comply with S.C. Code Ann. Section 23-36-110, 1976, as amended.

8. Storage of special effects pyrotechnics and other material.

a. All classes of explosives shall be stored in accordance with the South Carolina Explosives Control Act (S.C. Code Ann. Section 23-36-10, et seq., 1976, as amended) or Title 27 Code of Federal Regulations, Chapter II, Subchapter C, Part 555, Subpart K.

b. All other fireworks or pyrotechnic materials shall be stored per the appropriate NFPA standard.

9. The AHJ may require the permittee to furnish fire support personnel other than local firefighters.

B. Public Fireworks Displays.

1. Where unusual conditions exist, the AHJ may increase the minimum clearances as necessary before granting approval of the display site. The AHJ may not reduce clearances specified in NFPA 1123 without written approval of the OSFM.

2. A copy of the display permit shall be kept at the firing station.

3. Operators shall never use damaged fireworks, fireworks that are wet, or fireworks damaged by moisture. Operators shall not dry wet pyrotechnics for reuse. Operators shall handle and dispose of wet or damaged pyrotechnics per the manufacturer's instructions.

4. The operator of the display shall keep a record of all shells that fail to ignite or function. The form shall be completed and returned to the supplier within fifteen days of the display and the operator shall retain a copy for their records. The operator and supplier shall retain Malfunction Reports for three years from the date of the display. The operator and supplier must produce these reports upon request of the OSFM. The "Malfunction Report" form shall be available on the OSFM website.

5. Moorings or anchors shall secure floating vessels or platforms used for firing of a Public Fireworks Display.

6. Operators shall not reload mortars during a display.

7. It shall be the responsibility of the permittee to arrange with the AHJ for the detailing of firefighters and equipment as required.

C. Proximate Audience Display.

1. The licensed pyrotechnic operator is responsible for the storing, handling, supervision, discharge, and removal of all pyrotechnic devices and materials based on their license classification and the terms of their permit. The licensed pyrotechnic operator is responsible for supervising and training of their assistants in the safe handling and discharge of all pyrotechnic devices.

2. The permit package shall contain a copy of the permit, Certificate of Insurance, and the MSDS(s) for material used.

3. A copy of the permit package shall be kept at the control site used to initiate the display. An audible announcement shall be made not more than 10 minutes before the display to notify personnel of the use of proximate audience pyrotechnics.

4. Motion Picture productions shall display one permit package at the production office, and maintain the second permit package on the film site through the First Assistant Director. Before the start of any effect, verbal notification of Proximate Audience Pyrotechnic use shall be required before each camera roll.

5. The AHJ may inspect the proximate audience display. As a minimum, the inspection shall cover the requirements in Annex B of NFPA 1126.

6. The permittee shall furnish a fire watch during the times the special effects materials have been removed from storage and/or magazines and the conclusion of the performance. This person shall be identified by an orange shirt or vest (or other color approved by the AHJ) with three-inch white letters on the front and back stating FIRE WATCH. For motion picture productions, the method for identifying the FIRE WATCH shall be a mutually agreed means of designation between the OSFM, the permittee, and the First Assistant Director.

7. Indoor facilities used for Proximate Audience Displays must be equipped with an automatic fire alarm system and a public address system.

a. The fire alarm system shall be zoned so that the areas affected by special effects smoke can be overridden during the event.

b. An override switch shall be provided at the firing point and a second switch in the control room to shut off stage sound and make the public address system available for evacuation instructions. These switches must be labeled and visible throughout the show.

c. The fire alarm system must be returned to normal operation before the fire watch and the display operator may leave the facility.

71-8305.7. Use of Consumer Fireworks in South Carolina.

A. It shall be deemed a violation of these regulations to:

1. Explode or ignite fireworks within 600 ft. of any Assembly Occupancy, Educational Occupancy, Hazardous Occupancy, Institutional Occupancy, or any facility storing or dispensing flammable liquids, combustible liquids, LP-Gas, or other hazardous materials;

2. Explode or ignite fireworks within 75 ft. of where fireworks are stored, sold or offered for sale;

3. Ignite, discharge, and/or throw fireworks from any motor vehicle or to place, ignite, discharge, and/or throw fireworks into or at any motor vehicle; and

4. Ignite or discharge fireworks in a wanton or reckless manner to constitute a threat to the personal safety or property of another.

B. The distances in R.71-8305.7 A (1) may be reduced if the display is permitted with the OSFM as a Public Fireworks Display or as a Proximate Audience Display.

C. Consumer Fireworks shall not be used for a Public Fireworks Display unless permitted by the OSFM per the applicable provisions of this regulation and all permit fees are paid.

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71-8305.8. Transportation of Fireworks or Pyrotechnics in South Carolina.

A. Vehicles transporting Display Fireworks (pyrotechnics classified as 1.3 explosives) in any quantity and Consumer Fireworks (pyrotechnics classified as 1.4 explosives) in quantities greater than 1000 lbs. shall be in the custody of drivers possessing an appropriate valid commercial drivers license (CDL) with a hazardous materials endorsement.

B. On both sides, on the front, and on the rear, vehicles transporting Display Fireworks (pyrotechnics classified as 1.3 explosives) in any quantity and Consumer Fireworks (pyrotechnics classified as 1.4 explosives) in quantities greater than 1000 lbs. shall prominently display signs marked "EXPLOSIVES" that conform to the USDOT and other federal regulations.

C. Appropriate fire and police authorities shall be promptly notified when a vehicle transporting pyrotechnics is involved in an accident, break down, or fire. Only in the event of such an emergency shall the transfer of pyrotechnics from one vehicle to another be allowed on highways and then only when qualified supervision is provided.

D. Any vehicle used for the transportation of pyrotechnics covered by item A or B above shall have not less than one approved-type fire extinguisher with a minimum rating of 2A 10 B:C and shall be so located as to be readily available for use.

E. Operators must notify the OSFM within 24 hours of any fires or thefts involving fireworks. The operator shall provide the OSFM with a copy of the report filed with the police department or the incident report from the fire department. Operators must also provide the OSFM with a copy of ATF Form 5400.5.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

Document No. 4621
DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL
CHAPTER 71

Statutory Authority: 1976 Code Sections 23-9-60, 23-9-550, 23-35-45, and 23-36-80

71-8306. Hydrogen Facilities.

Synopsis:

The Office of State Fire Marshal proposes to eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

A Notice of Drafting was published in the *State Register* on September 25, 2015.

Instructions:

Regulation 71-8306 is amended as shown below.

Text:

SUBARTICLE 7
HYDROGEN FACILITIES

71-8306. Hydrogen Facilities.
(Statutory Authority: 1976 Code Section 23-9-550)

71-8306.1. General.

A. The purpose of these regulations are to provide reasonable safety and protection to the public, public property, private property from the hazards associated with the handling, use, storage, transfer and dispensing at a hydrogen facility.

B. This regulation shall apply to:

1. Hydrogen dispensing stations for public or commercial use as a transportation fuel and motor vehicle fuel or in a fuel cell;
2. Bulk hydrogen compressed gas systems for a hydrogen facility;
3. Bulk liquefied hydrogen gas systems for a hydrogen facility;
4. Commercial hydrogen generation systems connected to a hydrogen facility; and
5. Engineered and pre-engineered hydrogen fuel cell systems.

C. This regulation shall not apply to:

1. The manufacture, sale, or storage of small scale hydrogen generation or consumption systems where hydrogen is held in containers of one liter or less and Maximum Allowable Quantities (MAQ) are not exceeded.
2. The transportation, handling, and/or use of hydrogen by the State Fire Marshal, his employees, or any commissioned law enforcement officers acting within their official capacities.
3. The manufacture or transportation of bulk hydrogen.
4. Hydrogen used as an ingredient or by product in the manufacture of a product.

71-8306.2. Codes and standards.

A. All references to codes and standards found in these regulations refer to the editions adopted in R.71-8300.2 and are modified by the following regulations as shown below.

B. All facilities shall be designed and installed in accordance with the adopted codes and standards listed in R.71-8300.2.

71-8306.3. Engineered and pre-engineered systems.

A. Engineered hydrogen systems.

1. All installations shall be in accordance with South Carolina Laws, Regulations, and adopted Codes.
2. Plans and specifications prepared by a licensed engineer or prepared under the licensee's direct supervision must be stamped with seals prior to submission and review by OSFM.

B. Pre-engineered hydrogen systems.

1. All installations shall be in accordance with South Carolina Laws, Regulations, and adopted Codes.
2. Plans and specifications are not required to be prepared by a licensed engineer nor be stamped with seals prior to submission and review by OSFM.

71-8306.4. Permit application requirements for hydrogen facilities.

A. The OSFM may issue a permit to a location when presented a completed application that contains at least the following, where applicable:

1. A site plan, drawn to scale, which shows equipment locations and point(s) of transfer with respect to property lines, nearby structures, roads & dikes, power lines, and other potential ignition sources;
2. An accidental release plan;

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3. The piping layout with valves and fitting details;
4. Normal and emergency ventilation designs;
5. Container capacity (or capacities) and design standards;
6. Electrical plan;
7. Container and piping support details;
8. Information concerning onsite fire protection equipment;
9. Information concerning the project's beginning and ending points, if part of a larger system;
10. Listed equipment with listing agency;
11. Unless exempted, design documents sealed by an engineer licensed in South Carolina; and,
12. All applicable fees paid in full.

71-8306.5. Licensing and permitting fees.

- A. All fees are due at time of application for licenses, tests, or permitting.
- B. Permit applications are due in the OSFM prior to construction or installation.
- C. Approval of plans for hydrogen facilities are to be obtained prior to start of construction or installation.
- D. The OSFM is responsible for all administrative activities of the licensing program. The OSFM shall employ and supervise personnel necessary to effectuate the provisions of this article and shall establish fees sufficient but not excessive to cover expenses, including direct and indirect costs to the State for the operation of this licensing program.
- E. Fees shall be established for the following:
 1. Application fee \$10
 2. Permitting fee (includes plan review and initial site inspection) \$250.
 3. Inspection fee (semi-annual) \$100.
 4. Renewal of permits (annual – includes inspection) \$100.
- F. The application fee is due at time of application for license.
- G. All fees paid to the OSFM are nonrefundable.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

Document No. 4622

**DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL**

CHAPTER 71

Statutory Authority: 1976 Code Sections 23-9-60, 23-9-550, 23-35-45, and 23-36-80

71-8304. Liquefied Petroleum (LP) Gas

Synopsis:

The Office of State Fire Marshal proposes to eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

A Notice of Drafting was published in the *State Register* on September 25, 2015.

Instructions:

Regulation 71-8304 is amended as shown below.

Text:

SUBARTICLE 5
LIQUEFIED PETROLEUM GAS

71-8304. Liquefied Petroleum (LP) Gas.
(Statutory Authority: 1976 Code Sections 23-9-20, 23-9-40, 23-9-60, 40-82-70)

71-8304.1. General.

A. The purpose of this regulation is to provide reasonable protection of the health, welfare, and safety of the public and LP-Gas operators from the hazards associated with the handling, use, transportation, and storage of LP-Gas.

B. These regulations apply to:

1. LP-Gas Dealers, Installers, Gas Plants, Wholesalers, Resellers, or Cylinder Exchange operators and;
2. Any person handling, dispensing, transporting, or storing LP-Gas.

C. These regulations shall not apply to:

1. LP-Gas pipeline transmission.
2. Gas plants after the point where LP-Gas or LP-Gas and air mixture enters a utility distribution system.
3. Natural gas systems covered by the IFGC.

71-8304.2. Codes and Standards.

A. All references to codes and standards found in these regulations refer to the editions adopted in R.71-8300.2 and are modified by the following regulations as shown below.

B. The building code shall define occupancy classifications referenced in these regulations.

71-8304.3. Licensing and Permitting Fees.

A. The OSFM is responsible for all administrative activities of the licensing program. The SFM shall employ and supervise personnel necessary to effectuate the provisions of this article and shall establish fees sufficient but not excessive to cover expenses, including direct and indirect costs to the State for the operation of this licensing program. Fees may be adjusted not more than once each two years, using the method set out in S.C. Code Ann. Section 40-1-50(D), 1976, as amended.

B. Fees shall be established for the following:

1. Application
2. Testing
3. Permitting
4. Licensing
5. Inspection
6. Renewal

C. All fees are due at time of application for licenses, testing, permits, inspection, or renewal.

D. All fees paid to the OSFM are nonrefundable.

71-8304.4. Licensing Requirements.

A. Licenses

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1. Each company shall possess a license issued by the OSFM.
2. Licenses shall be displayed in a conspicuous location at the place of business for the LP-Gas Dealer, Installer, Gas Plant, Wholesaler, Reseller, or Cylinder Exchange operator.

B. Permits

1. Each site shall have a designated person that has a permit issued by the OSFM to supervise people handling, dispensing, installing, transporting, repairing, or exchanging LP-Gas.
2. Any applicant who fails the written examination is allowed one (1) re-test after a minimum seven (7) day waiting period. Any applicant who fails the re-test shall wait at least thirty (30) days before reapplying.
3. Permits shall bear the name, photograph, and any other identifying information deemed necessary by the OSFM.
4. Permit holders shall have their permit in their possession when supervising the handling, dispensing, installing, manufacturing, transporting, repairing, or exchanging LP-Gas.
5. Permit holders shall exhibit their permits on request of any AHJ.
6. Permits shall expire on the day of expiration shown on the permit and shall be renewed biennially.
7. Permits issued under this subarticle are not transferable.
8. Expired permits shall not be renewed. A new permit shall be obtained by complying with all requirements and procedures for an original permit.

71-8304.5. Plan Submittal Requirements.

Licenses that are required to obtain a site approval per S.C. Code Ann. Section 40-82-220, 1976, as amended, shall comply with the plan submittal requirements of the applicable codes and standards referenced in R.71-8304.2.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

Document No. 4623

DEPARTMENT OF LABOR, LICENSING AND REGULATION
OFFICE OF STATE FIRE MARSHAL
CHAPTER 71

Statutory Authority: 1976 Code Sections 23-9-60, 23-9-550, 23-35-45, and 23-36-80

71-8303. Portable Fire Extinguishers and Fixed Fire Extinguishing Systems.

Synopsis:

The Office of State Fire Marshal proposes to eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.

A Notice of Drafting was published in the *State Register* on September 25, 2015.

Instructions:

Regulation 71-8303 is amended as shown below.

Text:

SUBARTICLE 4
PORTABLE FIRE EXTINGUISHERS AND FIXED FIRE EXTINGUISHING SYSTEMS

71-8303. Portable Fire Extinguishers and Fixed Fire Extinguishing Systems.
(Statutory Authority: 1976 Code Sections 23-9-40, 23-9-45)

71-8303.1. General.

A. The purpose of this subarticle is to regulate the leasing, renting, reselling, servicing and testing of portable fire extinguishers and the installation, testing, and servicing of fixed fire extinguishing systems in the interest of protecting lives and property.

B. This regulation shall apply to:

1. The filling, charging, and recharging of all portable fire extinguishers other than the initial filling by the manufacturer.

2. The testing and servicing of all types of portable fire extinguishers.

3. The installation, testing, and servicing of all types of fixed fire extinguishing systems.

C. This regulation shall not apply to the following:

1. The filling or charging of a portable fire extinguisher by the manufacturer before the initial sale;

2. The installation or servicing of water-based extinguishing systems addressed by S.C. Code Ann. Section 40-10-240 et seq; and

3. Firms engaged in the retailing or wholesaling of new portable fire extinguishers.

71-8303.2. Codes and Standards.

A. All references to codes and standards found in these regulations refer to the editions adopted in R. 71-8300.2 and are modified by the following regulations as shown below.

B. The building code shall define occupancy classifications referenced in these regulations.

71-8303.3. Fees for Licensing, Testing, and Inspections.

A. The OSFM is responsible for all administrative activities of the licensing program. The OSFM shall employ and supervise personnel necessary to effectuate the provisions of this article and shall establish fees sufficient but not excessive to cover expenses, including direct and indirect costs to the State for the operation of this licensing program. Fees may be adjusted not more than once each two years, using the method set out in S.C. Code Ann. Section 40-1-50(D), 1976, as amended.

B. Fees shall be established for the following:

1. Application

2. Testing

3. Permitting

4. Licensing

5. Inspection

6. Renewal

C. All fees are due at time of application for licenses, testing, permits, inspection or renewal.

D. All fees paid to the OSFM are nonrefundable.

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71-8303.4. Licensing and Permitting Requirements.

A. General Licensing Requirements.

1. Each firm testing and servicing portable fire extinguishers; installing, testing, and servicing fixed fire extinguishing systems; or hydrostatic testing portable fire extinguishers or portions of fixed fire extinguishing systems must have a license issued by the OSFM.

2. Each firm's license shall be displayed in a conspicuous location at their place of business.

3. Each firm shall apply in writing on a form available from the OSFM, for the license classification the firm is seeking.

4. Each firm shall furnish a certificate of insurance with their application in the amount required for their license classification. The firm shall list the State of South Carolina and its agents as a certificate holder. The coverage company must be an insurer which is either licensed by the DOI in this State or approved by the DOI as a nonadmitted surplus lines carrier for risks located in this State. In the event the liability insurance is canceled, suspended, or not renewed, the insurer shall give immediate notice to the OSFM.

5. Each firm shall possess or have access to the equipment necessary for the class of license sought. The OSFM shall inspect the firm's facilities, fixed or mobile, to verify the firm has the necessary required equipment. The OSFM shall not license a firm until deficiencies discovered by inspection are corrected.

6. Licenses issued under this subarticle are not transferable.

7. All licenses expire when insurance coverage lapses or is cancelled and on the day of expiration shown on the license and shall be renewed biennially.

8. Expired licenses shall not be renewed. A new license shall be obtained by complying with all requirements and procedures for an original license.

B. General Permitting Requirements.

1. Each individual servicing, recharging, repairing, installing, or testing portable fire extinguishers or fixed fire extinguishing systems shall possess a valid permit issued by the OSFM.

2. Each individual shall apply in writing on a form available from the OSFM, for the permit classification they are seeking.

3. Applicants must provide a current color photograph in an approved electronic format as specified by OSFM on the application form.

4. Applicants must be at least eighteen (18) years old.

5. Applicants shall pass a written examination administered by the OSFM before a permit is issued. The exam will cover the applicable codes, state laws, and regulations and the additional requirements for the specific class of permit for which they are applying. Completed applications must be received by OSFM prior to scheduling an examination.

6. Any applicant who fails the written examination is allowed one (1) re-test after a minimum seven-day waiting period. Any applicant who fails the re-test shall wait at least six (6) months before reapplying.

7. Permit holders shall have their permits in their possession while working on equipment or systems covered by their permit.

8. Permit holders shall show their permits on the request of any AHJ.

9. Permit holders shall be limited to specific type of work allowed by the class of permit they hold and the specific systems covered by their permit.

10. Permits issued under this subarticle are not transferable and specifically identify the affiliated company. Upon leaving the employ of the specifically identified company, the permit immediately becomes invalid and must be surrendered to the OSFM within 15 business days.

11. Permits shall expire on the day of expiration shown on the permit and shall be renewed biennially.

12. Expired permits shall not be renewed. A new permit shall be obtained by complying with all requirements and procedures for an original permit.

C. License and Permit Classifications.

1. Class "A" - may service, recharge, or repair, all types of portable fire extinguishers, including recharging carbon dioxide units; and to conduct hydrostatic tests on all types of fire extinguishers.

2. Class "B" - may service, recharge, or repair all types of portable fire extinguishers, including recharging carbon dioxide units and conducting hydrostatic tests on water, water chemical, and dry chemical types of extinguishers only.

3. Class "C" - may service, recharge, or repair all types of portable fire extinguishers, except recharging carbon dioxide units; and to conduct hydrostatic tests of water, water chemical, and dry chemical types of fire extinguishers only.

4. Class "D" - may service, recharge, repair, or install all types of fixed fire extinguishing systems.

5. Class "E" is an apprentice permit classification only. Permits in this classification may perform the services only under direct supervision of a person holding a valid permit and who works for the same firm as the apprentice. An apprentice permit is valid for one (1) year from the day of issuance and may not be renewed.

D. Firms applying for a Class "A", "B", or "C" License must meet all of the general requirements for licensing and provide proof of public liability insurance for an amount not less than one million (\$1,000,000) dollars.

E. Firms applying for a Class "D" License must:

1. Designate on their application for licensing each type of fixed fire extinguishing system for which they want to be licensed;

2. Provide proof of public liability insurance for an amount not less than one million (\$1,000,000) dollars; and

3. Provide proof of manufacturer's certification for at least one type of fixed fire extinguishing system.

4. For each additional type of fixed fire extinguishing system, the applicant may submit proof of a manufacturer's certification or an affidavit which shall attest to the ability to obtain the proper manufacturer's installation, maintenance and service manuals and manufacturer's parts or alternative components that are listed for use with the specific extinguishing system and provide testament that all installations and maintenance shall be performed in complete compliance with the manufacturer's installation, maintenance and service manuals and NFPA standards.

F. Individuals applying for a Class "A", "B", or "C" Permit must meet all of the general requirements.

G. Individuals applying for a Class "D" Permit must:

1. Designate on their application for licensing each type of fixed fire extinguishing system for which they want to be permitted.

2. Provide proof of manufacturer's certification for at least one type of fixed fire extinguishing system.

3. For each additional type of fixed fire extinguishing system, the applicant may submit proof of a manufacturer's certification or an affidavit which shall attest to the ability to obtain the proper manufacturer's installation, maintenance and service manuals and manufacturer's parts or alternative components that are listed for use with the specific extinguishing system and provide testament that all installations and maintenance shall be performed in complete compliance with the manufacturer's installation, maintenance and service manuals and NFPA standards.

H. Employees applying for a Class "E" Permit must file an application for a Class "E" Permit and provide a current photograph.

71-8303.5. Renewal of Licenses and Permits.

A. To qualify for biennial renewal of a Class "A", "B" or "C" license, a firm must:

1. Apply in writing on a form available from the OSFM designating the Class of license sought;

2. Provide proof of public liability insurance.

B. To qualify for biennial renewal of a Class "A", "B" or "C" permit, an individual must:

1. Apply in writing on a form available from the OSFM, designating the permit classification they are seeking.

C. To qualify for biennial renewal of a Class D license, a firm must:

1. Apply in writing on a form available from the OSFM, designating each type of fixed fire extinguishing system for which they wish to be licensed to install, test, or service;

2. Provide proof of public liability insurance;

3. Provide proof of manufacturer's certification for at least one type of fixed fire extinguishing system;

4. For each additional type of fixed fire extinguishing system, the applicant may submit proof of a manufacturer's certification or an affidavit which shall attest to the ability to obtain the proper manufacturer's installation, maintenance and service manuals and manufacturer's parts or alternative components that are listed for use with the specific extinguishing system and provide testament that all installations and maintenance shall

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be performed in complete compliance with the manufacturer’s installation, maintenance and service manuals and NFPA standards.

D. To qualify for biennial renewal of a Class D permit, an individual must:

1. Apply in writing on a form available from the OSFM, designating each type of fixed fire extinguishing system for which they wish to be permitted to install, test, or service;
2. Provide an up to date manufacturers training certificate for each type of fixed fire extinguishing system, that renewal is sought;
3. Provide an affidavit to attest to the applicant’s ability to obtain the proper manufacturer’s installation, maintenance and service manuals and manufacturer’s parts or alternative components that are listed for use with the specific extinguishing system and provide testament that all installations and maintenance shall be performed in complete compliance with the manufacturer’s installation, maintenance and service manuals.

71-8303.6. Restrictions for Class D Fire Equipment Licenses and Permits.

A. A firm or person shall not willfully engage in the business of installing, testing or servicing Class D fire equipment or use in any advertisement or on a business card or letterhead, or make any other verbal or written communication that the person is a Class D Fire Equipment Dealer or acquiesce in such a representation, unless that person is licensed as a Class D Fire Equipment Dealer by the OSFM.

B. No person shall install or service any type of Class D fire equipment not covered on their permit.

71-8303.7. Licensing Requirements: For Firms Performing Hydrostatic Testing.

A. Each firm performing hydrostatic testing of fire extinguishers manufactured according to the specifications of the USDOT shall be required to possess a valid license issued by the USDOT. All hydrostatic testing of fire extinguishers shall be performed per the appropriate USDOT standards and NFPA standards.

B. Each employee certified to conduct hydrostatic testing shall attend a USDOT certification refresher course every three years and provide a copy of the current certification to the OSFM upon completion.

71-8303.8. Installation and Maintenance Procedures.

A. All Portable Fire Extinguishers and Fixed Fire Extinguishing Systems covered by these regulations shall be installed, inspected, tested and serviced per the applicable NFPA standards and the manufacturer’s installation, service and maintenance manuals.

B. Any portable fire extinguisher or fixed fire extinguishing system that cannot be maintained per the manufacturer’s installation, service, and maintenance manuals or the applicable NFPA standards shall be removed from service and replaced.

C. Tamper seals on all portable fire extinguishers and fixed fire extinguishing systems shall be imprinted with the year. Handwritten dates are not acceptable. The year imprinted on the tamper seal shall match the date on the maintenance tag affixed to the portable fire extinguisher or fixed fire extinguishing system.

71-8303.9. Recommended Equipment and Facilities for Fire Equipment Dealer License.

						YES	NO	N/A
1	A			D	Hydrostatic test equipment for high pressure testing and calibrated cylinder. (0-11,000 psi)			
2	A			D	Equipment for test dating high-pressure cylinders (over 900 psi). Die stamps must be a minimum of one-quarter inches.			
3	A			D	Clock with sweep secondhand on or close to hydrostatic test apparatus.			
4	A	B		D	Carbon dioxide receiver--cascade system for proper filling of Carbon dioxide extinguishers.			
5	A	B		D	Supply of metallic labels Carbon dioxide hose conductivity test. Labels attached to the hose must include month and year of testing,			

					name or initials of person performing test, and name of agency performing test.			
6	A	B	C	D	Scales graduated in one-eighth ounce or 1 gram weight if refilling Carbon dioxide cartridges. Minimum of 20 lbs.			
7	A	B	C	D	All scales calibrated within the last 12 months. Certification date(s) _____ Certified by _____			
8	A	B	C	D	Approved drying method for high and low pressure cylinders. Listed for its use.			
9	A	B	C	D	Proper wrenches with non-serrated jaws or valve puller (hydraulic or electric).			
10	A	B	C	D	Inspection light.			
11	A	B	C	D	Low-pressure test apparatus.			
12	A	B	C	D	Low-pressure hydrostatic test labels per NFPA 10.			
13	A	B	C	D	Scales for weighing extinguisher/system agent bottles during inspection and filling, minimum of 500 lbs. Calibrated and certified annually.			
14	A	B	C	D	Closed recovery system(s) and storage to remove and store chemicals from fire extinguishers or system cylinders during servicing.			
15	A	B	C	D	Closed recovery system(s) and storage to remove and store chemicals from halon type fire extinguishers or system cylinders during servicing.			
16	A	B	C		Current installation, maintenance and service manuals from the manufacturer of each make or brand of fire extinguisher or system the company installs, services, recharges, repairs, or maintains.			
17	A	B	C		Supply of extinguisher recharge agents for the type/brands of fire extinguishers the company requests to recharge or service.			
18	A	B	C	D	Vise 6-inch minimum (chain or bench).			
19	A	B	C	D	Facilities for proper storage of extinguishing agents.			
20	A	B	C	D	Facilities for leak testing of pressurized extinguishers.			
21	A	B	C	D	Nitrogen with regulator and indicator. Regulator not to exceed 1500 psi--minimum 500 psi.			
22	A	B	C	D	Supply of "Verification of Service" collars containing month and year the service was performed.			
23	A	B	C		Adapters, fittings, and tools and equipment for properly servicing and/or recharging all extinguishers being serviced and recharged.			
24	A	B	C	D	Safety cage (in shop) for hydrostatic testing of low-pressure cylinders.			
25	A	B	C	D	One-quarter pound graduated scales minimum 150 pounds for weighing chemical recharging.			
26				D	Cable crimping tool (where required).			
27				D	Cocking lever (where required).			
28				D	Pipe vise, dies, reamer, etc.			
29				D	Stock and supply of fuse links, proper elbows, and nozzles for system which is being installed.			
30				D	Parts from each manufacturer's system that the permittee is permitted to work on or service, including original service manuals and all up to-date technical bulletins.			
31				D	Listed links from each manufacturer that the permittee is permitted to service or work on.			

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32				D	Current service manuals from the manufacturer for each model of fixed fire extinguishing system being installed, tested, or serviced by the fire equipment license holder.			
33				D	System reports - custom or generic.			
34				D	Non-compliance tags for non compliant systems.			
35	A	B	C	D	Supply of tags with the appropriate company and other related information on them.			
36				D	Thermometer with a minimum of 2 degrees Fahrenheit or 1 degree Celsius increments.			
37				D	Agent transfer pump (for halon or clean agents).			
38				D	Torque wrench.			
39				D	Leak test device (for halon or clean agents).			
40				D	Liquid level detector ("halon scanner").			

71-8303.10. Powers and Duties of the Office of State Fire Marshal.

A. Powers and duties of the OSFM are:

1. To evaluate the applications of firms or individuals for a license and permits to engage in the business of servicing portable fire extinguishers or installing, testing and servicing fixed fire extinguishing systems;
2. To administer written examinations to ascertain the competency of applicants for a license to service portable fire extinguishers or install fixed fire extinguishing systems;
3. To issue licenses, permits, and apprentice permits required by this subarticle;
4. To suspend or revoke licenses and permits for cause; and
5. To administer these regulations and supervise personnel in carrying out the requirements of this regulation.

B. The OSFM may conduct hearings or proceedings concerning the suspension, revocation, or refusal to issue or renew licenses or permits issued under this subarticle or the application to suspend, revoke, refuse to renew, or refuse to issue the same.

C. An applicant, licensee, or permit holder whose license or permit has been refused or revoked under this subarticle, except for failure to pass a required written examination, shall not file another application for a license or permit within one year from the effective date of the refusal or revocation. After one year from that date, the applicant may re-apply, and in a public hearing, show good cause why the issuance of a license or permit does not hinder public safety and health.

D. The OSFM shall maintain a registry of all applications for licenses or permits and of all firms or persons holding licenses or permits. The OSFM shall make the roster of Fire Equipment Dealers Licenses or Fire Equipment Permits, available on the OSFM website.

71-8303.11. Fitness to Practice; Investigation of Complaints.

If the OSFM has reason to believe that a person licensed under this chapter has become unfit to practice as a Fire Equipment Dealer or if a complaint is filed with the OSFM alleging a violation of a provision of this chapter by a license or permit holder or if a complaint is filed with the OSFM alleging that an licensed person is fraudulently holding him or herself out as qualified to engage in business as a Fire Equipment Dealer, the OSFM may initiate an investigation per the procedures of Title 40, Chapter 1.

71-8303.12. Administrative Sanctions.

A. If after an investigation it appears that the license or permit holder under this regulation has become unfit to practice or has violated these regulations, the OSFM may file a Petition with the Administrative Law Court stating the facts and the particular statutes and regulations at issue.

B. The Administrative Law Court may, after opportunity for hearing, order that the license or permit be revoked, suspended, or otherwise disciplined on the grounds that the license or permit holder:

1. Used a false, fraudulent, or forged statement or document in obtaining a license or permit under this chapter; or
2. Committed a fraudulent, deceitful, or dishonest act or omitted a material fact in obtaining a license or permit under this chapter; or
3. Has had an authorization to practice a regulated profession or occupation in another state or jurisdiction canceled, revoked or suspended, or has otherwise been disciplined by another jurisdiction; or
4. Has intentionally used a fraudulent statement in a document connected with the license or permit; or
5. Obtained fees or assisted in obtaining fees under fraudulent circumstances; or
6. Sustained a physical or mental disability or uses alcohol or drugs to such a degree as to render further practice as a Fire Equipment Dealer dangerous to the public; or
7. Failed to perform all installation, service, and testing in complete compliance with the manufacturer's manuals.

71-8303.13. Sanctions for Unlawful Practice.

A. The Administrative Law Court may, after opportunity for hearing, order injunctive relief against a person who, without possessing a valid license or permit under this chapter, practices or offers to practice or uses the title or term Fire Equipment Dealer. For each violation, the administrative law judge may impose a fine of no more than ten thousand (\$10,000) dollars.

B. A person who does not hold a license or permit as required by this Chapter, may not bring any action either at law or in equity to enforce the provisions of any contract for providing services as a Fire Equipment Dealer.

71-8303.14. Certain Acts Prohibited.

A. No person or firm shall:

1. Engage in the business of installing or servicing portable fire extinguishers without a valid and current license;
2. Engage in the business of installing or servicing fixed fire extinguishing systems without a valid and current license;
3. Service, test, or install fixed fire extinguishing systems without a valid and current license;
4. Perform hydrostatic testing of USDOT cylinders for portable fire extinguishers or parts of a fixed fire extinguishing systems without a valid and current hydrostatic license;
5. Obtain or attempt to obtain a license or permit by fraudulent representation;
6. Service portable fire extinguishers or test, service, or install fixed fire extinguishing systems contrary to the provisions of these regulations;
7. Service or hydrostatic test a fire extinguisher that does not have the proper identifying labels;
8. Sell, offer for sale, or give any make, type, or model of new or used fire extinguisher, unless extinguisher has first been tested and is currently approved or listed by Underwriters' Laboratories, LLC., FM Approvals, or other nationally recognized testing laboratory whose testing procedures used for approval in the listing of portable fire extinguishers are acceptable to the OSFM, and unless such extinguisher carries an Underwriters' Laboratories, Inc., or manufacturer's serial number. The serial number shall be permanently stamped on the manufacturer's identification and instruction plate;
9. Permit an individual who works for the firm to engage in installation, repair, recharge, maintenance or servicing fire extinguishers or fixed fire extinguishing systems without a valid permit or license.

71-8303.15. Cease and Desist Orders; Notice to Correct Hazardous Conditions.

When the OSFM shall have reason to believe that any person is or has been violating any provisions of this regulation or any rules or regulations adopted and promulgated pursuant thereto, the OSFM may issue and deliver to such person an order to cease and desist such violation or to correct such hazardous condition.

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71-8303.16. Suspensions or Revocation of License or Permit.

A. The license of any company or individual may be suspended or revoked because of failure to comply with the terms of any order to correct violations within the specified abatement period or for failure to comply with any cease and desist orders. A license may be suspended for a period not to exceed one year from the date of license suspension. A license may be revoked for a period not to exceed two years from the date of license revocation.

B. In addition, a license may be suspended or revoked where the license or permit holder is found to have:

1. Rendered inoperative a fire extinguisher or fixed fire extinguishing system, which is required by any rule of the OSFM, except during such time as the extinguisher, or fixed fire extinguishing system is being inspected, serviced, or tested;
2. Falsified any records required to be maintained by this chapter or rules adopted thereto;
3. Improperly serviced, tested, or inspected a fire extinguisher or fixed fire extinguishing system;
4. Allowed another person to use his permit or license number or use a license or permit number other than the license or permit holder's valid license or permit number; or
5. Obliterated the serial number on a fire extinguisher for purposes of falsifying service records.

71-8303.17. Responsibility of Equipment Manufacturer.

All manufacturers of portable fire extinguishers and fixed fire extinguishing systems doing business in South Carolina shall provide the OSFM with all technical information as well as installation instructions that apply to their systems and equipment sold, installed, serviced or tested in South Carolina. This technical information shall include design revisions and updating information on systems sold in South Carolina.

71-8303.18. Penalties.

The OSFM may issue a citation for each offense to any person, firm, or corporation licensed under these regulations who has violated any provision of this subarticle. The OSFM may assess fines for each charge to both the fire equipment company and the permit holder. Citations may be assessed by the OSFM at not more than two thousand (\$2000.00) per violation.

Fiscal Impact Statement:

There will be no cost incurred by the State or any of its political subdivisions for these regulations.

Statement of Rationale:

The updated regulations will eliminate redundant and unnecessary provisions of the regulations; update, correct, and/or otherwise improve by amending the remaining existing regulations; use a standardized format for all regulations; and to make the current regulations compatible with current federal and state statutes.