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**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-93-10 et seq.

61-105. Infectious Waste Management Regulations

**Preamble:**

The Department of Health and Environmental Control (Department) proposes to amend R.61-105. These proposed amendments seek to provide greater protections for the public, remove any perceived uncertainty with respect to existing provisions, and ensure consistency with U.S. Department of Transportation regulations. Stylistic changes are included that will improve the overall quality of the Regulation.

These proposed regulations require facilities having a permit by rule to notify the Department of the type of treatment they will utilize and clarify requirements for any waste facilities that are pre-treating. The proposed regulations include body art facilities (tattoo and body piercing) in the types of facilities that generate infectious waste in order to make the Infectious Waste Management Regulation consistent with Health Licensing requirements. Recordkeeping requirements include a timeframe for records to be provided to the Department after an inspection. Timeframes are addressed for variances and alternative treatment technology approvals, including expiration and opportunities for renewal. The requirements also allow better communication with facilities and tracking of facilities. Annual reporting requirements for treatment facilities are revised and clarified to require amounts of waste treated to correspond to the state of origin. Facilities that treat waste through steam sterilization will be required to record the pressure during the treatment process as well as having the pressure gauge calibrated annually. These records are already required for temperature and are already being provided by the permitted treatment facility in the State. Demonstration of need requirements are more consistent with those of other similar programs. The definition(s) and requirements for storage of waste are clarified. Requirements for financial assurance documentation requirements are revised to better protect the Department and South Carolina residents. The requirements for the handling of products of conception are revised to include documentation of donation and notification of necessary incineration. The standards for waste treatment technologies are updated. The amendments allow transporters to only disinfect their vehicles once a day, while still requiring immediate disinfection of visible debris and a now requiring a log to be kept of disinfection. The requirement that transporters submit training documentation annually is removed, as inspectors check for these records during regular inspections. Finally, the proposed regulations include nonsubstantive stylistic revisions and a table of contents will be added.

A Notice of Drafting for these proposed amendments was published in the *State Register* on April 22, 2016.

**Section-by-Section Discussion of Proposed Amendments:**

SECTION CITATION/EXPLANATION OF CHANGE:

**Statutory Authority** is revised to replace the section symbol with written text to “Section;” Section 44-93-100 is deleted because the entire statute applies and this is not needed. Also, identification of the Act is removed; each change is made pursuant to Legislative Council standards for drafting regulations. These changes are not substantive.

**TITLE**

The title is changed to Regulation 61-105, Infectious Waste Management Regulation to reflect that the Regulation should be taken as a single body of work.

**TABLE OF CONTENTS**

A Table of Contents will be added.

All Section titles are bolded for ease of reference.

**A. Purpose and Scope.**

A(1) is revised for grammatical consistency.

A(2) is revised for grammatical consistency.

A(3) has been revised for clarity of language and the language from A(4) and A(5) are added as subsections, as all the language relates to requirements of the regulated community.

A(3) through A(5) have been recodified.

A(4) is renumbered as A(3)(b) as it is also a requirement of the facilities listed in A(3).

A(5) is renumbered as A(3)(c) as it is also a requirement of the facilities listed in A(3).

A(4) and A(5) are deleted.

**B. Severability.**

This paragraph was revised for grammatical consistency and moved for stylistic consistency.

**C. Use of Number and Gender.**

C is revised for grammatical consistency and moved for stylistic consistency.

C(1) is revised to delete the word “and” at the end and for grammatical consistency.

C(2) is revised to delete the word “and” at the end and for grammatical consistency.

C(3) is revised to add the word “and” at the end and for grammatical consistency.

C(4) is revised for grammatical consistency.

**D. Definitions.**

D(1) is revised for grammatical consistency.

**At D(1) eight definitions are added in alphabetical order. Twenty-six existing definitions are revised. Eleven existing definitions are deleted.**

New definitions include: “Alternate treatment technology”, “Demonstration of need”, “Director”, “Donate”, “Planning radius”, “Trust agreement”, “U.S. DOT”, and “USPS”.

The following definitions are revised: “Certification”, “Closure”, “Contingency Plan”, “Dispose”, “EPA”, “Expand”, “Generator facility”, “Generator Registration Status”, “Hazardous waste”, “Infectious waste”, “Intermediate handling facility”, “Manifest”, “Offsite”, “Products of conception”, “Pump event”, “Radioactive material”, “Release”, “Site”, “Solid waste”, “State”, “Supersaturated”, “Transfer Facility”, “Transporter”, “Transport vehicle”, “Treatment facility”, and “Universal biohazard symbol”.

The following definitions are deleted: “CFR”, “Commissioner”, “Containment”, “Destination facility”, “EPA identification number”, “Existing facility”, “Final closure”, “Free liquids”, “Onsite”, “Secured area”, and “Transport”.

**E. Definition of Infectious Waste.**

E(1) introduction is expanded by adding regulated body piercing and tattooing to the types of activities that generate regulated infectious waste and revised for grammatical consistency.

E(1)(a) is revised for brevity and clarity of language. “Including but not limited to” is replaced with “e.g.,”.

E(1)(b) is revised for brevity and clarity of language. “Including but not limited to” is replaced with “e.g.,”.

E(1)(c) is revised for brevity and clarity of language. “Including but not limited to” is replaced with “e.g.,”.

E(1)(d) is revised for brevity and clarity of language. “Including but not limited to” is replaced with “e.g.,”. Language is added to explicitly include any material that results from the termination of a pregnancy as pathological waste (written policy per letter from Phil Morris) and other visibly bloody bodily fluids. Exemption for preserved tissues is moved to create E(2)(h).

E(1)(e) is revised for consistency with other categories, brevity and clarity of language.

E(1)(f) is revised to update and clarify the possible sources of isolation waste. “Guidelines” no longer has a complete list of highly communicable diseases although it does include some criteria.

E(1)(g) is revised to clarify requirement to manage solid waste that comes in contact with infectious waste. Generators must include solid waste in written policy if they choose to dispose of it as infectious waste. Otherwise, solid waste should only be included with infectious waste accidentally.

E(1)(h) is revised for clarity of language and formatting consistency.

E(2)(a) is revised for grammatical and formatting consistency.

E(2)(b) is revised for grammatical and formatting consistency.

E(2)(c) is revised to remove unnecessary language.

E(2)(d) is revised to replace “Commissioner” with “Director” and for grammatical consistency.

E(2)(e) is revised for grammatical and formatting consistency and for clarity of language.

E(2)(f) is revised for clarity of language and grammatical consistency.

E(2)(g) is revised for grammatical consistency.

E(2)(h) is created from language moved from E(1)(d) so that all exemptions are in the same paragraph.

**F. Generator Requirements.**

F(1) is reorganized and revised for clarity of language.

F(1)(b) is revised for clarity of language.

F(1)(c) is revised for clarity of language.

F(1)(d) is revised for clarity of language.

F(1)(e) is revised for clarity of language.

F(1)(f) is revised to allow the possibility of multiple coordinators and to clarify what the coordinator(s) have responsibility for.

F(1)(g) is revised for formatting and data-gathering consistency.

F(1)(h) is revised to delete the word “and” at the end.

F(1)(i) is revised by adding: “an email address for the facility or the infectious waste coordinator;” and moving the original text to create F(1)(j).

F(1)(j) is created from the text that was originally in F(1)(i).

F(1)(k) is added to require generators to include the name of the transporter they are using. This data was already being collected and helps the Program determine if the generator is using a properly registered transporter.

F(1)(l) is added to help generators determine if the transporter they are using is properly registered with the Program.

F(2) is revised to clarify requirements.

F(3) is reorganized for clarity and to clarify the requirements for generators who store waste in holding tanks.

F(4) is revised to clarify requirements.

F(5) Language is revised to clarify and separate requirements for protocol and to allow for the possibility that some small doctor’s offices may have a single person in charge of the handling of infectious waste, instead of a committee.

F(5)(a) is created from language that was previously in F(5).

F(5)(b) is created from requirements previously in F(5) and further details are added detailing what inspectors will expect to see in the protocol.

F(5)(c) is created from requirements previously in F(5).

F(6)(a) is revised to clarify requirements.

F(6)(b) is revised to clarify requirements and for grammatical consistency.

F(6)(c) is reorganized for clarity and grammatical consistency.

F(6)(d) is revised to clarify requirements.

F(6)(e) is revised for grammatical consistency.

F(6)(f) is revised for grammatical consistency.

F(6)(g) is revised for grammatical consistency and to remove the word “and” from the end.

F(6)(i) is reorganized for clarity and to recognize parcel delivery services other than the USPS.

F(6)(j) is revised for grammatical consistency, to clarify the timeframes for weight records, and to add “and” at the end.

F(6)(k) is added to put the primary (but not complete) responsibility on generators to properly manage product of conception waste, including examples of how they can convey the need to incinerate to the transporter and treatment facility.

F(7) is revised for clarity and grammatical consistency.

F(9) is created so that generators have the same requirement as other members of the regulated community to prevent discharges and have the same process in the case of a discharge.

F(10) is created to lay out requirements for the donation of products of conception.

F(10)(a) is created to require that a record be created when products of conception are donated on a Department-approved form.

F(10)(a)(i) is created to require that the form used to record a donation of products of conception include the weight of the material donated.

F(10)(a)(ii) is created to require that the form used to record a donation of products of conception include the date of donation.

F(10)(a)(iii) is created to require that the form used to record a donation of products of conception include assurances that: the materials were donated and no payment exceeds reasonable compensation for costs.

**G. Small Quantity Generators.**

G(1) is revised for clarity of language and to include new requirements created in Section F.

G(1)(a) is reorganized for clarity and revised for grammatical consistency and to add more detail to the requirements for small quantity generators.

G(1)(b) is revised to reduce redundancy.

G(2) is revised to be consistent with U.S. Department of Transportation (U.S. DOT) requirements.

G(2)(a)-(e) are deleted to be consistent with U.S. DOT requirements..

G(3) is revised to explicitly list the options generators have for untreated waste that is picked up at their facility and for grammatical and technical consistency.

G(4) is revised and reorganized for grammatical consistency and clarity of language.

**H. Segregation Requirements.**

H is revised for clarity of language and reorganized.

H(1), (2) and (3) are created from requirements previously included in the body of H, also adding specificity.

**I. Packaging Requirements.**

I(1) is revised for clarity, technical consistency, to update the source of requirements for parcels going through the mail (as the requirements are no longer in the Domestic Mail Manual but are in a separate document, Publication 52), and to recognize parcel delivery services other than the USPS.

I(2) is revised to reduce redundancy and for grammatical consistency.

I(3) is revised so that it will stand alone as a citation and for grammatical consistency.

I(4) is revised for grammatical consistency.

I(5) is revised for clarity of language and grammatical consistency.

I(6) is revised to separate requirements and for grammatical consistency.

I(6)(a) is created from requirements that were originally in I(6).

I(6)(b) is created from requirements that were originally in I(6).

I(7) is revised for clarity of language.

I(8) is revised for grammatical consistency.

I(9) is revised for grammatical consistency.

I(11) is deleted, as it is redundant to requirements already included in Section H.

I(12) is deleted and the requirement moved to Section J, becoming J(7). The requirement is related to labeling of waste once it has been treated, so it fits better in Section J.

**J. Labeling of Containers.**

J(1) is revised for grammatical consistency and to specify where further information is provided.

J(2) is revised for grammatical consistency.

J(a)-(d) are reorganized and revised to be consistent with U.S. DOT and Occupational Safety and Health Administration (OSHA) requirements.

J(2)(a) is revised to combine, in one citation, the required physical properties of labeling on containers of infectious waste that were previously found in separate citations.

J(2)(b) language is moved to J(2)(d).

J(2)(b) is added to require consistency with OSHA standards.

J(2)(c) language is moved to J(2)(a).

J(2)(c) is added to be consistent with U.S. DOT standards.

J(2)(d) language is moved to J(2)(e).

J(2)(d) is revised to include language moved from J(2)(b) and delete language moved to J(2)(e).

J(2)(e) is created from what was originally J(2)(d).

J(2)(f) is created to require labeling of containers with any special handling instructions, such as incineration.

J(3) is revised to specify where further information is located and to allow regulation of bags that are not inside a container.

J(4) is revised to specify where further information is located and for grammatical consistency.

J(5) is revised for grammatical consistency.

J(7) is created from language that was originally I(12). This language was also revised to allow exemptions from labeling of treatment residue if the person treating the waste has a written agreement with the landfill accepting the treatment residue. Extra-large quantity generators (generators generating 1000 pounds or more in any one month as defined in the Environmental Protection Fees Regulation) and treatment facilities have such volumes of treatment residue that labeling would be prohibitively expensive and labor-intensive, but they have agreements in place with landfills, including requirements that the waste be treated before disposal that will ensure public health and the environment are protected.

J(7)(a) is created from language that was originally in I(12).

J(7)(b) is created from language that was originally in I(12).

J(7)(c) is created from language that was originally in I(12).

**K. Storage of Infectious Waste.**

K(1) is revised for grammatical consistency and for clarity of language.

K(1)(a) is revised for grammatical consistency.

K(1)(b) is revised to strengthen the requirement to protect infectious waste packaging (proactive vs. reactive) and for grammatical consistency.

K(1)(c) is revised for grammatical consistency.

K(1)(d) is created to clarify requirements for packaging, so that waste meets U.S. DOT requirements for transport.

K(2) is revised for brevity and clarity of language. “For example” is replaced with “e.g.,”.

K(3) is revised to make the requirement to allow access proactive instead of reactive.

K(4) is revised for grammatical consistency.

K(4)(a) is added to include a requirement for sign size. This will make it easier for inspectors to require the replacement of signs that are ineffective.

K(4)(b) is added to include a requirement for sign replacement as needed. This will make it easier for inspectors to require the replacement of signs that are ineffective.

K(5) is revised for grammatical consistency and to explicitly require that putrescent waste must be handled immediately.

K(5)(a) is revised for grammatical and formatting consistency.

K(5)(b) language is moved to K(5)(c).

K(5)(b) is added to clarify storage requirements and timeframes when a generator chooses to properly treat waste and then send it for further treatment.

K(5)(c) language is moved to K(5)(d).

K(5)(c) is revised to include language originally in K(5)(b) and for formatting consistency.

K(5)(d) is created from language that was originally in K(5)(c) and this language is revised for grammatical and formatting consistency.

K(6) is revised for clarity of language.

K(7) is reorganized for clarity of language.

**L. Disinfection Standards.**

L(1) is revised for grammatical consistency.

L(1)(a) is revised for grammatical consistency.

L(1)(b) is revised to include changes from internal review for the Governor’s Regulatory Review Task Force to ease the burden of disinfecting the cargo-carrying body of the vehicle if more than one transport route is driven per day. Facilities are still required to disinfect spilled waste immediately. The language is reorganized to take these new requirements into account.

L(1)(b)(i) is created to change the time requirement for disinfection.

L(1)(b) (ii) is created to require rented vehicles that are used to transport infectious waste be disinfected before being returned to their owner.

L(1)(c) is revised for clarity and for grammatical consistency.

L(1)(d) is created to require transporters to keep a record of disinfecting vehicles.

L(2) is deleted, as it is a suggestion, not a requirement. It will therefore be moved to a guidance document rather than staying in the Regulation.

L(3) is renumbered as L(2) and revised for clarity and grammatical consistency.

**M. Manifest Form Requirements for Generators.**

M(1) is reorganized for clarity of language, grammatical consistency, and to separate requirements.

M(1)(a) through M(1)(k) are moved to M(2) and renumbered.

M(1)(a) is revised to include language that was originally in M(1).

M(1)(b) is revised to include language that was originally in M(1).

M(1)(c) is revised to include language that was originally in M(1).

M(1)(d) is revised to include language that was originally in M(1).

M(2) is renumbered as M(3).

M(2) is created from language that was originally in M(1).

M(1)(a) is renumbered as M(2)(a).

M(1)(b) is renumbered as M(2)(b).

M(1)(c) is renumbered as M(2)(c).

M(1)(d) is renumbered as M(2)(d).

M(1)(e) is renumbered as M(2)(e).

M(1)(f) is revised for clarity and consistency with U.S. DOT requirements and renumbered as M(2)(f).

M(1)(g) is revised for formatting consistency and renumbered as M(2)(g).

M(1)(h) is revised for formatting consistency and renumbered as M(2)(h).

M(1)(i) is revised for clarity of language and renumbered as M(2)(i).

M(1)(j) is revised for clarity of language, to add “and” at the end, and renumbered as M(2)(j).

M(1)(k) is revised for formatting consistency, renumbered as M(2)(k), and ‘and’ is added at the end.

M(1)(l) is revised to delete the requirement that the treatment facility must sign the manifest because the generator has no direct contact with the treatment facility and may be unable to get this piece of information. Language is added to require that any special handling instructions be noted on the manifest, such as incineration requirements.

M(2) is revised for grammatical and formatting consistency and renumbered as M(3).

M(3) is revised for grammatical and formatting consistency as well as clarity of language and renumbered as M(4).

M(4) is revised for formatting consistency and renumbered as M(5).

M(6) is created to match the U.S. DOT exemption for waste that is transported by USPS.

**N. Infectious Waste Transporter Requirements.**

N(1) is revised for formatting and grammatical consistency.

N(2) is revised for grammatical consistency and clarity of language.

N(3) is revised for grammatical consistency.

N(3)(a) is revised for formatting consistency and clarity of language.

N(3)(b) is revised for grammatical consistency.

N(4) is revised for clarity of language and grammatical consistency.

N(5) is revised for clarity of language and grammatical consistency.

N(5)(a) is revised for grammatical consistency.

N(5)(b) is revised for internal grammatical consistency.

N(5)(c) is revised for internal grammatical consistency.

N(6) is revised for clarity and grammatical consistency.

N(6)(b) is revised to refer to the newly revised definition of ‘contingency plan’.

N(6)(d) is revised for internal grammatical consistency.

N(7) is revised to clarify that the plan submitted is a draft and it must be revised as needed to meet the Department’s approval, in language originally from N(7)(a).

N(7)(a) is deleted because this language is now included in N(7).

N(7)(b) is renumbered N(7)(a) and revised for grammatical consistency.

N(7)(c) is renumbered as N(7)(b) and revised for clarity of language and grammatical consistency.

N(8) is revised for clarity of language.

N(9) is reorganized so that requirements are listed in the order that they should be completed and clarified as to who should complete actions.

N(10) is deleted as the language about cleaning up discharges was strengthened in N(9) during the most recent regulatory revision and N(10) is now redundant.

N(11) is renumbered as N(10) and revised for grammatical consistency.

N(12) is renumbered as N(11), clarified, and language moved from Q(1)(b) as it pertains better to Section N.

N(12) is revised to delete language added for N(11) and language is added to match the U.S. DOT exemption for waste that is transported by government employees in government vehicles.

**O. Transporter Registration Requirements.**

O(1) is revised for grammatical consistency.

O(1)(a) is revised for clarity and to reduce redundancy.

O(1)(b) language is moved to O(1)(d).

O(1)(b) is revised to require the transporter provide more information about company structure.

O(1)(c) language is moved to O(1)(e).

O(1)(c) is revised to require the transporter provide more information about contacts at the company.

O(1)(d) language is moved to O(1)(f).

O(1)(d) is revised with language originally in O(1)(b).

O(1)(e) language is moved to O(1)(g).

O(1)(e) is revised with language originally in O(1)(c) and for grammatical consistency.

O(1)(f) language is moved to O(1)(j).

O(1)(f)(i) language is moved to O(1)(j)(i).

O(1)(f)(ii) language is moved to O(1)(j)(ii).

O(1)(f)(iii) language is moved to O(1)(j)(iii).

O(1)(f) is revised with language originally in O(1)(d) and revised for grammatical consistency.

O(1)(g) language is moved to O(1)(h).

O(1)(g) is revised with language originally in O(1)(e) and revised for grammatical consistency.

O(1)(h) is created with language originally in O(1)(g) and revised for clarity of language.

O(1)(i) is created to require that transporters provide their Employer Identification Number upon registration, if they have one, to allow better identification and tracking of business identities and for consistency with Department standards.

O(1)(j) is created from language originally in O(1)(f) and revised to be more explicit about the U.S. DOT insurance requirements that transporters have to meet, allowing for the possibility that these requirements may get more stringent in the future.

O(1)(j)(i) is created from language originally in O(1)(f)(i) and revised to clarify insurance requirements and to require that the Department be notified if there are changes in a transporter’s insurance.

O(1)(j)(ii) is created from language originally in O(1)(f)(ii) and revised for grammatical consistency.

O(1)(j)(iii) is created from language originally in O(i)(f)(iii).

O(1)(k) is added to require the transporter to provide an email address so that the Department can have better, easier communication with them.

O(2) is revised for formatting consistency and to clarify at whom the requirement is directed.

O(2)(a) is revised for clarity of language and grammatical consistency.

O(2)(b) is revised for grammatical consistency.

O(2)(c) is revised for clarity and grammatical consistency.

O(3) is revised for grammatical and formatting consistency and updated codification.

O(6) is revised for clarity and to update the source of requirements for parcels going through the mail.

**P. Transporter Acceptance of Infectious Waste.**

P is revised to recognize that a transporter becomes responsible for infectious waste when they load it on their vehicle or take it off the generator or previous transporter’s property. P is moved for stylistic consistency.

P(1) is revised for grammatical consistency.

P(1)(a) is revised for clarity and to add an exception for trailers loaded and sealed prior to a transporter’s acceptance (language originally in P(3)).

P(1)(b) is revised for clarity and to add an exception for trailers loaded and sealed prior to a transporter’s acceptance (language originally in P(3)).

P(1)(c) is revised for formatting consistency.

P(2) is revised for grammatical consistency and to separate requirements.

P(2)(a) is revised with language originally in P(2) and for clarity of language and grammatical consistency. The original language from P(2)(a) is moved to P(2)(c).

P(2)(b) is revised with language originally in P(2).

P(2)(c) is created from language originally in P(2)(a).

P(3) is deleted because the language was added to P(1)(a) and P(1)(b).

P(3)(a) is deleted because the language is redundant to that in P(1)(c).

P(3)(b) is deleted because the requirement is redundant to that in Q(1)(c).

**Q. Transport Vehicle Requirements.**

Q(1) is revised to pull a common factor out of the following requirements, so that it does not have to be repeated in each phrase.

Q(1)(a) is revised for grammatical consistency and to make the transporter proactive instead of reactive.

Q(1)(b) is moved to Section N as the information pertains to that Section.

Q(1)(b) is revised to add language originally in Q(1)(c).

Q(1)(c) is renumbered as Q(1)(b).

Q(1)(c) is revised to add language originally in Q(1)(d).

Q(1)(d) is renumbered as Q(1)(c).

Q(1)(d) is revised to add language originally Q(1)(e).

Q(1)(e) is revised renumbered as Q(1)(d).

Q(1)(e) is revised to add language originally in Q(1)(f).

Q(1)(f) is renumbered as Q(1)(e).

Q(1)(f) is revised to add language originally in Q(1)(g).

Q(1)(f)(i) through (iii) are deleted and the language is moved to Q(1)(g)(i) through (iii).

Q(1)(g) is renumbered as Q(1)(f).

Q(1)(g) is revised to add language originally in Q(1)(h).

Q(1)(g)(i) is created from language originally in Q(1)(f)(i).

Q(1)(g)(ii) is created from language originally in Q(1)(f)(ii).

Q(1)(g)(iii) is created from language originally in Q(1)(f)(iii) and revised to add “and” at the end.

Q(1)(h) is renumbered as Q(1)(g).

Q(1)(h) is deleted, as the language was moved to Q(1)(g).

Q(2) is revised for clarity and for formatting consistency.

Q(3)(a) is revised for clarity and grammatical consistency.

Q(3)(b) is revised for clarity and grammatical consistency and to include “and” at the end.

Q(3)(c) is revised for grammatical consistency.

Q(4) is revised for technical consistency.

**R. Manifest Requirements for Transporters.**

R(1) is revised as not all transporters use the Department provided form, therefore its instructions would not be applicable in all cases and for grammatical consistency.

R(2) is revised for grammatical consistency.

R(2)(a) is revised for grammatical consistency and to include “and” at the end.

R(2)(b) is revised for grammatical consistency.

R(3) is revised for grammatical consistency and clarity of language.

R(4) language is moved to R(5).

R(4) is revised to add language to clarify who is responsible for filling in the date that waste is transferred on the manifest and for grammatical consistency.

R(5) language is moved to R(6).

R(5) is revised to add language originally in R(4).

R(5)(a) language is moved to create R(6)(a) and deleted.

R(5)(b) language is moved to create R(6)(b) and deleted.

R(6) language is moved to R(7).

R(6) is revised to add language originally in R(5) and for clarity of language and grammatical consistency.

R(7) language is moved to create R(8).

R(7) is revised to add language originally in R(6), for clarity of language, and grammatical consistency.

R(7)(a) language is moved to create R(8)(a) and deleted.

R(7)(b) language is moved to create R(8)(b) and deleted.

R(8) is created from language originally in R(7).

R(8)(a) is created from language that was originally in R(7)(a) and is revised for technical consistency.

R(8)(b) is created from language that was originally in R(7)(b) and is revised for clarity of language.

**S. Storage Tank Requirements.**

The title of the section is revised to reflect that we are concerned with the storage of treatment residue, and the tank only as a storage method.

S(1) is revised to clarify the timeline for installing tanks that meet the new requirements, which were added when the Regulation was revised in 2010, for clarity, and for grammatical consistency.

S(2) is revised for grammatical consistency and to reflect the primary concern is the storage of treatment residue.

S(2)(a) is revised for clarity and formatting consistency.

S(2)(b) is revised for formatting and grammatical consistency.

S(2)(c) is revised for formatting and grammatical consistency.

S(2)(d) is revised for clarity and formatting and grammatical consistency.

S(2)(e) is revised for clarity and formatting and grammatical consistency.

S(2)(f) is revised for clarity of language.

S(2)(g) is revised for formatting and grammatical consistency.

S(2)(h) is revised for formatting and grammatical consistency and to delete an outdated reference.

S(3) is revised for clarity of language.

**T. Infectious Waste Treatment.**

T(1) is revised to add the requirement that treatment must be in accordance with this Regulation (originally in T(2)), for clarity of language, and for grammatical consistency.

T(2) is revised for clarity and to delete the requirement that was added in T(1).

T(3) is revised for grammatical consistency and to clarify the requirements for alternate treatment technology approvals and renewals.

T(4)(a) and (b) are created from language moved from T(5)(a) and (b).

T(5)(a) and (b) are moved to T(4)(a) and (b) as the requirements in (a) and (b) are related to waste disposal before treatment as opposed to storage.

T(5)(a) and (b) are deleted.

T(6) is deleted, as this requirement is a duplicate of that already included for each type of facility regulated.

T(7) is renumbered as T(6), revised for clarity, and reorganized to separate requirements.

T(6)(a) is created from a requirement that was originally in T(7).

T(6)(b) is created from a requirement that was originally in T(7).

T(8) is renumbered as T(7) and revised to refer to treatment standards already incorporated in Section U .

T(9) is renumbered as T(8).

T(9) is deleted, as the language was moved to T(8).

**U. Infectious Waste Treatment Facility Standards.**

The title of the section is revised to better reflect the contents and reduce redundancy.

U(1) is revised to include Section X as a possible exemption because facilities in Section X are regulated under permit by rule requirements and revised for clarity.

U(2) is revised for clarity of language and for grammatical consistency.

U(3) is deleted because it is redundant to T(1).

U(4) is renumbered as U(3), revised for clarity and grammatical consistency, and to pull a common factor out of the following requirements, so that it does not have to be repeated in each phrase.

U(4)(a) is renumbered as U(3)(a) and revised for internal grammatical consistency.

U(4)(b) is renumbered as U(3)(b) and revised for internal grammatical consistency.

U(4)(c) is renumbered as U(3)(c) and revised for internal grammatical consistency.

U(4)(d) is renumbered as U(3)(d) and revised for internal grammatical consistency.

U(4)(e) is renumbered as U(3)(e) and revised for a more complete description of the plan required.

U(4)(f) is renumbered as U(3)(f) and revised for internal technical consistency.

U(4)(g) is renumbered as U(3)(g) and revised for clarity and technical consistency.

U(4)(h) is renumbered as U(3)(h) and revised for clarity and internal grammatical consistency.

U(4)(i) is deleted because it is a duplicate requirement based on W(7)(i).

U(4)(j) is renumbered as U(3)(i) and revised for internal grammatical consistency.

U(4) is revised to delete language moved to U(3) and to include language moved from U(5).

U(4)(a) is deleted because the language was moved to U(3)(a).

U(4)(b) is deleted because the language was moved to U(3)(b).

U(4)(c) is deleted because the language was moved to U(3)(c).

U(4)(d) is deleted because the language was moved to U(3)(d).

U(4)(e) is deleted because the language was moved to U(3)(e).

U(4)(f) is deleted because the language was moved to U(3)(f).

U(4)(g) is deleted because the language was moved to U(3)(g).

U(4)(h) is deleted because the language was moved to U(3)(h).

U(4)(j) is deleted because the language was moved to U(3)(i).

U(5) is revised to delete language moved to U(4) and to include language moved from U(6).

U(5) is renumbered as U(4) and revised to remove the reference to disposal facilities, as this Regulation is not designed to regulate facilities that dispose of infectious or other waste.

U(6) is revised to delete language moved to U(5) and separate requirements.

U(6) is revised to describe how untreated waste must be handled.

U(7) is revised for grammatical consistency.

U(7)(a) is revised to reduce redundancy.

U(7)(b) is revised for clarity of language.

U(7)(c) is revised to include the word “and” at the end.

U(7)(d) is revised to delete the word “and” at the end.

U(7)(e) is renumbered U(8) because it is a separate statement from the rest of U(7) and is revised to put actions in order of priority.

U(7)(e) is deleted bacause the language was moved to U(8).

U(8) is revised to include text originally in U(7)(e) and to delete text moved to U(9).

U(8) is renumbered as U(9) and revised for clarity and the requirement to submit a training protocol is moved to Section W. The requirement to submit training documentation is deleted as an unnecessary burden, as that documentation can be checked during a regular inspection.

U(9) is revised to include text originally in U(8) and to delete text moved to U(10).

U(9) is renumbered as U(10) and revised for clarity of language and to separate requirements.

U(10) is revised to include text originally in U(9) and to delete language moved to U(10)(a), (b), and (c).

U(10)(a) is revised to include text originally in U(10) and to delete language moved to U(11)(a).

U(10)(b) is revised to include text originally in U(10) and to delete language moved to U(11)(a).

U(10)(c) is revised to include text originally in U(10) and to delete language moved to U(11)(a).

U(10)(d) is deleted and the text moved to create U(11)(d).

U(10)(e) is deleted and the text moved to create U(11)(e).

U(11) is revised to include text originally in U(10), to delete language moved to U(12), and revised for clarity of language.

U(11)(a) is created to include text originally in U(10)(a) and revised for grammatical consistency.

U(11)(b) is created to include text originally in U(10)(b) and revised for clarity of language and grammatical consistency.

U(11)(c) is created to include text originally in U(10)(c) and revised for clarity of language and grammatical consistency.

U(11)(d) is created to include text originally in U(10)(d).

U(11)(e) is created to include text originally in U(10)(e) and revised to simplify and clarify language.

U(11) is renumbered as U(12) and revised for clarity of language.

U(12) revised to include text originally in U(11) and to delete text moved to U(13).

U(12) is renumbered as U(13) and revised for clarity of language and grammatical consistency.

U(13) is revised to include text originally in U(12) and to delete text moved to U(13)(a), U(13)(b), U(13)(c), and U(14).

U(13)(a) is created from language originally in U(12), revised to delete the requirement of a bound log book, and revised to include changes from internal review for the Governor’s Regulatory Review Task Force, and to delete language moved to U(14)(a).

U(13)(b) is revised to include text from U(12)(a) and to delete text moved to U(14)(b).

U(13)(c is revised to include text from U(12)(c) and to delete language moved to U(14)(c).

U(13) is renumbered U(14) and revised for clarity of language.

U(14)(a) is created from language moved from U(13)(a).

U(13)(b) is created from language moved from U(13)(b).

U(13)(b) is renumbered as U(14)(b) and revised to use the correct term.

U(14)(c) is created from language moved from U(13)(c) revised to recognize that the Infectious Waste Program would not be issuing authorizations to landfills and should not be setting requirements.

U(13)(c) is renumbered as U(14)(c) and revised to recognize that the Infectious Waste Program would not be issuing authorizations to landfills and should not be setting requirements.

U(14) is renumbered as U(15) and revised for clarity of language.

U(14)(a) is renumbered as U(15)(a) and revised for clarity of language and grammatical consistency.

U(14)(b) is renumbered as U(15)(b) and revised to separate requirements and include the requirement that pressure be recorded during treatment.

U(14)(c) is renumbered as U(15)(c) and revised to require calibration for pressure gauges and thermometers annually. The requirement to calibrate thermometers annually was originally in U(14)(b).

U(15)(d) is created to require that steam sterilizers meet manufacturer’s specifications for treatment or prove that treatment is effective, if specifications are not available or need to be updated. Requirements for treatment are moved from U(14)(b) and revised to allow flexibility for updates of technology.

U(14)(d) is renumbered to U(15)(e).

U(14)(e) is renumbered as U(15)(f) and revised to match current biological naming standards and for clarity.

U(14)(f) is renumbered as U(15)(g) and revised to update and specify citations.

U(14)(g) is renumbered as U(15)(h) and revised for grammatical and formatting consistency.

**V. Intermediate Handling Facilities Standards.**

The section title is revised for grammatical consistency.

V(1) is revised to specify the citation and for grammatical consistency.

V(2) is revised for clarity and to pull a common factor out of the following requirements, so that it does not have to be repeated in each phrase.

V(2)(a) is revised for internal grammatical consistency.

V(2)(b) is revised for internal grammatical consistency.

V(2)(c) is revised for internal grammatical consistency.

V(2)(d) is revised for internal grammatical consistency.

V(2)(e) is revised for a more complete description of the plan required.

V(2)(f) is deleted as redundant with V(2)(e).

V(2)(g) is renumbered as V(2)(f), revised for technical consistency, and revised to add the word “and” at the end.

V(2)(h) is renumbered as V(2)(g) and revised for grammatical consistency.

V(2)(i) and (j) are deleted. A contingency plan is required in the permit application and an intermediate handling facility should not be generating waste for disposal.

V(3) is revised for clarity of language.

V(4) is revised for clarity and grammatical consistency, to add Department approval to the closure process, and to separate requirements.

V(5) is revised from language originally in V(4) and revised to reflect that the Program does not regulate facilities that dispose of infectious waste.

V(5) is renumbered as V(6).

V(6) is revised for clarity of language.

V(5)(a) is renumbered as V(6)(a) and revised to reduce redundancy.

V(5)(b) is renumbered as V(6)(b) and revised to use clearer language.

V(5)(c) is renumbered as V(6)(c) and revised to include “and”.

V(5)(d) is renumbered as V(6)(d) and revised to delete “and”.

V(5)(e) is renumbered as V(7) because it should be a separate requirement and revised to put actions in order of priority and for clarity of language.

V(6) is renumbered as V(8), revised for clarity, and the requirement to submit a training protocol is moved to Section W. The requirement to submit training documentation is deleted as an unnecessary burden, as that documentation can be checked during a regular inspection.

V(7) is renumbered as V(9).

V(9) is revised to clarify responsibilities, for grammatical consistency, and to separate requirements.

V(9)(a) is created from language originally in V(9).

V(9)(b) is created from language originally in V(9).

V(9)(c) is created from language originally in V(7).

V(8) is renumbered as V(10) and revised for grammatical consistency.

V(9) is renumbered as V(11) and revised for clarity of language and to separate requirements.

V(9)(a) is deleted and the language is moved to V(11)(b).

V(9)(b) is deleted and the language is moved to V(11)(c).

V(10) is created from text originally in V(8).

V(11)(a) is created from language in V(11) and revised for clarity.

V(11)(b) is created from language in V(9)(a) and revised to ease the burden of disinfecting the cargo-carrying body of the vehicle if more than one transport route is driven per day. Facilities are still required to disinfect spilled waste immediately.

V(11)(c) is created from language in V(9)(b) and revised to use more precise language.

**W. Permit Applications and Issuance.**

W(1) is revised to include intermediate handling facilities in the requirement for a permit to be consistent with the rest of the regulation.

W(1)(a) through (d) are added to describe requirements for demonstration of need. These are derived from the requirements for solid waste facilities.

W(1)(a) is created to provide a geographical boundary for demonstration of need.

W(1)(b) is created to provided a maximum yearly treatment capacity.

W(1)(b)(i) is created to include the host county in a permitted treatment facility’s yearly treatment capacity.

W(1)(b)(ii) is created to include some of the waste treatment of surrounding counties in a permitted treatment facility’s yearly treatment capacity.

W(1)(c) is created to provide conditions under which a permitted treatment facility can request an expansion of their yearly treatment capacity.

W(1)(d) is created to provide conditions under which a short-term variance can be provided to a treatment facility’s permitted capacity.

W(2) is revised for grammatical consistency and formatting.

W(3) is revised for clarity of language.

W(3)(a) is revised for grammatical consistency.

W(3)(b) is revised for clarity of language.

W(3)(c) is revised to remove the word “or” at the end.

W(3)(d) is revised for clarity and to add the word “or” at the end.

W(3)(e) is created from language is W(4), as it is also an exemption from demonstration of need.

W(4) is deleted and the language moved to W(3)(e).

W(5) is renumbered W(4) and revised to allow forms other than Department-generated forms.

W(6) is renumbered W(5) and revised to clarify that the operations manual must be reviewed by the Department and that Section U and Section V each have instructions for the manual for the respective facilities.

W(7) is renumbered as W(6).

W(7)(a) is renumbered as W(6)(a) and revised for grammatical consistency.

W(7)(b) is renumbered as W(6)(b) and revised for grammatical consistency.

W(7)(c) is renumbered as W(6)(c).

W(7)(d) is renumbered as W(6)(d) and revised for formatting consistency and to remove the reference to disposal, as no infectious waste treatment facility would also be a final disposal facility for treated infectious waste.

W(7)(e) is renumbered as W(6)(e) and revised to elucidate which governmental body should have priority.

W(7)(f) is renumbered as W(6)(f) and revised to remove disposal from the processes that the facility can use with infectious waste.

W(7)(g) is renumbered as W(6)(g) and revised to remove disposal from the ways to handle infectious waste.

W(7)(h) is renumbered as W(6)(h) and revised to delete the requirement for a quality assurance and quality control report, as this was included in the requirements in Sections U and V. The requirement for training program requirements was added, moved from Sections U and V.

W(7)(i) is renumbered as W(6)(i) and revised to point to the new definition of ‘contingency plan’, to remove the specific requirement for a flood plan, as that may not be the most likely hazard for all facilities, and for grammatical consistency.

W(7)(j) is renumbered as W(6)(j).

W(7)(k) is renumbered as W(6)(k).

W(7)(l) is renumbered as W(6)(l).

W(7)(m) is renumbered as W(6)(m) and revised to better lead to the requirements for a treatment facility’s closure plan in (i) and (ii).

W(7)(m)(i) is renumbered as W(6)(m)(i) and revised to include closure procedures in the closure plan, which were not previously required.

W(7)(m)(ii) is renumbered as W(6)(m)(ii) and revised to give more detail to the requirements foreclosure cost estimates, including that they be based on permit conditions and industry pricing.

W(6)(n) is added to require treatment facilities to provide their Employer Identification Number upon registration, if they have one, to allow better identification and tracking of business identities and for consistency with Department specifications.

W(6)(o) is added to require treatment facilities to provide an email address, if they have one, to allow easier and better communication between the Department and the facility.

W(7)(n) is renumbered to W(6)(p) and revised to allow the Department to request information.

W(8) is renumbered as W(7) and revised to specify the citation and for grammatical consistency and to add expansion as a condition that would require notifying the Department..

W(7)(a) through W(7)(n) are deleted because the text is moved to W(6)(a) through W(6)(o).

W(9) is renumbered as W(8) and revised for formatting consistency.

W(10) is renumbered as W(9) and revised, based on the hazardous waste regulation, for clarity of language.

W(11) is renumbered as W(10) and revised to allow more flexibility for renewal permit applications.

W(12) is renumbered as W(11) and revised to separate requirements for clarity. A requirement is added that financial responsibility coverage must be in place before a final permit will be issued. The Department is given the ability to use financial responsibility coverage to provide better protection for the health and safety of the public and the environment if the owner or operator is in violation of permit requirements.

W(12), (13), and (14) are added from requirements originally in W(11).

W(13) is renumbered as W(15) and revised so that it is explicitly required that at no time should a permittee operate without financial responsibility coverage.

W(14) is renumbered as W(16) and revised for clarity and to explicitly allow the Department the ability to approve or deny requests for new waste streams.

**X. Permit by Rule.**

X(1) is revised to clarify that facilities that properly treat infectious waste but then send it for further treatment do not need a permit by rule and for grammatical consistency.

X(2) is revised for grammatical consistency.

X(2)(a) is revised for technical consistency and to clarify the citation.

X(2)(b) is revised so that the waste stored or disposed of by a permit by rule facility does not count toward the seventy-five percent that must have been generated onsite.

X(2)(c) is revised for grammatical consistency and for internal technical consistency.

X(2)(d) is revised for clarity of language and for internal technical consistency.

X(2)(d)(i) is revised for clarity of language and for internal technical consistency.

X(2)(d)(ii) is revised to allow for the possibility that a generator may accept waste from more than one type of facility.

X(2)(d)(iii) is revised to delete “and”.

X(2)(d)(v) is added to require facilities that treat waste under permit by rule to inform the Department of the method of treatment at the time of their notification.

X(3) is revised to clarify the citations and for grammatical consistency.

X(4) is revised for grammatical and technical consistency and to clarify the citations.

**Y. Manifest Form Requirements For Permitted Treatment Facilities.**

Y(1) is revised for grammatical consistency.

Y(2) is revised for clarity of language.

Y(2)(a) is revised for internal grammatical consistency.

Y(2)(b) is revised for internal grammatical consistency.

Y(2)(c) is revised for internal grammatical consistency.

Y(3) is revised for clarity and grammatical consistency.

Y(4) is revised for grammatical consistency.

Y(4)(f) is revised to explain what the representative is certifying.

Y(4)(g) is revised to allow for the possibility that the manifest is present but incorrect or that the treatment facility representative does not know the reason behind the manifesting issues.

**Z. Reporting For Permitted Treatment Facilities.**

Z(1) is revised to specify where in the Act the fees for permitted treatment facilities can be found.

Z(2) is revised for grammatical consistency.

Z(2)(a) is revised to clarify the requirement that permitted treatment facilities report the amount of waste accepted from each state rather than a total accepted and a list of those states.

**AA. Inspections and Record Keeping.**

AA(1) is revised for grammatical consistency.

AA(2) is revised to require facilities provide required documentation within 5 business days of a request and for grammatical consistency.

AA(3) is revised to reduce redundancy and for grammatical consistency.

AA(4) is revised to reduce redundancy and for grammatical consistency.

**BB. Enforcement.**

BB(1) is revised for grammatical and formatting consistency.

BB(2) is revised to reduce redundancy .

BB(2)(c) is revised for clarity of language.

**CC. Variances.**

CC(1) is revised to specify that variance requests must be written and that they may include more information than that required.

CC(1)(a) is revised for internal grammatical consistency.

CC(1)(b) is revised for internal grammatical consistency.

CC(1)(c) is revised for internal formatting and grammatical consistency.

CC(2) is revised to clarify the requirements for variance renewal requirements.

**DD. Fees Section.**

“Section” is deleted from the title for formatting consistency. Language is revised for formatting consistency and moved for stylistic consistency.

**EE. Appeals.**

This section is deleted to be consistent with Department policy.

**Notice of Public Hearing and Opportunity for Public Comment:**

DHEC Staff-Conducted Informational Forum:

Staff of the Department of Health and Environmental Control invites the public and regulated community to attend a staff-conducted informational forum to be held on October 21, 2016, from 9:00 a.m. to 11:00 am in Peeples Auditorium, third floor of the Sims Building at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC. The purpose of the forum is to answer questions, clarify any issues, and receive comments from interested persons on the proposed amendments to R.61-105, Infectious Waste Management Regulation.

Public Comment Period:

Interested persons are also provided an opportunity to submit written comments on the proposed amendments by writing to David Scaturo by mail at Division of Waste Management, Bureau of Land and Waste Management, South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201; by facsimile at (803) 898-0391; or by email at [infectiouswaste@dhec.sc.gov](mailto:infectiouswaste@dhec.sc.gov). To be considered, comments must be received no later than 5:00 p.m. on October 24, 2016, the close of the public comment period.

Comments received at the forum and/or submitted in writing by the close of the comment period on October 24, 2016, no later than 5:00 p.m. as noticed above shall be considered by staff in formulating the final proposed regulations for public hearing on December 8, 2016, as noticed below. Comments received shall be submitted in a Summary of Public Comments and Department Responses for the Board of Health and Environmental Control’s consideration at the public hearing noticed below.

Copies of the proposed amendments for public comment as published in the *State Register* on September 23, 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 topic and scan down to the proposed amendments of R.61-105. A copy can also be obtained by contacting Susan Jenkins at the above address or by email at [infectiouswaste@dhec.sc.gov](mailto:infectiouswaste@dhec.sc.gov).

Notice of Public Hearing Pursuant to S.C. Code Section 1-23-111:

Interested members of the public and regulated community are also invited to make oral and/or written comments on the proposed amendments of 61-105 at a public hearing to be conducted by the Board of Health and Environmental Control at its regularly scheduled meeting on December 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 twenty-four (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 Regulation has no anticipated substantial fiscal or economic impact on the State or its political subdivisions. Implementation of these regulation amendments 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 these proposed amendments.

**Statement of Need and Reasonableness:**

This Statement of Need and Reasonableness complies with S. C. Code Ann. Sections 1-23-115(C)(1)-(3) and (9)-(11) and 1-23-110(3)(h).

DESCRIPTION OF REGULATION: Proposed amendment of Regulation 61-105, Infectious Waste Management Regulations (R.61-105).

Purpose: These amendments seek to provide greater protections for the public, remove any perceived uncertainty with respect to existing provisions, and ensure consistency with U.S. Department of Transportation regulations.

Legal Authority: The legal authority for R.61-105 is 1976 Code Sections 44-93-10 *et seq.*

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.61-105, which 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 category and scroll down to R.61-105. 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:

The proposed amendments are needed to realize the following anticipated benefits:

1. The Department proposes to amend R.61-105 to require facilities that qualify for permit by rule to notify the Department of the type of treatment they will utilize and the requirements will be clarified for any waste facilities that are treating waste and then sending it offsite for further treatment. This will reduce the burden on these facilities while providing more information to the program about how waste is being treated in the State.

2. The Department proposes to amend R.61-105 to include body art facilities (tattoo and body piercing) in the types of facilities that generate infectious waste. According to Health Licensing Regulations S.C. Regulation 61-109, Standards for Permitting Body Piercing Facilities and S.C. Regulation 61-111, Standards for Licensing Tattoo Facilities, these facilities must meet the requirements of this Regulation. They are added to the definition of regulated infectious waste in this Regulation for consistency.

3. The Department proposes to amend R.61-105 to include a timeframe for records to be provided to the Department after an inspection. The program allows some flexibility for generators to provide paperwork if the primary contact is unavailable or records are stored offsite but wants to maintain consistency between inspectors for the timeframe for those records to be provided.

4. The Department proposes to amend R.61-105 to add timeframes to the requirements for variances and alternative treatment technology approvals, including expiration and opportunities for renewal. The program intends for these approvals to be reviewed periodically to provide opportunities to review changes to technology and best industry practices. This will allow the program to set these timeframes while still allowing facilities the opportunity to renew approvals if they so desire.

5. The Department proposes to amend R.61-105 to allow better communication with facilities and tracking of facilities. A requirement that facilities provide an email address will allow cheaper and more consistent communication with the regulated community. The requirement that facilities provide their Employer Identification Number is to provide consistency with Department standards.

6. The Department proposes to amend R.61-105 to revise and clarify annual reporting requirements for treatment facilities to require amounts of waste treated to correspond to the state of origin. This will provide information to the Department about how much waste from out of state is being sent to South Carolina for treatment. Facilities that treat waste through steam sterilization will be required to record the pressure during the treatment process as well as having the pressure gauge calibrated annually. These records are already required for temperature and are already being provided by the permitted treatment facility in the State.

7. The Department proposes to amend R.61-105 to ensure consistency with Department of Transportation regulations. These include marking and packaging requirements, exemptions for materials of trade, certain non-commercial transport, and transporter insurance requirements.

8. The Department proposes to amend R.61-105 to give protocol requirements for generators more specificity. The Regulation requires that regular generators have a protocol. The program intends to provide guidance about what should be included in that protocol.

9. The Department proposes to amend R.61-105 to clarify demonstration of need requirements and make them more consistent with those of other similar programs.

10. The Department proposes to amend R.61-105 to clarify the definition(s) and requirements for storage of waste. There are certain types of containers that are appropriate for waste collection but not storage. The amendments clarify this distinction.

11. The Department proposes to amend R.61-105 to revise financial assurance documentation requirements to better protect the Department and South Carolina residents. The amendments clarify this language adds the requirement that a facility will not receive a final permit until financial assurance coverage is in place.

12. The Department proposes to amend R.61-105 to update the standards for waste treatment technologies. These technologies are always being studied and upgraded. The amendments give treatment facilities the flexibility to utilize the most up-to-date technologies and practices while still requiring thorough treatment.

13. The amendments allow transporters to only disinfect their vehicles once a day, while still requiring immediate disinfection of visible debris and now requiring a log to be kept of disinfection. The requirement that transporters submit training documentation annually is removed, as inspectors check for these records during regular inspections.

14. The Department proposes to amend R.61-105 to revise requirements for handling product of conception waste and add specific requirements for treatment and documentation relating to this waste.

15. The Department proposes to amend R.61-105 to make stylistic changes to include corrections for internal consistency, clarification, references, codification, and spelling to improve the overall text of the Regulation, as well as to add or clarify definitions of terminology used in the Regulation.

16. The Department proposes to amend R.61-105 to add a table of contents.

The above 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:

There are no anticipated increased costs to the state and its political subdivisions associated with the implementation of these amendments. The proposed changes in the Regulation affect operational procedures by regulated facilities and would protect public health and the environment. There may be some increased costs for generators who were not packaging waste to meet U.S. Department of Transportation requirements. There are no other anticipated increased costs to generators.

There would be anticipated savings to transporters who would no longer have to disinfect their cargo-carrying body if more than one load of waste is carried per day. There also may be savings to governmental bodies transporting waste, due to exemptions by U. S. Department of Transportation. There may be an increased cost to transporters to purchase a log to record disinfection of the cargo-carrying body.

UNCERTAINTIES OF ESTIMATES:

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

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The proposed amendments to R.61-105 seek to support the Department’s goals relating to protection of the environment and public health through the anticipated benefits highlighted above.

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

If these amendments are not implemented, possible detrimental effects on the environment and public health include failure to realize the anticipated benefits highlighted above.

**Statement of Rationale:**

The Department proposes amending R.61-105, Infectious Waste Management to provide greater protections for the public, remove any perceived uncertainty with respect to existing provisions, and ensure consistency with U.S. Department of Transportation regulations.

~~Indicates Matter Stricken~~

Indicates New Matter

**Text:**

Text: Due to numerous revisions, R.61-105 will be replaced in entirety.

(Statutory Authority: 1976 S.C. Code ~~§§~~ Section 44-93-10 et seq. ~~; 44-93-100 (Act 351, July 20, 2002~~)

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**A. Purpose and Scope.**

(1) The purpose of this ~~regulation~~Regulation is to establish a program to carry out the provisions of the South Carolina Infectious Waste Management Act, Act Number 134 of 1989, Chapter 93 of Title 44 of the 1976 Code of Laws, as amended.

(2) This ~~regulation~~Regulation shall apply to infectious waste management as defined in 44-93-20 of the Act and as further defined herein, that is generated, stored, contained, transferred, transported, treated, destroyed, disposed, or otherwise managed within South Carolina.

(3) Generators, transporters, owners/operators of intermediate handling facilities, ~~and~~ or treatment facilities, ~~or~~ and any other persons who generate, store, contain, transport, transfer, treat, destroy, dispose, or otherwise manage infectious waste in South Carolina shall comply with:

(a) this ~~regulation.~~Regulation;

~~(4)~~ ~~In addition to the requirements of this regulation,~~ (b) all other applicable requirements of the Department of Health and Environmental Control ~~shall be met.~~; and

~~(5)~~ ~~In addition to the requirements of this regulation, generators, transporters, owners/operators of intermediate handling facilities and treatment facilities, or any other person shall comply with~~ (c) applicable Federal, State, county, and local rules, regulations, and ordinances.

**B. Severability.**

If any section, subsection, phrase, clause, or portion of this ~~regulation~~Regulation, or the applicability to any person, is adjudged to be unconstitutional or invalid for any reason by a court of competent jurisdiction, the remaining portions of this ~~regulation~~Regulation shall not be affected.

**C. Use of Number and Gender.**

As used in this ~~regulation~~Regulation:

(1) ~~W~~words in the masculine gender also include the feminine and neuter genders; ~~and~~

(2) ~~W~~words in the singular include the plural; ~~and~~

(3) ~~W~~words in the plural include the singular~~.~~; and

(4) ~~W~~words have common dictionary meaning unless otherwise specified.

**D. Definitions.**

(1) Definitions carry common dictionary meanings unless otherwise specified. When used in this ~~regulation~~Regulation the following words have the meaning given below~~:~~.

(a) “Act” means the S. C. Infectious Waste Management Act, Act Number 134 of 1989, Chapter 93 of Title 44 of the Code of Laws of 1976, as amended.

(b) “Alternate treatment technology” means any treatment technology not specifically defined in this Regulation, a combination of treatment technologies defined in this Regulation, or a combination of a treatment technology defined in this Regulation and a processing technology (a technology that alters, converts, or reduces size of the infectious waste without treating; e.g., shredding, screening, crushing, straining, grinding, magnetic separation).

(~~b~~c) “Board” means the South Carolina Board of Health and Environmental Control which is charged with the responsibility for implementation of the Infectious Waste Management Act.

(~~c~~d) “Certification” means a signed statement of professional opinion based upon knowledge and belief.

~~(de)~~ ~~“CFR” means the Code of Federal Regulations.~~ (e) “Closure” means the ~~point in time at which facility owners or operators discontinue operation by ceasing to accept, treat, store, or dispose of infectious waste~~ discontinuance of operation by ceasing to accept, treat, store, or dispose of infectious waste in a manner that eliminates the need for further maintenance and/or management and protects human health and the environment.

~~(f)~~ ~~“Commissioner” means the Commissioner of the Department or his authorized agent.~~

(~~g~~f) “Container” means any portable device in which a material is stored, transported, treated, disposed of, or otherwise managed.

~~(h)~~ ~~“Containment” means the packaging of infectious waste or the containers in which infectious waste is placed.~~ (~~i~~g) “Contingency Plan” means a document setting out an organized, planned, ~~and~~ coordinated, and technically and financially feasible course of action to be followed in case of a fire, flood, explosion, or release of infectious waste or infectious waste constituents, or interruption of normal procedures of infectious waste management including alternate treatment, storage, and/or disposal sites.

(h) “Demonstration of need” means the process through which a facility satisfies all of the requirements of Section W(1)(a) through (d). The dictionary or common meaning of “need” is not applicable for the purposes of this Regulation.

(~~j~~i) “Department” means the South Carolina Department of Health and Environmental Control, including personnel of the Department authorized by the Board to act on behalf of the Department or the Board.

~~(k)~~ ~~“Destination facility” means an infectious waste treatment facility which has received a permit from the Department in accordance with this regulation or an appropriate out-of-state facility and which is the facility designated by the generator to which waste is to be transported.~~ (~~l~~j) “Director” means the Director of the Department or his/her authorized agent.

(~~m~~k) “Discharge” or “infectious waste discharge” means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of infectious waste into or onto any land or waters of the State, including groundwater.

(~~m~~l) “Dispose” means to discharge, deposit, inject, dump, spill, leak, or place any waste into or on any land or water, including groundwater, so that the substance ~~may~~ has the potential to enter the environment or be emitted into the air or discharged into any waters, including groundwater.

(m) “Donate” means to transfer in exchange for no valuable consideration other than reasonable costs associated with transportation, implantation, processing, preservation, quality control, and/or storage.

(n) “EPA” means the U~~.~~nited S~~.~~tates Environmental Protection Agency.

~~(o)~~ ~~“EPA identification number” means the EPA assigned Medical Waste Identification Number.~~

~~(p)~~ ~~“Existing facility” means a facility which was in operation under permits issued by the Department on June 8, 1989.~~ (~~q~~o) “Expand” means ~~an~~to increase ~~in~~ the capacity of ~~the~~a facility or ~~an~~to increase ~~in~~ the permitted quantity of infectious waste ~~received by a facility that exceeds a permit condition~~treated.

(~~r~~p) “Facility” means a location or site within which infectious waste is treated, stored, and/or disposed of.

~~(s)~~ ~~“Final closure” means the closure of all infectious waste management units at the facility in accordance with all applicable closure requirements so that infectious waste management activities are no longer conducted at the facility.~~

~~(t)~~ ~~“Free liquids” means liquids which separate readily from the portion of a waste under ambient temperature and pressure.~~ (~~u~~q) “Generator” means the person producing infectious waste except waste produced in a private residence.

(~~v~~r) “Generator facility” means a facility that generates and treats infectious waste ~~that~~and is owned or operated by a combination or an association of generators, a nonprofit professional association representing generators, ~~or~~ a nonprofit corporation controlled by generators, a nonprofit foundation of hospitals, or nonprofit corporations wholly owned by hospitals, if the waste is generated in this State and treatment is provided on a nonprofit basis.

(~~w~~s) “Generator Registration Status” means classification of a ~~facility that generates regulated infectious waste~~generator (e.g., small quantity generator), based on the largest amount of infectious waste generated, documented ~~by~~ in weight records, in any one calendar month of the last 12 (twelve) consecutive calendar months.

(~~x~~t) “Hazardous waste” means a ~~Resource Conservation and Recovery Act (RCRA)~~ hazardous waste as defined in ~~R.61-79.~~Section 261.3 of ~~the~~ S.C. Regulation 61-79, Hazardous Waste Management Regulations.

(~~y~~u) “Infectious waste” ~~or “waste”~~ means any material as defined in Section E of this ~~regulation~~Regulation. If ‘waste’ is not modified by any other descriptor (e.g., hazardous, radioactive), it refers to ‘infectious waste’.

(~~z~~v) “Infectious waste management” means the systematic control of the collection, source separation, storage, transportation, treatment, and disposal of infectious waste.

(~~aa~~w) “Intermediate handling facility” means any transportation related facility including loading docks, parking areas, storage areas, and other similar areas where shipments of infectious waste are held and/or handled for storage during the normal course of transportation and may be off loaded and on loaded into fixed storage.

(~~bb~~x) “Manifest” means the shipping document authorized and signed by the generator ~~which contains the~~that lists information required ~~by~~ in this ~~regulation~~Regulation.

(~~cc~~y) “Offsite” means not ~~onsite~~ on the site.

~~(dd) “Onsite” means the same or geographically contiguous property which may be divided by public or private right-of-way provided the entrance and exit between the properties is at a crossroads intersection and access is by crossing as opposed to going along the right-of-way.~~

(~~ee~~z) “Person” means an individual, partnership, co-partnership, cooperative, firm, company, public or private corporation, political subdivison, agency of this State, county, or local government, trust, estate, joint structure company, or any other legal entity or its legal representative, agent, or assigns.

(aa) “Planning radius” means the area around a treatment facility that is used for determining the need for new facilities and expansions of existing facilities.

(~~ff~~bb) “Products of conception” means fetal ~~tissues~~ and embryonic tissues resulting from implantation in the uterus.

(~~gg~~cc) “Pump Event” means any action where treatment residue is removed from a tank as described in Section S of this Regulation~~holding treatment residue~~.

(~~hh~~dd) “Radioactive material” means any and all equipment or materials ~~which~~that are radioactive or have radioactive contamination and ~~which~~ that are required pursuant to any governing laws, regulations, or licenses to be disposed of or stored as radioactive material.

(~~ii~~ee) “Release” means to set free from restraint or confinement or the occurrence of waste becoming unrestrained or unconfined.

~~(jj) “Secured area” means an area which is fenced with a locking gate or which is regularly patrolled by security personnel which prevents access by the general public. An area which has controlled access and barriers to prevent exposure of the general public.~~ (~~kk~~ff) “Site” means contiguous land, structures, and other appurtenances and improvements on the land used for generating, treating, storing, transferring, or disposing of regulated infectious waste ~~with~~that are under the same ownership. If the transport of waste between any two (2) generators is subject to federal or state transportation regulations, the generators are considered separate sites.

(~~ll~~gg) “Small quantity generator” means any in-state generator that produces less than fifty (50) pounds of infectious waste per calendar month.

(~~mm~~hh) “Solid waste” means any garbage, refuse, or sludge from a waste treatment facility, water supply plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agriculture operations, and from community activities. This term does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to ~~NPDES~~ National Pollutant Discharge Elimination System permits under the Federal Water Pollution Control Act, as amended, or the Pollution Control Act of South Carolina, as amended, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended. Also excluded from this definition are application of fertilizer and animal manure during normal agricultural operations or refuse as defined and regulated pursuant to the South Carolina Mining Act, including processed mineral waste, which will not have a significant adverse impact on the environment.

(~~nn~~ii) “State” means the ~~S~~state of South Carolina.

(~~oo~~jj) “Storage” means the actual or intended holding of infectious wastes or treatment residues either on a temporary basis or for a period of time, in a manner as not to constitute disposing of the wastes.

(~~pp~~kk) “Supersaturated” means ~~the condition when~~ any absorbent material ~~contains enough fluid so that it freely drips that fluid or if lightly squeezed, that fluid would drip from it.~~that drips or, if compressed, would drip or release fluid.

(~~qq~~ll) “Transfer facility” means any transportation related facility where shipments of infectious waste are held during the normal course of transportation including storage in fully-enclosed, leak-resistant portable storage unit(s) that do not have a permanent foundation or footing (e.g., cargo containers, storage containers, truck trailers, construction trailers, bulk solid waste containers)~~,~~ but are not offloaded or onloaded into fixed storage areas.

~~(rr) “Transport” means the movement of infectious waste from the generation site to a treatment facility or site for intermediate storage and/or disposal.~~ (~~ss~~mm) “Transporter” means a person ~~engaged in the offsite transportation of~~ who transports infectious waste by air, rail, ~~highway~~road, or water.

(~~tt~~nn) “Transport vehicle” means ~~a method~~ a cargo-carrying vehicle such as an automobile, van, tractor, truck, semitrailer, tank car, or rail car used for the transportation of cargo by any mode. Each cargo-carrying body (e.g., trailer, railroad freight car~~, etc.~~) is a separate transport vehicle.

(~~uu~~oo) “Treatment” means a method, technique, or process designed to change the physical, chemical, or biological character or composition of infectious waste so as to sufficiently reduce or eliminate the infectious nature of the waste.

(~~vv~~pp) “Treatment facility” means a facility ~~which~~ that treats infectious waste to sufficiently reduce or eliminate the infectious nature of the waste.

(~~ww~~qq) “Treatment residue” means the solid or liquid part that remains after infectious waste has been treated to sufficiently reduce or eliminate the infectious nature of the waste.

(rr) “Trust agreement” means a formal document, duly executed and notarized, which vests the rights of a facility of one or more of its assets in the Department in order for the Department to protect the health and safety of the public or the environment.

(~~xx~~ss) “Universal biohazard symbol” means the ~~symbol design that conforms to the design shown in the federal Occupational Safety and Health Administration (OSHA) Standards~~symbol that is universally recognized as a warning against substances that pose a threat to the health of living organisms, primarily that of humans, and is also the symbol shown in the federal Occupational Safety and Health Administration Standards.

(tt) “U.S. DOT” means the United States Department of Transportation.

(uu) “USPS” means the United States Postal Service.

**E. Definition of Infectious Waste.**

(1) An infectious waste is any used material ~~which~~ that is: generated in the health care community in the diagnosis, treatment, immunization, or care of human beings; generated in embalming, autopsy, or necropsy; generated in research pertaining to the production of biologicals ~~which~~ that have been exposed to human pathogens; generated in research using human pathogens; generated in body piercing as regulated pursuant to S.C. Regulation 61-109, Standards for Permitting Body Piercing Facilities; or generated in tattooing as regulated pursuant to S.C. Regulation 61-111, Standards for Licensing Tattoo Facilities, ~~and~~ ~~which~~ that is not excluded in E(2) below and ~~which~~ that is listed in the following categories ~~below:~~.

(a) Sharps. Any discarded article that may cause puncture or cuts~~, including but not limited to:~~ (e.g., needles, syringes, Pasteur pipettes, lancets, broken glass or other broken materials, ~~and~~ scalpel blades).

(b) Microbiologicals. Specimens, cultures, and stocks of human pathogenic agents~~, including but not limited to:~~ (e.g., waste ~~which~~ that has been exposed to human pathogens in the production of biologicals; discarded live and attenuated vaccines; ~~and~~ discarded culture dishes/devices used to transfer, inoculate, and mix microbiological cultures).

(c) Blood and Blood Products. All waste unabsorbed human blood, or blood products, or absorbed blood when the absorbent is supersaturated~~, including but not limited to:~~ (e.g., serum, plasma and other components of blood, ~~and~~ visibly bloody body fluids such as suctioned fluids, excretions, and secretions).

(d) Pathological Waste. All tissues, organs, limbs, products of conception, and other body parts that have been removed from the whole body~~, excluding tissues which have been preserved with formaldehyde or other approved preserving agents, and the~~. All bodily fluids ~~which~~ that may be infectious due to bloodborne pathogens~~. These body fluids are:~~, (i.e., cerebrospinal fluids, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, semen, ~~and~~ vaginal/cervical secretions, and any other bodily fluid that is visibly bloody). All tissues and bodily fluids (e.g., blood) resulting from the termination of a pregnancy.

(e) Contaminated Animal Waste. ~~A~~Contaminated animal waste includes animal carcasses, body parts and bedding ~~when the~~ of an animal that has been intentionally exposed to human pathogens in research or in the production of biologicals.

(f) Isolation Waste. ~~All~~Isolation waste includes waste generated from ~~communicable disease isolation of the Biosafety Level 4 agents, highly communicable diseases, pursuant to the `Guidelines for Isolation Precautions in Hospitals', published by the Centers For Disease Control.~~dangerous and/or exotic agents that pose a high risk of life-threatening disease, may be transmitted by the aerosol route, and for which there is no vaccine or therapy.

(g) Other Waste. Any other material designated by written generator policy as infectious~~, or any other material designated by a generator as infectious by placing the material into a container labeled infectious as outlined in Section J. Any solid waste which is mixed with infectious waste becomes designated as infectious and must be so managed unless expressly excluded in 2 (c) below~~. Any solid waste that is unintentionally mixed with infectious waste is designated as infectious and shall be managed as such unless expressly excluded in E(2)(a) through (c) of this Regulation.

(h) Infectious Waste Residues Resulting from Discharges. ~~A~~Infectious waste residue includes any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of ~~any~~ infectious waste.

(2) The following are excluded from the definition of infectious waste:

(a) ~~Hazardous~~hazardous waste ~~which~~ that is required to be managed pursuant to ~~the Hazardous Waste Management Regulations, R.~~ S.C Regulation 61-79, as amended, et seq.;

(b) ~~Radioactive~~radioactive material ~~which~~that is required to be managed pursuant to ~~the Department~~ S.C. Regulation 61-63, Radioactive Materials (Title A)~~.~~;

(c) ~~Mixed~~mixed waste containing regulated quantities of both ~~RCRA~~ hazardous waste and source, special nuclear, or byproduct material subject to the Atomic Energy Act of 1954, as amended, ~~are~~that is to be managed pursuant to all applicable regulations~~.~~;

(d) ~~Infectious wastes~~infectious waste generated in a private residence except when determined by the ~~Commissioner~~ Director to be an imminent or substantial hazard to public health or the environment~~.~~;

(e) ~~Etiologic~~etiologic agents or specimens being transported for purposes other than disposal to a laboratory consistent with ~~shipping and handling~~ requirements of the ~~U.S. Department of Transportation~~U.S. DOT~~,~~ and the U.S. Department of Health and Human Services~~, and all other applicable requirements~~ (e.g., shipping requirements, handling requirements)~~.~~;

(f) ~~Human~~human remains, corpses, ~~remains,~~ products of conception, and anatomical parts that are intended to be interred, cremated, or donated for medical research. Teeth ~~which~~ that are returned to a patient~~.~~;

(g) ~~Infectious~~infectious waste samples transported offsite by the EPA or the Department for possible enforcement actions or transportation of materials from other governmental response actions~~.~~; and

(h) pathological waste that has been preserved with formaldehyde or another approved preserving agents.

(3) The Department will determine how individual waste fits into the definitions and/or categories.

**F. Generator Requirements.**

(1) All in-state generators of infectious waste shall register in writing with the Department ~~in writing~~ on a Department approved form. Registration will be in a manner prescribed by the Department. At a minimum, ~~R~~registration notices will include ~~at a minimum~~:

(a) name of the business;

(b) name of the owner and responsible party, if different;

(c) physical location of the site ~~of~~ where waste is generated (each site of waste generat~~ed~~ion ~~must~~shall apply separately);

(d) mailing address of the site ~~of generation~~where waste is generated;

(e) telephone number of the site where waste is generated;

(f) a contact name of the site’s infectious waste coordinator(s);

(g) the categories and corresponding amount of infectious waste generated ~~annually~~monthly (estimated within plus or minus (+ or -) twenty (20) percent)~~.~~;

(h) the method of waste treatment and disposal; ~~and~~

(i) ~~the Employer Identification Number (EIN).~~an email address of the generator or the infectious waste coordinator (if available);

(j) the Employer Identification Number (EIN);

(k) the name of the transporter that will pick up the site’s infectious waste (if applicable); and

(l) the infectious waste transporter registration number of the transporter that will pick up the site’s infectious waste (if applicable).

(2) ~~When~~ If any changes occur in the information required in Section F(1) above, the Department ~~must~~shall be notified in writing of such changes within thirty (30) days of the change.

(3) Renewal of registration will be every three (3) years for all generators. Registered generators will be notified in writing by the Department of renewal requirements ~~by the Department~~. At the time of renewal, ~~F~~facilities that store liquid treatment residue in holding tanks ~~must~~shall submit records showing monitoring and pump events for the previous twelve (12) consecutive calendar months.

(4) Fees for registration will be due at the time of initial registration and annually thereafter. Fees will be assessed in accordance with Section DD below based on the generator~~’s~~ registration status.

(5) Each generator, except small quantity generators, ~~must~~shall have a designated infection control committee or coordinator with the authority and responsibility for infectious waste management.

(a) This committee or coordinator ~~must~~shall develop or adopt a written protocol to manage the infectious waste stream from generation until offered for transport. ~~If the generator treats infectious waste onsite, the written protocol must include contingency plans and a Quality Assurance program to monitor these onsite treatment procedures. Small quantity generators are not required to have an infection control committee or a written protocol.~~

(b) The protocol shall detail procedures that will facilitate compliance with all applicable regulatory requirements, including packaging, labeling, storage, and manifesting.

(c) If the generator treats infectious waste onsite, the written protocol shall include a contingency plan, as defined in this Regulation, and a quality assurance program to monitor onsite treatment procedures.

(6) Each generator ~~must~~shall:

(a) segregate infectious waste from other types of waste at the point of generation;

(b) ~~assure~~ ensure proper packaging and labeling of waste that is to be transported offsite as required in Section I and J, respectively, of this ~~regulation~~Regulation;

(c) ensure initiation of a manifest ~~is initiated~~ if waste is to be transported offsite as outlined in Section M of this ~~regulation~~Regulation;

(d) prevent infectious waste ~~containing~~ that contains radioactive material, ~~which is~~ distinguishable from background levels of radiation, from leaving the site ~~of generation~~where waste is generated when the material is under the jurisdiction of the United States Nuclear Regulatory Commission or an Agreement State;

(e) maintain records as required ~~by this regulation~~ in Section AA of this Regulation;

(f) store waste as outlined in Section K of this ~~regulation~~Regulation;

(g) manage infectious waste in a manner ~~which~~ that prevents exposure to the public or ~~release to the environment~~discharge; ~~and~~

(h) treat infectious waste onsite or transport offsite for treatment at a permitted treatment facility;

(i) offer infectious waste for ~~offsite~~ transport offsite only to a transporter who maintains a current registration with the Department or to the ~~U.S. Postal Service~~USPS or another parcel delivery service; ~~and~~

(j) ~~Obtain and record accurate weight of waste within fifty (50) days of shipment. Unabsorbed liquid waste produced during the embalming process is exempt from this requirement.~~obtain or document accurate weight of infectious waste generated and maintain this record as required in Section AA of the Regulation. If waste is treated onsite, the weight shall be recorded at the time of treatment. If waste is offered for transport, the weight shall be obtained within fifty (50) days after shipment. Unabsorbed liquid waste produced during the embalming process is exempt from this requirement; and

(k) ensure that products of conception are incinerated, except as exempted in E.2.f above, (e.g., label waste containers with the word ‘incinerate’, include incineration as a special handling instruction or as additional information on the manifest).

(7) When a waste generator relocates, closes, or ceases to generate infectious waste, the generator ~~must~~shall~~,~~ ~~within thirty (30) days, dispose of~~ transport or treat all infectious waste and treatment residue in accordance with this ~~regulation~~Regulation and notify the Department ~~must be notified~~ of the closure or cessation in writing within thirty (30) days.

(8) A registered generator of infectious waste may accept non-regulated infectious waste generated in a private residence, but once accepted, the generator shall assume full responsibility of generation and manage the waste according to this and all applicable regulations.

(9) It is unlawful for any person to release infectious waste or treatment residue into the environment of this State, except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility shall immediately investigate and confirm all suspected releases and report the findings to the Department within twenty-four (24) hours. Additional action may also be required by local, state, or federal officials to ensure that the infectious waste or treatment residue discharge does not present an actual or potential hazard to human health or the environment.

(10) For products of conception that are donated for medical research, the donating party shall:

(a) create a record on a Department approved form. The record shall include, at a minimum:

(i) the amount in pounds of the products of conception donated;

(ii) the date the products of conception were donated; and

(iii) an assurance signed by an authorized representative of the donating party, which states that the products of conception were, or will be, donated for medical research to a specified party. The assurance shall also attest that no payment involved exceeds, or will exceed, reasonable costs associated with the transportation, implantation, processing, preservation, quality control, and/or storage of the products of conception; and

(b) maintain a record of the donation for the period of time specified in Section AA(2) below.

**G. Small Quantity Generators.**

(1) All in-state small quantity generators, as defined in Section D of this Regulation, ~~must~~shall comply with the provisions of Section E; Section F~~, Parts~~ (1)~~-~~ through (3), and ~~Section F~~(6)~~-~~ through (~~8~~10) above; and ~~the following~~:

(a) shall manage sharps, microbiological cultures, products of conception, and human blood and blood products ~~must be managed~~ pursuant to this ~~regulation~~Regulation including but not limited to: packaging, labeling, storage, treatment, and weight generation rate requirements; and

(b) ~~small quantity generators~~ may dispose of all other infectious waste as solid waste after properly packaging to prevent exposure to solid waste workers and the public.

(2) Small quantity generators may transport their own waste without registering with the Department as a transporter, provided the waste meets the U.S. DOT requirements as a material of trade.~~Generators who qualify as small quantity generators, as defined above, may transport their own waste provided:~~

~~(a)~~ ~~they never transport more than fifty (50) pounds at any one time;~~

~~(b) the vehicle is identified as required in Section Q(1)(g);~~

~~(c) the waste is manifested as required in Section M;~~

~~(d)~~ ~~the waste is packaged and labeled as required in Section I and Section J; and~~

~~(e)~~ ~~the waste is not transported in the passenger compartment of the vehicle and is in a fully enclosed compartment which protects the container from weather conditions which would compromise the integrity of the container.~~

(3) If a small quantity generator offers infectious waste ~~for transport offsite for treatment at a destination facility~~to a registered transporter, the USPS, or other parcel delivery service, the waste ~~must~~shall be managed pursuant to Sections H through DD of this ~~regulation~~Regulation.

(4) If ~~in any calendar month~~ fifty (50) pounds or more of infectious waste ~~or more~~ is produced in any calendar month, the generator ~~must~~shall notify the Department in writing; manage infectious waste pursuant to the entire ~~regulation~~Regulation; and pay the annual fee as outlined in Section DD of this ~~regulation~~Regulation. A generator will be able to claim designation as a small quantity generator after submitting documentation demonstrating twelve (12) consecutive calendar months of waste production less than fifty (50) pounds, or if at the time of registration, the generator estimates that less than fifty (50) pounds a month will be generated.

**H. Segregation Requirements.** ~~Generators shall segregate infectious waste from solid waste as close to the point of generation as practical~~

(1) In order to avoid commingling of ~~the~~ waste, generators shall segregate infectious waste from other types of waste as close to the point of generation as practical. ~~If infectious waste is put in the same container as other waste, or if solid waste is put into a container labeled as infectious waste, the entire contents of the container shall be managed as infectious waste unless hazardous and/or radioactive material regulations apply, then the most stringent regulations apply as outlined in Section E (2) (a), (b), and (c).~~

(2) If infectious waste is packaged with or put in the same container as other types of waste, the entire contents of the container shall be managed as infectious waste unless hazardous and/or radioactive material regulations apply, then the most stringent regulations apply as outlined in E(2)(a) through (c) of this Regulation.

(3) If solid waste is unintentionally packaged with or placed into a container containing infectious waste or labeled as infectious waste, the entire contents of the container shall be managed as infectious waste unless hazardous and/or radioactive material regulations apply, then the most stringent regulations apply as outlined in E(2)(a) through (c).

**I. Packaging Requirements.**

(1) ~~Generators shall assure that infectious~~Infectious waste ~~is~~shall be packaged in accordance with the requirements of this section and in a manner to prevent any release of infectious waste from its packaging before storing, transporting, or offering for transport offsite. Absorbents may be used to aid in the prevention of releases. Waste intended to be transported by the ~~U.S. Postal Service~~USPS or other parcel delivery service ~~must~~shall meet the packaging requirements for infectious ~~waste~~substances in ~~the Domestic Mail Manual~~applicable USPS laws, regulations, and standards and the requirements of this Section.

(2) All sharps shall be placed and maintained in rigid, leak resistant, ~~and~~ puncture resistant containers ~~which are secured tightly to preclude loss of the contents and which are~~ that are designed for the safe containment of sharps.

(3) All ~~other types~~ categories of infectious waste, except as described in I(2), ~~must~~shall be placed, stored, and maintained before and during transport in a rigid or semi-rigid, leak resistant container ~~which~~ that is impervious to moisture.

(4) Containers ~~must~~shall have sufficient strength to prevent bursting and tearing and withstand handling, storage, transfer, or transportation without impairing the integrity of the container.

(5) Containers ~~must~~shall be ~~sealed and~~ closed and sealed tightly and securely, when full by weight or volume, or when putrescent, to prevent any discharge of the contents, at any time, until the container enters the treatment system.

(6) Plastic bags used ~~inside of containers~~to collect, store, or package infectious waste shall:

(a) be a red or orange color and

(b) have sufficient strength to prevent tearing.

(7) Roll-off containers, trailer bodies, or other vehicle containment areas cannot be used as rigid ~~containment~~containers.

(8) Infectious waste ~~must~~shall be contained in containers that are appropriate for the type and quantity of waste and ~~must~~shall be compatible with selected storage, transportation, and treatment processes.

(9) Reusable or disposable containers are acceptable. Reusable containers ~~must~~shall be properly disinfected after each use as outlined in Section L of this ~~regulation~~Regulation.

(10) Compaction of waste by any means shall be prevented prior to entering the containment of the treatment process.

~~(11)~~ ~~Exempt or excluded waste shall not be packaged as infectious waste. Waste packaged as infectious waste must be managed as infectious waste, except as indicated in Section I(12).~~

~~(12)~~ ~~When infectious waste is treated by a technology which does not change the appearance of the bag or outer container immediately after treatment, it shall be clearly labeled with the word “Treated” and the date of treatment on the outside of the container to indicate that the waste was properly treated. This labeling method may be hand written, an indicator tape or chemical reaction. The labeling process shall be water‑resistant and indelible.~~

**J. Labeling of Containers.**

(1) Generators and transporters ~~must assure~~ shall ensure that once sealed, containers of infectious waste are properly labeled in English as outlined in J(2) through (3) below.

(2) ~~Containers of infectious waste offered for transport offsite must be labeled on outside surfaces so that it is readily visible with:~~Containers of infectious waste intended to be offered for transport offsite shall be labeled with:

(a) ~~the universal biohazard symbol sign;~~required labeling, printing, or imprinting that is readily visible, indelible, and water-resistant;

(b) ~~the Department issued number of the in-state generator~~the universal biohazard symbol sign, if the container is not red;

(c) ~~a labeling process which is water-resistant and indelible; and~~the U.S. DOT Hazardous Materials label for an Infectious Substance, if the container is not labeled with the universal biohazard symbol sign;

(d) ~~the date the container was placed in storage or sent offsite, if not stored.~~the Department issued number of the in-state generator;

(e) the date the container was placed in storage or sent offsite, if not stored; and

(f) a communication indicating if there are special requirements (e.g., treatment method).

(3) Each bag used to ~~line the inside of an outer container shall~~collect, store, or package infectious waste shall be labeled, with indelible ink or imprinted, as outlined in J(2)(b) above~~(a) and (c)immediately above~~.

(4) Transporters ~~must~~shall label each outer container at the time it is accepted as specified in Section P(2), including (a) through (c), of this Regulation.

(5) Transporters ~~must~~shall affix required labels so that no other required markings or labels are obscured.

(6) Abbreviations may not be used in required labeling except for the common dictionary standard abbreviations.

(7) When infectious waste is treated according to the requirements of this Regulation by a technology or process that does not change the appearance of the bag or outer container immediately after treatment,

(a) the outside of the waste bag or container shall be clearly labeled with the word “Treated” and the date of treatment;

(b) the labeling process (e.g., handwriting, indicator tape, adhesive label) shall be water‑resistant and indelible; and

(c) if the person operating the treatment technology or process has a written agreement with the landfill accepting the treatment residue, the treatment residue is exempt from this labeling requirement.

**K. Storage of Infectious Waste.**

(1) Storage shall be in a manner and location ~~which~~ that affords protection from animals, vectors, ~~weather~~ adverse conditions (e.g., water, chemicals, fire, wind), theft, and vandalism and ~~which~~ that minimizes exposure to the public. Storage begins at the time the container is sealed.

(a) The waste ~~must~~shall not provide a food source or breeding place for insects or rodents.

(b) The waste ~~must~~shall be stored in a manner to prevent a loss of integrity of the packaging ~~protected to maintain the integrity of the packaging and provide protection from weather conditions such as water, rain, and wind~~.

(c) The waste ~~must~~shall be stored in a manner to prevent a release or discharge of the contents.

(d) Containers not designed to meet the packaging requirements of the U.S. DOT (e.g., small volume sharps containers, non-Packing Group II rated large volume sharps containers), shall not be stored without first packaging to meet those requirements.

(2) Outdoor storage areas ~~must~~shall be locked (~~for example:~~ e.g., roll-off containers, sheds, trailers, van bodies~~, or any other storage area~~).

(3) Storage areas ~~must allow access to authorized personnel only~~shall be managed to prevent access by unauthorized persons.

(4) Storage areas ~~must~~shall be labeled with the universal biohazard symbol sign.

(a) The symbol shall be of sufficient size to be readily visible.

(b) The sign shall be repaired or replaced when it no longer conveys an effective message (e.g., faded, damaged, missing letters).

(5) Infectious waste ~~must~~shall be maintained in a non-putrescent state, using refrigeration when necessary. Infectious waste determined to be putrescent shall be treated or sent offsite for treatment immediately.

(a) Generator onsite storage shall not exceed fourteen (14) days without refrigeration or thirty (30) days if maintained at or below forty-two (42) degrees Fahrenheit.

(b) If waste that is intended for offsite treatment is treated by the generator according to the treatment requirements of this Regulation, it shall be transported within fourteen (14) days after onsite treatment or thirty (30) days if maintained at or below forty-two (42) degrees Fahrenheit.

(~~b~~c) Once infectious waste leaves the generator site, the waste ~~must~~shall be delivered to a treatment facility within fourteen (14) days without refrigeration or thirty (30) days if maintained at or below forty-two (42) degrees Fahrenheit.

(~~c~~d) Treatment facility onsite storage shall not exceed fourteen (14) days at ambient temperature or thirty (30) days if maintained below forty-two (42) degrees Fahrenheit ~~and~~.

(6) All floor drains in storage areas ~~must discharge into~~ shall connect to a Department approved sanitary sewer system or be transported to a Department approved ~~sewerage~~wastewater treatment facility or to a permitted infectious waste treatment facility.

(7) All ventilation in storage areas ~~must~~ shall minimize human exposure and be in compliance with applicable Department air quality requirements ~~and minimize human exposure~~.

**L. Disinfection Standards.**

(1) Any material or surface ~~which~~ that comes in contact with infectious waste ~~must~~shall be disinfected prior to reuse.

(a) Reusable containers ~~which~~ that have been used to contain infectious waste ~~must~~shall be disinfected immediately after being emptied or treated along with the waste.

(b) ~~Vehicle bodies which have been used to store or transport infectious waste must be disinfected immediately after unloading.~~Cargo-carrying body disinfection requirements are listed below.

(i) Any cargo-carrying body that has been used to store or transport infectious waste shall be disinfected at least once each day of use.

(ii) Rented cargo-carrying bodies that have been used to store or transport infectious waste shall be disinfected immediately prior to returning them to the owner.

(c) ~~Spillage~~ Areas of visible contamination or spillage of infectious waste ~~must~~shall be disinfected immediately.

(d) A record of disinfection of cargo-carrying bodies shall be created. This record shall be maintained as required in Section AA of this Regulation.

~~(2)~~ ~~Disinfection can be accomplished by appropriate use of an EPA registered disinfectant used according to the label instructions at the tuberculocidal strength.~~ (~~3~~2) Drainage from decontamination processes ~~shall discharge~~shall connect to a Department approved sanitary sewer system or be transported to a Department approved sew~~er~~age treatment facility or permitted infectious waste treatment facility.

**M. Manifest Form Requirements For Generators.**

(1) A generator who transports, or offers for transport, infectious waste for offsite treatment, storage, or disposal, ~~must~~shall ensure~~prepare~~ a manifest is prepared. This manifest shall:

(a) ~~using~~be completed using DHEC Form 2116 or another Department approved form ~~and~~;

(b) be completed legibly;~~filled out in a legible manner~~

(c) be completed according to the instructions ~~for that form.~~; and

(d) ~~The manifest form must~~  accompany the waste at all times after leaving the generator's facility.

(2) The manifest form, ~~will~~at a minimum, shall include~~, but is not limited to~~:

(a) the name of the generator;

(b) the Department identification number (if applicable);

(c) the address of the site where the waste was generated;

(d) a general description of the nature of the waste being shipped;

(e) the number of containers of waste;

(f) the weight or volume (accurate to within ten (10) percent) of the total amount of waste;

(g) a certification by the generator stating “This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the U.S. D~~epartment of~~OT~~ransportation~~”;

(h) a certification by the generator that the shipment does not contain regulated quantities of hazardous waste as defined by ~~the~~ S.C. ~~Hazardous Waste Management~~ Regulation~~s~~ 61-79;

(i) a certification by the generator that the shipment does not contain radioactive material or waste above levels ~~determined~~ outlined in Section F(6)(d) of this Regulation;

(j) the name of the transporter who is to receive~~s~~ the waste from the generator, or subsequent transporter, and that transporter’s Department issued transporter registration number;

(k) the date the transporter accepted the shipment; and

(l) ~~the date the treatment facility accepted the shipment onsite;~~ a communication indicating if there are special requirements for waste handling (e.g., treatment method), if applicable.

(~~2~~3) The generator who offers regulated infectious waste for transport offsite shall ensure a manifest is initiated as required in Section M(1) above.

(~~3~~4) ~~This~~ The generator shall sign by hand or by another legally defensible signature ~~where required~~ in accordance with M(~~1~~2)(g) through (i), ~~(h), and (i)~~above.

(~~4~~5) The generator shall retain one (1) copy of the manifest after the transporter has accepted the shipment.

(6) Infectious waste that meets the packaging requirements for infectious substances in applicable USPS laws, regulations, and standards and is transported by the USPS or other parcel delivery service is exempt from the requirements of this Section.

**N. Infectious Waste Transporter Requirements.**

(1) Transporters of infectious waste ~~which~~ that is generated, stored, transferred or treated within ~~South Carolina~~ the State ~~must~~shall be registered with the Department prior to such activity unless otherwise provided ~~by~~ in this ~~regulation~~Regulation.

(2) Generators who transport their own infectious waste offsite, except those generators who qualify as small quantity generators in Section G of this ~~regulation~~Regulation, ~~must~~shall ~~also~~ comply with all applicable transporter requirements of this ~~regulation~~Regulation.

(3) Transporters of infectious waste ~~must~~shall comply with all applicable requirements of this ~~regulation~~Regulation during transportation and when the waste is at a transfer facility.

(a) ~~i~~Infectious waste may only be transferred from one vehicle to another ~~only~~ at a designated transfer facility~~; and~~.

(b) ~~i~~Infectious waste ~~may~~ shall not be unloaded into fixed storage at a transfer facility.

(4) Transporters ~~must also~~ shall comply with the requirements of Sections I and J of this Regulation when ~~they~~ the transporter repacks defective boxes of infectious waste.

(5) Transporters ~~must also~~ shall comply with applicable requirements of this ~~regulation~~Regulation when ~~they~~the transporter:

(a) stores infectious waste, even in the course of transport, in which case the requirements of Section K ~~must~~shall be met;

(b) removes infectious waste from reusable containers; or

(c) repackages or ~~modify~~ modifies packaging of infectious waste.

(6) Transporters ~~must~~shall develop a written infectious waste management plan ~~which~~ that ~~must address~~ includes at a minimum:

(a) a spill plan;

(b) contingency plans ~~for alternate treatment, storage and/or disposal sites~~ as defined in this Regulation;

(c) handling and storage of waste; and

(d) personnel health and safety training procedures.

(7) ~~A draft of the~~ The plan required in Section N(6) of this Regulation ~~must accompany~~shall be submitted for review with the annual registration application.

~~(a)~~ ~~The plan must meet the approval of the Department or be modified so that it will meet approval.~~

(~~b~~a) After approval by the Department, the infectious waste management plan ~~shall~~ becomes part of the registration and ~~must~~shall be adhered to by the registrant.

(~~c~~b) Changes in this plan ~~must~~shall be made by submittal of a written request to the Department. ~~which~~ ~~may~~ This request will be approved or ~~deny such request~~denied by the Department in writing.

(8) Transporters shall prevent ~~discharge~~release of infectious waste from a transport vehicle into the environment.

(9) It is unlawful for any person to ~~discharge~~release infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the ~~facility~~ transporter ~~must~~shall immediately investigate and confirm all suspected releases and report the findings to the Department within twenty-four (24) hours ~~and immediately investigate and confirm all suspected releases~~. ~~Action~~ Additional action may ~~then~~ also be required by local, state, or federal officials ~~so~~ to ensure that the infectious waste or treatment residue discharge does not ~~longer~~ present~~s~~ an actual or potential hazard to human health or the environment.

~~(10) The Department may require transporters to clean up and/or disinfect any infectious waste discharge that occurs during transportation or take such action as may be required by state, federal, or local officials so that the infectious waste discharge no longer presents a potential hazard to human health or the environment.~~

(~~11~~10) Transport vehicles containing infectious waste ~~must~~shall be managed to prevent access by unauthorized persons.

(~~12~~11) Containers of waste shall be loaded and unloaded so that no compaction or mechanical stress of the waste occurs during handling or transport.~~Reserved.~~

(12) Transportation of infectious waste in a vehicle operated onsite by a government employee solely for non-commercial governmental purposes is exempt from the requirements of Sections N through R of this Regulation.

**O. Transporter Registration Requirements.**

(1) Each transporter or transfer facility operator ~~must~~shall register with the Department on a form ~~which~~ that includes at a minimum:

(a) the ~~transporter’s~~ name of the business;

(b) the name of the owner and responsible party, if different;

(c) the contact person’s name:

(~~b~~d) the ~~transporter’s~~ mailing address;

(~~c~~e) the name for each intermediate handling facility, transfer facility, or transportation-related site ~~that~~ where the transporter will operate ~~at~~ in ~~South Carolina~~the State;

(~~d~~f) the address for each intermediate handling facility, transfer facility, or transportation-related site ~~that~~ where the transporter will operate ~~at~~ in ~~South Carolina~~the State;

(~~e~~g) the telephone number for each intermediate handling facility, transfer facility, or transportation-related site ~~that~~ where the transporter will operate ~~at~~ in ~~South Carolina~~the State;

~~(f) proof of financial responsibility for sudden and accidental occurrences in the amount of at least one million dollars ($1,000,000) per occurrence exclusive of legal defense costs. This financial responsibility may be established by any one or a combination of the following:~~

~~(i) evidence of liability insurance, either on a claim made or an occurrence basis, with or without the deductible, with the deductible, if any, to be on a per occurrence or per accident basis and not to exceed ten (10) percent of the equity of the registrant;~~

~~(ii) self insurance, the level of which shall not exceed ten (10) percent of equity of the registrant as evidenced by submission of financial information as required by the Department; or~~

~~(iii) other evidence of financial responsibility approved by the Department; and~~

(~~g~~h) this statement signed by hand by the owner or his authorized agent: “I certify, under penalty of criminal and/or civil prosecution for making or ~~submission of~~ submitting false statements, representations, or omissions, that I have read, understand, and will comply with S.C. Regulation 61-105, ~~the South Carolina~~ Infectious Waste Management Regulation ~~R.61-105~~.”

(i) the Employer Identification Number (EIN), if applicable;

(j) proof of financial responsibility as required by U.S. DOT. At a minimum, transporters are responsible for bodily injury, property damage, and environmental restoration due to sudden and accidental occurrences in the amount of at least one million dollars ($1,000,000) per occurrence exclusive of legal defense costs. This financial responsibility may be established by any one or a combination of the following:

(i) evidence of liability insurance. This insurance may be on a claim made or a per occurrence basis, with or without a deductible. The deductible, if any, shall be on a per occurrence or per accident basis and shall not exceed ten (10) percent of the equity of the registrant. The Department shall be notified prior to the policy being changed or cancelled;

(ii) self insurance, the level of which shall not exceed ten (10) percent of equity of the registrant as evidenced by submission of financial information as required by the Department; or

(iii) other evidence of financial responsibility approved by the Department; and

(k) an email address of the transporter (if available).

(2) ~~No person shall~~ A transporter shall not engage or continue to engage in transportation of infectious waste (except as outlined in Section N(2) above) in ~~South Carolina~~the State unless ~~they~~the transporter registers annually with the Department as an infectious waste transporter, and pays applicable fees as outlined in Section DD of this Regulation.

(a) Transporters ~~must~~shall notify the Department, in writing within thirty (30) days, if any changes occur in the information required for registration as outlined in Section O(1) above or if ~~they terminate their~~ the business is closed by the transporter~~; and~~.

(b) Transporters who fail to re-register by the expiration date of their registration ~~must~~shall cease all infectious waste transport activities on the expiration date.

(c) A transporter’s registration may be terminated or a new or renewal application may be denied by the Department for that transporter’s noncompliance ~~by the transporter~~ with any conditions of the registration, or requirements of this ~~regulation~~Regulation~~,~~ or the Act.

(3) The financial responsibility required in Section (O)(1)(~~c~~j), including (i) through (iii), above ~~must~~shall be maintained. If any change occurs in a registered transporter's financial responsibility, he ~~must~~shall cease to transport infectious waste and immediately notify the Department ~~immediately~~ to determine when and how transportation may be resumed.

(4) Transporters will receive an Infectious Waste Transporter Number upon completion of the registration process. Use of a false, expired, or invalid registration number is prohibited.

(5) Transporter registration and Infectious Waste Transporter Numbers are not transferable.

(6) Transporters ~~which~~ who~~neither~~ transport infectious waste in the State but do not pick up ~~infectious waste nor~~ or deliver infectious waste within ~~this state~~ the State are exempt from registration. Transporters who only transport ~~into or within this state~~ regulated infectious waste packaged in accordance with applicable ~~United States Postal Service~~USPS ~~Domestic Mail Manual~~ laws, regulations, and standards for infectious ~~waste~~substance packaging ~~requirements~~ (e.g., parcel carriers) are also exempt from registration.

**P. Transporter Acceptance of Infectious Waste.**

Transporter acceptance of infectious waste occurs when the transporter takes the waste offsite or when the waste is loaded onto the transport vehicle.

(1) Transporters shall accept for transport only infectious waste ~~which~~ that is:

(a) packaged as required in Section I above (unless accepted in a loaded and sealed trailer from a broker or generator);

(b) labeled as required in Section J above (unless accepted in a loaded and sealed trailer from a broker or generator); and

(c) accompanied by a properly completed manifest, as required in Section R of this Regulation.

(2) Transporters ~~must attach a waterproof identification label~~ shall ensure that labeling, printing, or imprinting on~~to~~ the outside of each container of infectious waste ~~they~~ accepted for transport~~. The label must~~:

(a) ~~be affixed~~is applied in a manner ~~which~~ that does not cover any other required labels or markings;~~. This identification label must include but is not limited to:~~  ~~(a)~~

(b) is readily visible, indelible, and water-resistant; and

(c) includes the transporter’s Department issued identification number~~,~~ or the transporter’s name, address, and phone number~~; and~~.  ~~(b)~~ ~~Reserved.~~

~~(3)~~ ~~If the transporter accepts loaded and sealed trailers from a broker or generator, that transporter does not have to assure proper packaging as required in Section I or proper labeling as required in Section J. However, the transporter must:~~  ~~(a)~~ ~~assure that the load is accompanied by a properly completed manifest; and (b)~~ ~~prevent discharges of infectious waste, especially fluids, from the cargo‑carrying body.~~

**Q. Transport Vehicle Requirements.**

(1) Each vehicle used to transport infectious waste ~~must~~ shall have a cargo-carrying body that meets at a minimum these requirements:

(a) ~~the vehicle shall have a fully enclosed, leak resistant cargo-carrying body which protects the waste from animals, vectors, weather conditions, and minimizes exposure to the public;~~fully enclosed, leak resistant and protects the waste from animals, vectors, weather conditions, and minimizes exposure to the public;

(b) ~~the containers of waste shall be loaded and unloaded so that no compaction or mechanical stress of the waste occurs during handling or during transit; (c)~~ ~~the cargo-carrying body shall be maintained in a sanitary condition and disinfected immediately after each unloading and as spills are detected;~~ maintained in a sanitary condition and disinfected at least once each day of use and as spills are detected;

(~~d~~c) ~~the cargo-carrying body shall be designed to prevent discharges of infectious waste, especially fluids, into the environment;~~ designed to prevent discharges of infectious waste, especially fluids;

(~~e~~d) ~~the cargo-carrying body shall be decontaminated of visible debris after each unloading;~~ decontaminated of visible debris after each unloading;

(~~f~~e) ~~the cargo-carrying body shall have doors which close tightly and can be sealed with a tamper resistant seal or otherwise secured if left unattended while carrying infectious waste;~~ have doors that close tightly and can be sealed with a tamper resistant seal or otherwise secured if left unattended;

(~~g~~f) identification ~~must~~shall be permanently affixed ~~to the cargo-carrying body~~on two sides and the back in letters a minimum of three (3) inches in height ~~which~~that states:

(i) the registered name of the transporter;

(ii) the transporter’s Department issued registration number; and

(iii) the words ‘INFECTIOUS WASTE’, ‘MEDICAL WASTE’, or ‘BIOHAZARDOUS WASTE’~~.~~: and

(~~h~~g) the universal biohazard symbol sign permanently affixed to ~~the cargo-carrying body~~ it on two sides and the front and back.

(2) If a transporter transports or stores infectious waste and ~~other~~ solid waste in the same cargo-carrying body, each waste ~~must~~shall be managed as infectious waste unless the waste is subject to the requirements in Section (E)(2)(a)~~-~~ through (c) of this Regulation.

(3) If a transport vehicle is used to store infectious waste, such storage ~~must~~shall, at a minimum:

(a) be ~~in a location which is~~ inside a building with limited access ~~and~~ that is locked when unattended; or

(b) be ~~in a location outside which is~~ secured by a barrier ~~which~~ that limits access and ~~must be~~ is locked when unattended; and

(c) ~~and~~ meet the requirements ~~of~~ in Section K of this Regulation.

(4) All drainage from the cargo-carrying body shall ~~discharge directly~~connect to or through a holding tank to a Department approved sanitary sewer system or approved container for appropriate treatment.

**R. Manifest Requirements For Transporters.**

(1) ~~No transporter shall~~ A transporter shall not accept a shipment of infectious waste ~~which~~ that is to be transported within ~~South Carolina~~ the State unless it is accompanied by an infectious waste manifest ~~which~~ that has been completed according to requirements in Section M, this Section, and elsewhere in this Regulation as applicable~~the instructions for the Department approved form~~ and signed by the generator.

(2) Before accepting for transport any infectious waste the transporter ~~must~~shall:

(a) visually inspect the containers to ~~assure~~ ensure proper packaging, if the waste is loaded by the transporter; and

(b) return ~~a~~ one (1) copy of the manifest form to the generator before leaving the site.

(3) The ~~transporter, transfer facility operator, and/or intermediate handling facility operator~~ person (e.g., transporter, transfer facility operator, intermediate handling facility operator) responsible for the waste shall ensure that the manifest form accompanies the infectious waste at all times until ~~unloaded for treatment~~ the waste is transferred to the treatment facility.

(4) At the time of transfer, the transporter shall ensure that the manifest is updated with the date of transfer in accordance with the form’s instructions.

(~~4~~5) The transporter who delivers infectious waste ~~within or into South Carolina~~to a location in the State ~~must~~shall ensure that the delivery is to a registered or properly permitted person (i.e., ~~infectious waste management~~ transporter, transfer facility, intermediate handling facility, generator facility, or treatment facility).

(~~5~~6) The transporter, upon delivery of infectious waste to a permitted treatment facility, transfer facility, generator facility, or intermediate handling facility, shall:

(a) retain ~~a~~ one (1) copy of the completed manifest ~~for his records~~; and

(b) ~~turn~~ submit the remaining copies of the manifest ~~over~~ to the ~~treatment facility~~person who will be responsible for the waste after its delivery.

(~~6~~7) The transporter shall deliver the entire quantity ~~represented on the~~ of ~~manifest~~accepted waste ~~that he accepted from the generator or another transporter~~ to another transporter, a generator facility, an intermediate handling facility, or a ~~destination~~ treatment facility.

(~~7~~8) ~~All transporters and/or management companies~~ Any person ~~which~~ that is listed ~~themselves~~ as the generator on ~~the manifest or~~ a ~~consolidated~~ manifest showing consolidated shipments ~~must~~shall assume full responsibility ~~of the generator(s)~~ as listed in Section M for that manifest and ~~must~~shall:

(a) attach a copy of the ~~completed new~~ manifest showing consolidated shipments ~~form~~ to the original manifest form and retain a copy of ~~the new and original~~ each manifest ~~form~~; and

(b) maintain a transporter consolidation log ~~indicating~~ listing all shipments that have been consolidated.

**S. ~~Storage~~ Tank Storage Requirements.**

(1) ~~Liquid~~ If stored, liquid treatment residue generated during the embalming process ~~may~~ shall be stored in an underground or aboveground storage tank located onsite at the generating facility. Tanks in operation ~~at the time this regulation takes effect~~ prior to June 25, 2010, ~~must~~shall meet the use, monitoring, ~~record keeping~~recordkeeping, disposal, and clean-up requirements of this Section. Tanks installed after ~~the date this regulation becomes effective~~ June 25, 2010, ~~must~~shall meet all requirements of ~~these regulations~~this Regulation.

(2) ~~Storage tanks~~ Tank storage ~~must~~shall meet the following conditions:

(a) ~~A~~a facility ~~must~~shall notify the Department in writing before installing a tank ~~to be used~~ for storage of treatment residue. Notification should include facility name and address, number of tanks, and storage capacity;

(b) ~~Tank~~ materials ~~of construction~~used to construct the tank(s) ~~must~~shall be compatible with treatment residue to be stored;

(c) ~~T~~tank(s) ~~must~~shall be installed and maintained in accordance with manufacturer’s instructions;

(d) ~~W~~when treatment residue is removed from the tank(s), it ~~must~~shall be ~~pumped~~ removed by a person licensed by the Department ~~for the~~ to clean~~ing of~~ disposal systems and the residue shall be sent directly to a regulated facility for further treatment or disposal;

(e) ~~T~~tank(s) ~~must~~shall be monitored following pump events and with a frequency that sufficiently ~~to~~ demonstrates ~~it~~ that the tank is not leaking. Monitoring may be performed utilizing a dipstick~~,~~; however monitoring ~~must~~shall be performed when tank contents are sufficiently settled;

(f) ~~The facility generating waste that is treated and stored in the tank must maintain create a~~ the generator is responsible for ensuring a record of tank monitoring and pump events shall be created. The generator shall maintain this record as required in Section AA of this Regulation;

(g) ~~T~~tank(s) ~~must~~shall be used exclusively for treatment residue storage; and

(h) ~~T~~tank(s) and records ~~must~~shall meet all applicable state and federal requirements~~, including Industrial Wastewater and Disposal System Clean-out requirements~~.

(3) The Department may require the generating facility to clean up any treatment residue discharge that occurs during storage or take such action as may be required by state, federal, or local officials ~~so~~ to ensure that the treatment residue discharge ~~no longer~~ does not present~~s~~ a potential hazard to human health or the environment.

**T. Infectious Waste Treatment.**

(1) Infectious waste ~~must~~shall be treated prior to disposal except as indicated in Section G. Treatment shall be in accordance with this Regulation and other applicable state and federal laws and regulations. After approved and adequate treatment, resulting treatment residue ~~must~~shall be disposed of in accordance with state and federal solid waste requirements. Any unused treatment media ~~must~~shall be characterized, handled, and disposed of in accordance with applicable regulations.

(2) ~~Treatment must be by one~~ One of the following treatment methods shall be utilized ~~in accordance with this regulation and other applicable state and federal laws and regulations~~:

(a) incineration;

(b) steam sterilization;

(c) chemical disinfection;

(d) embalming fluid containing at least two (2) percent formaldehyde; or

(e) any other Department approved treatment method.

(3) Approval for alternate treatment technologies ~~other forms of treatment must~~shall be obtained from the Department, in writing, based on an application on a Department approved form, prior to the use of the alternate technology, and meet current Department standards ~~set at that time by the Department~~. Approvals will be valid for the period stated on the approval. If an application for renewal is received, the existing approval will be in effect until the Department makes a decision on the renewal.

(4) The following infectious waste may be disposed of before treatment:

(a) a liquid or semi-liquid waste, other than microbiological cultures and stocks, that is directed to a Department-approved wastewater treatment system permitted under S. C. Regulation 61-9, Water Pollution Control Permits, when the liquid is approved by the treatment system owner or operator; and

(b) recognizable human anatomical remains that are disposed of by interment or donated for medical research.

(5) Storage of infectious waste prior to treatment ~~must~~shall be in accordance with Section K of this ~~regulation~~Regulation.

~~(a)~~ ~~an approved liquid or semi-liquid waste other than microbiological cultures and stocks may be discharged directly into a Department approved wastewater treatment disposal system; and~~

~~(b)~~ ~~recognizable human anatomical remains may be disposed of by interment or donated for medical research.~~

~~(6)~~ ~~It is unlawful for any person to discharge infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment.~~

(~~7~~6) Facilities that are not required to be permitted as a treatment facility include:

(a) those that only treat liquid embalming waste with at least a two (2) percent formaldehyde solution and

(b) small quantity generators that treat, by an approved method onsite, infectious waste ~~which~~ that~~they~~ is generated onsite ~~are not required to be permitted as a treatment facility~~.

(~~8~~7) Treatment of infectious waste ~~must~~shall be monitored to ensure proper treatment using methods described in Section U of this Regulation ~~by use of~~ ~~biological indicators or laboratory culture of the treatment residue to ensure that pathogens have been adequately treated~~. Frequency of this ~~testing shall~~ monitoring shall be determined by the Department on a case-by-case basis or as outlined in this ~~regulation~~Regulation.

(~~9~~8) Products of conception ~~must~~shall be incinerated, cremated, interred, or donated for medical research.

**U. ~~Infectious Waste~~ Treatment Facility and Generator Facility Standards.**

(1) No person may operate an infectious waste treatment facility ~~or disposal facility~~ or generator facility without first obtaining a permit as required ~~by~~ in Section W of this ~~regulation~~Regulation except as exempted in Section T or as specified in Section X of this Regulation. A separate permit shall be required for each site or facility although the Department may include one or more different types of facilities in a single permit if the facilities are ~~col~~located on the same site.

(2) All treatment facilities ~~must~~shall treat the waste as ~~indicated~~ required in Section T above.

~~(3) Infectious waste treatment residue must not be disposed of until or unless Department approved monitoring methods confirm effectiveness of the treatment process.~~

(~~4~~3) All treatment facilities ~~must~~shall develop and submit to the Department for approval a standard operating procedure manual ~~which will~~ to include, at a minimum, procedures for:

(a) unloading and handling ~~procedures~~;

(b) safety ~~procedures~~;

(c) emergency preparedness and response ~~plans~~;

(d) receiving, ~~record keeping~~recordkeeping, and reporting ~~procedures~~;

(e) ~~remedial action plans~~remediating spills or other contamination, including the requirements of U(8) below;

(f) quality assurance ~~plans for treatment methods~~and quality control;

(g) ~~radiological~~ radioactive and hazardous waste monitoring ~~procedures~~;

(h) ~~procedures for~~ identifying types and quantities of ~~infectious~~ waste received; and

(i) ~~contingency plans for use of alternate facilities; and~~

~~(j)~~ ~~procedures for~~ disposition of treatment residues.

(~~5~~4) Approval for acceptance of infectious waste at a treatment ~~or disposal~~ facility may be withdrawn by the Department for noncompliance with the facility’s standard operating procedure manual.

(~~6~~5) When a facility ceases infectious waste management activities, it shall notify the Department in writing, immediately, and it shall thoroughly clean and disinfect the facility and all equipment used in the handling of infectious waste. Closure is not final until written approval is provided by the Department.

(6) Before closure, ~~All~~all untreated waste shall be ~~disposed of~~ transported or treated in accordance with the requirements of this ~~regulation~~Regulation.

(7) In the event of an accidental spill of infectious waste the designated personnel at the facility shall:

(a) contain the spill ~~to the area immediately affected~~;

(b) immediately disinfect the contaminated area ~~which is contaminated~~;

(c) pick up~~,~~ and repackage as required or ~~otherwise~~ immediately ~~remove~~treat the spilled material ~~into the treatment system~~; and

(d) create a record of the incident ~~in a bound log book~~, ~~including~~to include the quantity spilled, personnel involved, and the nature and consequences of the event and this record shall be maintained as required in Section AA of this Regulation~~; and~~.

(~~e~~8) It is unlawful for any person to ~~discharge~~release infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility ~~must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases~~shall immediately investigate and confirm all suspected releases and report the findings to the Department within twenty-four (24) hours. Additional action may ~~then~~ also be required by local, state, or federal officials ~~so~~ to ensure that the infectious waste or treatment residue discharge ~~no longer~~ does not present~~s~~ an actual or potential hazard to human health or the environment.

(~~8~~9) All ~~individuals~~persons involved with handling and management of waste shall receive thorough training in their responsibilities and duties. ~~A training protocol shall be submitted to the Department at the time of application for a permit. Training documentation for individuals shall be submitted to the Department within thirty (30) days of completion.~~A record of training shall be created. This record shall be maintained as required in Section AA below.

(~~9~~10) ~~Permittees shall notify the Department, in writing within thirty (30) days prior to any changes in ownership, operating control, name, or location.~~ The Department may ~~upon written request~~ transfer a permit to a new owner or operator ~~where no other change in the permit is necessary provided that~~ under the following conditions:

(a) a written agreement ~~containing a specific date~~is submitted that includes a specific date of transfer and details for transfer of ~~permit responsibility and~~ financial ~~assurance~~ and permit responsibilities between the current and new owner~~has been submitted to the Department~~;

(b) no change to the permit, other than the name of the owner and/or operator, is necessary; and

(c) a request for this transfer is received by the Department no later than thirty (30) days prior to any proposed changes.

(1~~0~~1) A facility receiving waste generated ~~in~~ by a hospital or by another generator ~~which~~ that uses radioactive material ~~must~~shall screen incoming waste for radioactivity as ~~they~~ it arrives at the treatment or generator facility. ~~Such~~ As part of this screening process, facilities ~~must~~shall:

(a) use instrumentation ~~which~~ that is approved by the Department for this ~~purpose~~process;

(b) ~~have~~ ensure the operator is properly trained on such equipment;

(c) ~~have such~~ ensure the equipment is calibrated at least once a year by an authorized calibrator;

(d) maintain a log of quality assurance testing and calibration of such instrumentation; and

(e) report to the Department any and all incidents when radioactive materials are detected ~~to the Department for~~in order to obtain guidance in dealing with the radioactive materials. The Department may allow a treatment facility to hold containers of waste containing radioactive material for radioactive decay ~~after the facility has submitted procedures for appropriately managing the containers and has received approval from the Department~~ in accordance with Department-approved procedures. However, under no circumstance may a treatment facility solicit the receipt of radioactive material.

(1~~1~~2) Facilities shall schedule shipments of waste to prevent a backlog of loaded transportation vehicles at the facility or offsite. The number of loaded and unloaded transport vehicles stored onsite will be controlled by permit conditions.

(1~~2~~3) A facility receiving waste generated offsite ~~must~~shall: ~~log-in~~

(a) create a record of transport vehicles as they arrive at the facility ~~in a bound log book~~ and note, in this ~~book~~ record, if any of these shipments are rejected. This record shall be maintained as required in Section AA below;~~The treatment facility must:~~

(~~a~~b) disinfect the cargo-carrying ~~compartment~~body(s) ~~immediately after unloading the waste~~at least once each day of use; and create a record of when the cargo-carrying body was disinfected. This record shall be maintained as required in Section AA below; and

(~~b~~c) clean out visible debris and immediately ~~put~~ place the debris into the treatment system.

(1~~3~~4) ~~Incinerators must, in addition to items (1) through (12) above~~The operator of a treatment facility where incineration is used, in addition to meeting the requirements in Section U(1) through (13) above, shall:

(a) provide complete combustion of the waste and packaging to carbonized or mineralized ash;

(b) comply with all applicable regulations ~~issued~~ promulgated by the Department; and

(c) receive authorization from the Department for disposal of treatment residue ~~from the Department~~ prior to disposition into a State landfill ~~located in this state, and said authorization shall be based on relevant analyses and requirements deemed necessary by the Department~~. Such authorization may be incorporated into a landfill permit.

(1~~4~~5) ~~All steam sterilizers must, in addition to items (1) through (12) above.~~The operator of any treatment facility using steam sterilization, in addition to meeting the requirements in Section U(1) through (13), shall:

(a) use Department approved indicator organisms in test runs to ~~assure~~ ensure proper treatment of the waste. ~~Indicator~~ In each treatment unit, indicator organisms ~~must~~shall be used daily at a commercial facility and monthly at a generator facility ~~in each steam sterilizer~~;

(b) ~~record the temperature and time during each complete cycle to ensure the attainment of a temperature of 121 degrees Centigrade (250 degrees Fahrenheit) for 45 minutes or longer at fifteen (15) pounds pressure, depending on quantity and density of the load, in order to achieve sterilization of the entire load; (Thermometers shall be checked for calibration at least annually.)~~

create record(s) of the temperature, pressure, and time during each complete cycle;

(c) ~~have a gauge which indicates the pressure of each cycle;~~calibrate pressure gauges and thermometers at least annually;

(d) operate in accordance with the manufacturer’s specifications for waste regarding time, temperature, pressure, composition, and capacity, if these specifications provide effective treatment. If no manufacturer’s specifications for waste exist, or if another combination of time, temperature, pressure, composition, and capacity is used, proposed specifications that provide effective and proven treatment shall be approved by the Department;

(~~d~~e) use heat sensitive tape or other device for each container that is treated, to indicate that the steam sterilization temperature has been reached. The waste will not be considered appropriately treated if the indicator fails;

(~~e~~f) ~~use~~place the biological indicator Geobacillus stearothermophillus~~, placed~~ at the center of a load ~~processed under~~ and treat using standard operating ~~conditions~~ specifications ~~to confirm the attainment of adequate sterilization conditions~~;

(~~f~~g) ~~maintain~~create records of the procedures specified in Section U(15)(b), U(15)(c), and U(15)(f) and ~~(e) above~~ maintain these records as required in ~~for period of not less than three (3) years~~Section AA below; and

(~~g~~h) ~~assure~~ ensure that treatment residues are disposed of in accordance with applicable ~~S~~state and ~~F~~federal ~~R~~requirements.

**V. Intermediate Handling ~~Facilities~~ Facility Standards.**

(1) No person may operate an infectious waste intermediate handling facility without first obtaining a permit as required ~~by~~ in Section W of this ~~regulation~~Regulation. A separate permit shall be required for each site or facility although the Department may include one or more different types of facilities in a single permit if the facilities are ~~co-~~located on the same site.

(2) All intermediate handling facilities ~~must~~shall develop, and submit to the Department for approval, a standard operating procedure manual ~~which will~~ to include, at a minimum, procedures for:

(a) unloading and handling ~~procedures~~;

(b) safety ~~procedures~~;

(c) emergency preparedness and response ~~plans~~;

(d) receiving, ~~record keeping~~recordkeeping, and reporting ~~procedures~~;

(e) ~~remedial action plans~~remediating spills or other contamination, including the requirements of V(6) below;

~~(f)~~ ~~procedure for treatment of spills;~~

(~~g~~f) ~~radiological~~ radioactive and hazardous waste monitoring ~~procedures~~; and

(~~h~~g) ~~procedures for~~ identifying types and quantities of ~~infectious~~ waste received~~;~~.

~~(i)~~ ~~contingency plans for use of alternate facilities; and~~

~~(j)~~ ~~procedures for disposition of treatment residues.~~

(3) Approval for acceptance of infectious waste at an intermediate handling facility may be withdrawn by the Department for noncompliance with the facility’s standard operating procedure manual.

(4) When a facility ceases infectious waste management activities, it shall notify the Department in writing, immediately, and it shall thoroughly clean and disinfect the facility and all equipment used in the handling of infectious waste. Closure is not final until written approval is provided by the Department.

(5) All untreated waste shall be ~~disposed of~~ transported or treated in accordance with the requirements of this ~~regulation~~Regulation.

(~~5~~6) In the event of an accidental spill of infectious waste, the designated personnel at the facility shall:

(a) contain the spill ~~to the area immediately affected~~;

(b) immediately disinfect the contaminated area ~~which is contaminated~~;

(c) ~~immediately~~ pick up and repackage as required ~~or treat the spilled material~~; and

(d) create a record of the incident ~~in a bound log book~~, including the quantity spilled, personnel involved, and the nature and consequences of the event and maintain this record as required in Section AA of this Regulation~~; and~~.

(~~e~~7) It is unlawful for any person to ~~discharge~~release infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility ~~must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases~~shall immediately investigate and confirm all suspected releases and report the findings to the Department within twenty-four (24) hours. Additional action may ~~then~~also be required by local, state, or federal officials ~~so~~ to ensure that the infectious waste or treatment residue discharge ~~no longer~~ does not present~~s~~ an actual or potential hazard to human health or the environment.

(~~6~~8) All ~~individuals~~ persons involved with handling and management of waste shall receive thorough training in their responsibilities and duties. ~~A training protocol shall be submitted to the Department at the time of application for a permit. Training documentation for employees shall be submitted to the Department within thirty (30) days of completion.~~ A record of this training shall be created. This record shall be maintained as required in Section AA below.

(~~7~~9) ~~Permittee shall notify the Department in writing within thirty (30) days prior to any changes in ownership, operating control, name, or location. The Department may upon written request transfer a permit to a new owner or operator where no other change in the permit is necessary provided that a written agreement containing a specific date for transfer of permit responsibility and financial assurance between the current and new owner has been submitted to the Department.~~The Department may transfer a permit to a new owner or operator under the following conditions:

(a) a written agreement is submitted that includes a specific date of transfer of financial and permit responsibilities between the current and new owner;

(b) no change to the permit, other than the name of the owner and/or operator, is necessary; and

(c) a request for this transfer is received by the Department no later than thirty (30) days prior to any proposed changes.

(~~8~~10) Facilities shall schedule shipments of waste to prevent a backlog of loaded transportation vehicles at the facility or offsite. The number of loaded and unloaded transport vehicles stored onsite will be controlled by permit conditions.

(~~9~~11) A facility receiving waste generated offsite ~~must~~shall:

(a)  ~~log-in~~ create a record of transport vehicles as they arrive at the facility ~~in a bound log book~~ and note, in this ~~book~~ record, if any of these shipments are rejected. ~~The intermediate handling facility must:~~This record shall be maintained as required in Section AA below;

(~~a~~b) disinfect the cargo-carrying ~~compartment~~body(s) ~~immediately after unloading the waste~~at least once each day of use; and create a record of this disinfection. This record shall be maintained as required in Section AA below; and

(~~b~~c) clean out visible debris and immediately ~~put~~ place the debris into the treatment system.

**W. Permit Applications and Issuance.**

(1) No person may ~~expand or~~ construct a new treatment facility or intermediate handling facility without obtaining an Infectious Waste Management permit issued by the Department. To obtain a permit, the applicant shall demonstrate the need for such a facility or expansion. To determine if there is a need, infectious waste generated outside of the State may not be considered without Department approval.

(a) Commercial treatment facilities shall have a seventy-five (75) mile planning radius.

(b) Each commercial treatment facility permitted after the effective date of this Regulation shall initially be allowed up to a maximum yearly treatment capacity equal to the total amount of regulated infectious waste generated in the planning area as follows:

(i) one hundred (100) percent of the host county; and

(ii) fifty (50) percent of each county, other than the host county, that falls wholly or partially within the seventy-five (75) mile planning radius that does not have a commercial treatment facility that accepts regulated infectious waste within that county.

(c) A commercial treatment facility operating within twenty (20) percent of the permitted yearly treatment capacity stated in their current permit may submit a request for an increase in their permitted yearly treatment capacity. This increase may be granted only if there has been an increase in the amount of regulated infectious waste generated in their planning area as stated in Section W(1)(b), including (i) and (ii), above.

(d) A variance to the permitted yearly treatment capacity may be granted for a specific term, corresponding to the need, in the event of an emergency or documented large project with a specified term, as determined solely by the Department. This temporary increase in yearly treatment capacity, if granted, is not considered by the Department when determining if a facility is within twenty (20) percent of its permitted yearly treatment capacity.

(2) The Department will determine and publish annually an estimate of the amount of infectious waste to be generated in ~~South Carolina~~the State during the ensuing twelve (12) months.

(3) The requirement to ~~demonstration of~~ demonstrate need does not apply to:

(a) facilities owned by counties, municipalities, or public service districts ~~which~~ that accept only infectious waste generated in this state;

(b) facilities that are owned or operated by the generator of the waste ~~and this~~, for waste ~~is~~ generated in this state;

(c) generator facilities; ~~or~~

(d) facilities currently operated under permits issued by the Department, or ~~to~~ the renewal of existing permits issued by the Department if there is no expansion of the capacity as prescribed in the conditions of the permit~~.~~; or

~~(4)~~ ~~No person may expand or construct a new intermediate handling facility without an Infectious Waste Management permit issued by the Department. I~~

(e) intermediate handling ~~facility permit applicants do not have to demonstrate a need~~facilities.

(~~5~~4) To obtain an Infectious Waste Management Permit, the person ~~must~~shall complete a permit application ~~as designed by the~~ on a Department approved form. Permit applications will not be processed until they are deemed administratively complete by the Department.

(~~6~~5) ~~A draft of the~~ The manual required in Section U(4) above or Section V(2) above, as appropriate, ~~must accompany~~ shall be submitted for review with the permit application. ~~The manual must meet the approval of the Department or be modified so that it will meet approval.~~ After approval by the Department, the standard operating procedure manual ~~shall~~ becomes part of the permit and ~~must~~shall be adhered to by the permittee. Changes in this manual ~~must~~shall be made by submittal of a written request to the Department which may approve or deny such request.

(~~7~~6) In addition to other requirements, a permit application for a treatment facility or intermediate handling facility ~~must~~shall include, at a minimum:

(a) an engineering report ~~which~~that, at a minimum, contains a description of the facility, the process and equipment to be used, the proposed service area, and storage of the waste;

(b) engineering plans and specifications ~~which must~~that, at a minimum, describe the architectural, mechanical, electrical, plumbing, heating, ventilating, process equipment, instrumentation and control diagrams, and performance specifications for all major equipment and control centers;

(c) the latitude and longitude of the facility;

(d) a topographic map (or similar map) extending one (1) mile beyond the property boundaries of the source, depicting the facility and each of its intake and discharge structures; each of its infectious waste management, treatment, or storage~~, or disposal~~ facilities; those wells, springs, other surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant within ~~the~~ a quarter-mile of the facility property boundary; and the hundred (100)-year flood plain;

(e) a written acknowledgment from the governing body of the city, ~~or~~ town, ~~and/~~or county (whichever has the most stringent applicable requirements) in which the facility is to be located that the location and operation of the facility are consistent with all applicable ordinances;

(f) a description of the process to be used for treating, storing, handling, and transporting ~~and disposing of~~ infectious waste, and the design capacity of these items;

(g) a description of the type of the infectious waste to be treated, stored, or transported ~~or disposed~~ at the facility, an estimate of the quantity of such wastes to be treated, stored, and transported~~, and disposed~~ annually;

(h) ~~a quality assurance and quality control report~~a training program that includes a description of topics covered and training frequency;

(i) a contingency plan as defined in this Regulation~~describing a technically and financially feasible course of action to be taken in response to~~ for contingencies which may occur during construction ~~and~~ or operation of the facility ~~to include a description of how the waste will be managed to protect the waste from flood waters.~~;

(j) an identification of possible air releases and groundwater or surface water discharges;

(k) a waste control plan describing the manner in which waste will be received, stored, and otherwise managed;

(l) a plan outlining the flow of traffic associated with the facility;

(m) a closure plan that includes; ~~a closure plan which includes the estimated cost of closure;~~

(i) ~~a closure cost estimate which must be based on the cost of hiring a third party to close the facility; and~~procedures outlining actions required to properly close the facility; and

(ii) ~~a cost estimate which may not include any salvage value from the sale of any structures, equipment, and other assets.~~a closure cost estimate based on permitted storage amounts and current industry prices for treatment, transport, and disposal of all stored waste as well as cleaning and disinfecting the facility. The cost estimate may not include any salvage value from the sale of any structures, equipment, or other assets;

(n) the Employer Identification Number (EIN), if applicable;

(o) an email address of the treatment facility (if available); and

(~~n~~p) other information ~~as may be~~ requested or required by the Department.

(~~8~~7) The Permittee shall notify the Department in writing within thirty (30) days of any changes of the information required in Section W(~~7~~6) ~~above~~ or changes ~~which~~ that would require modifications of the permit as issued, including expanding the facility.

(~~9~~8) A permit may be terminated or a new or renewal application may be denied by the Department for noncompliance by the permittee with any conditions of the permit, requirements of this ~~regulation~~Regulation, or the Act.

(~~10~~9) ~~In addition to conditions required in all permits, the~~The Department shall establish conditions for all permits, on a case by case basis, ~~conditions as required on a case-by-case basis,~~ for the duration of the permits, schedules of compliance, monitoring, and to provide for and ~~assure~~ ensure compliance with all applicable requirements of this ~~regulation~~Regulation.

(~~11~~10) Permits will be valid for the period stated on the permit. ~~If the application for renewal is received as above, the permit will continue in force until the Department makes a permit decision.~~ If an application for renewal is received as required in the facility’s permit, the existing permit will be in effect until the Department issues a final decision on the renewal.

(~~12~~11) ~~As a condition of approval for an Infectious Waste Management Permit, any person who owns or operates a facility or group of facilities for the treatment, storage, or disposal of infectious waste must demonstrate financial responsibility for bodily injury and property damage to third parties caused by sudden accidental occurrences arising from the operation of the facility or group of facilities and assure the satisfactory maintenance, closure, and postclosure care of any facility or group of facilities, and to carry out any corrective action which may be required by the Department. Such form and amount of financial responsibility shall be a permit condition specified by the Department. At any time, should the Department determine that the levels of financial responsibility required are not consistent with the degree and duration of risk associated with treatment, storage, or disposal at the facility or group of facilities, the Department may adjust the level of financial responsibility required as may be necessary to protect human health and the environment. This adjusted level will be based on the Department's assessment of the degree and duration of risk associated with the ownership or operation of the facility or group of facilities.~~Any person who owns or operates a facility or group of facilities for the treatment or storage of infectious waste shall demonstrate financial responsibility coverage for the satisfactory closure of any facility or group of facilities.

(12) Any person who owns or operates a facility or group of facilities for the treatment or storage infectious waste shall demonstrate financial responsibility coverage for bodily injury and property damage to third parties caused by sudden and accidental occurrences arising from the operation of the facility or group of facilities.

(13) Before a final permit will be issued, the applicant shall ensure that the funds needed for financial responsibility coverages are available by establishing assurance through one (1) or more of the following mechanisms: certificate(s) of deposit, irrevocable letter(s) of credit, or other sureties deemed satisfactory to the Department and a trust agreement approved by the Department. If the owner or operator is in violation of permit requirements, the Department will have the right to use part or all of the fund to protect the health and safety of the public or the environment.

(14) Should the Department determine, at any time, that the levels of financial responsibility required are not consistent with the degree and duration of risk associated with treatment, storage, or disposal at the facility or group of facilities, the Department may adjust the level of financial responsibility coverage required as may be necessary to protect human health and the environment. This adjusted level will be based on the Department's assessment of the degree and duration of risk associated with the ownership or operation of the facility or group of facilities.

(~~13~~15) ~~The permittee must immediately notify the Department upon loss of the financial responsibility coverage. A permittee shall cease to treat or store infectious waste upon loss of financial responsibility coverage.~~The permittee shall immediately notify the Department upon loss of financial responsibility coverage. A permittee shall not treat or store infectious waste without financial responsibility coverage.

(~~14~~16) A facility may receive only those waste streams for which it is permitted; however, a facility may, in writing, request ~~in writing~~ to receive new waste streams ~~which are subject to Department approval or denial~~. Approval to grant or deny these requests is solely within the Department’s authority.

**X. Permit By Rule.**

(1) ~~All infectious waste generators which comply with the conditions of (2) below shall be deemed to have a permit by rule.~~ All infectious waste generators that comply with the conditions of Section X(2) below shall be deemed to have a permit by rule. If an infectious waste generator treats the infectious waste and it is then transported for treatment at a permitted treatment facility such that the generator receives a complete record of treatment in accordance with Section AA, the generator will not be required to obtain permit by rule status.

(2) To qualify for permit by rule the owner and~~/or~~ operator, if different, of the ~~facility shall~~generator shall:

(a) comply with all ~~parts~~ provisions of the Act and this ~~regulation~~Regulation except permitting ~~procedures of~~ requirements of Section W above~~.~~;

(b) demonstrate that more than seventy-five (75) percent (by weight, in a calendar year) of all infectious waste that is ~~stored,~~ treated ~~or disposed of~~ by the ~~facility~~generator is generated onsite~~.~~;

(c) ~~assure~~ ensure that no activities ~~at~~of the ~~facility~~generator involve the placing of infectious waste directly into the environment~~.~~;

(d) notify the Department in writing that the ~~facility~~generator is operating under a permit by rule and ~~supply~~ provide the following information:

(i) the name, mailing address, ~~location~~site address, and phone number of the ~~facility~~generator;

(ii) type(s) of businesses served;

(iii) the type of ~~facility~~generator; ~~and~~

(iv) the ~~principal officer~~name of the treatment coordinator; and

(v) the method of treatment; and

(e) notify the Department in writing before onsite treatment activities begin.

(3) All infectious waste generators who treat infectious waste, ~~and~~ are not exempted in Section T, and do not meet~~ing~~ the requirements ~~of~~ in Section X(2) above, shall apply for an infectious waste treatment permit as outlined in Section W of this Regulation.

(4) Any ~~facility deemed to have~~generator operating under a permit by rule ~~which~~ who fails to satisfy any one of the conditions set forth in Section X(2) above or this ~~regulation~~Regulation may have its permit by rule revoked and ~~must~~shall obtain a permit as outlined in Section W above to continue to store~~,~~ or treat~~, or dispose of~~ infectious waste.

**Y. Manifest Form Requirements For Permitted Treatment Facilities.**

(1) Treatment facilities ~~must~~shall not accept infectious waste to be treated, stored, or otherwise managed unless accompanied by a Department approved manifest form if the waste is generated offsite.

(2) ~~The~~ When accepting a manifested shipment, the facility owner or operator ~~or his authorized agent of a treatment facility when accepting a manifested shipment~~ shall ensure:

(a) ~~write on the manifest~~ the number of containers accepted and the total weight are listed on the manifest;

(b) ~~note~~ any discrepancies greater than ten (10) percent of the container count are noted on the manifest; and

(c) ~~retain~~ a copy of the completed manifest form ~~for two (2) years~~is maintained as required in Section AA below.

(3) When there is any variation in piece count greater than one (1) percent or in weight greater than ten (10) percent ~~is discovered~~, the owner or operator shall attempt to resolve the discrepancy with the waste generator or the transporter. If the discrepancy is not resolved, the owner or operator shall submit a letter to the Department, within five (5) days~~,~~ of receipt of the waste, describing the nature of the discrepancy and the attempts the owner or operator ~~has undertaken~~ took to reconcile it. The owner or operator shall include with this letter a legible copy of the manifest in question.

(4) If a facility receives any infectious waste from offsite ~~which~~ that is not accompanied by a manifest, or ~~which~~ that is accompanied by a manifest ~~which~~ that is incorrect, incomplete, or not signed, the owner~~/~~ or operator ~~must~~shall prepare and submit to the Department a written ~~copy of a~~ report within fifteen (15) days ~~after~~ of receiving the waste. ~~The "Unmanifested Waste Report" must~~ This report shall include the following information:

(a) the name and address of the facility;

(b) the date the facility received the waste;

(c) the identification number or name and address of the generator and the transporter if available;

(d) a description and the quantity of the waste;

(e) the method of treatment, storage, or disposal of the waste;

(f) a certification ~~signed~~ of the accuracy of the information provided in response to Y(4)(a) through (e) above by the owner or operator of the facility or his authorized representative; and

(g) a brief explanation of why the waste was unmanifested or why the manifest was incorrect, if ~~possible~~ known.

**Z. Reporting For Permitted Treatment Facilities.**

(1) All commercial treatment facilities are required to submit the monthly fees and reports as required by the Act in Section 44-93-160.

(2) All treatment facilities are required to submit an annual report to the Department, covering the period from January 1st through December 31st of each calendar year ~~which~~ that shall be submitted to the Department by February 15th of the subsequent year. The report shall include, but is not limited to:

(a) ~~a description of the sources by state, and amounts of infectious waste treated;~~ a description of the amounts of infectious waste treated by state of origin;

(b) the method used to treat the waste; and

(c) the amount and disposition of the residue.

**AA. Inspections and Record Keeping.**

(1) Department representatives are authorized to enter and inspect any property or premises for the purpose of ascertaining compliance or noncompliance with this ~~regulation~~Regulation.

(2) All generators, transporters, transfer facilities, intermediate handling facilities and treatment facilities handling infectious waste generated, treated, transported, or otherwise managed in the State shall maintain all records and manifest copies required ~~by~~ in this ~~regulation~~Regulation for a minimum of two (2) years in a location within ~~South Carolina~~the State easily accessible to the Department during regular business hours and shall provide these records to the Department immediately upon request or, with Department approval, within five (5) business days. Records may be maintained in paper form or electronically.

(3) If the waste is no longer infectious because of treatment, the generator, or permitted facility if waste was generated out of state, shall maintain a record of the treatment ~~for two (2) years afterward~~ to include the date and type of treatment, amount of waste treated, and the individual operating the treatment unit. ~~Records for onsite treatment shall be maintained by the generator for a minimum of two (2) years in a location easily accessible to the Department and shall be provided to the Department upon request. Records may be maintained in paper form or electronically.~~

(4) If the waste is no longer infectious because of treatment, and the treatment residue is stored onsite in a tank, the generator shall maintain a record of monitoring and pump events ~~for two (2) years afterward~~ to include the date and type of monitoring, the name of the person who conducted the monitoring, date and amount of waste pumped, and the name of the business or person that provided the pumping service. Pump event data may be in the form of a manifest or log. ~~Records shall be maintained by the generator for a minimum of two (2) years in a location within South Carolina easily accessible to the Department and shall be provided to the Department upon request. Records may be maintained in paper form or electronically.~~

**BB. Enforcement.**

(1) Any person who violates any of the provisions of this ~~regulation~~Regulation or any permit issued pursuant hereto, or any order issued by the Department or Board shall be subject to applicable civil, administrative, and criminal penalties as provided for in the ~~Infectious Waste Management~~ Act.

(2) Any registered generator or transporter~~,~~ or any permitted ~~intermediate handling facility or treatment~~ facility is subject to having its registration or permit suspended or revoked upon finding by the Department that:

(a) false or inaccurate information has been submitted in the application process;

(b) laws, Department orders, regulations, or registration or permit conditions have been violated;

(c) reports or other information required by the Department have not been submitted or have been inaccurately submitted; and/or

(d) lawful inspection has been refused.

**CC. Variances.**

(1) The Department may, upon written petition from any person who is subject to this ~~regulation~~Regulation, grant a variance from one or more specific provisions of this ~~regulation~~Regulation under the following conditions. The written petition~~er~~, ~~shall~~at a minimum, shall include:

(a) ~~identify~~ the specific provision(s) of this ~~regulation~~Regulation from which variance is sought;

(b) ~~demonstrate~~ a demonstration that compliance with the identified provision would, on the basis of conditions unique and peculiar to the applicant's particular situation, tend to impose a substantial financial, technological, or safety burden on the petitioner or the public; and

(c) ~~demonstrate~~ a demonstration that the proposed activity will have no significant adverse impact on the public health, safety, or welfare, the environment or natural resources and will be consistent with the provisions of the S.C. Infectious Waste Management Act.

(2) In granting any variance, ~~hereunder~~ the Department may impose specific conditions reasonably necessary to ensure that the subject activity will have no adverse impact on ~~the~~ public health, safety, or welfare, the environment or natural resources. Variances will be valid for the period stated on the variance approval. If an application for renewal is received while the variance is valid, the existing variance will be in effect until the Department makes a decision on the renewal.

(3) Any variance granted by the Department may be immediately withdrawn when the Department finds on the basis of complaints, noncompliance with conditions of the variance or other information that the variance is not in the public interest or protective of human health and/or the environment, or that the petitioner has provided false or inaccurate information on which the variance was granted.

(4) Nothing herein shall be construed as a waiver of the Department’s right to deny any petition for a variance.

**DD. Fees****~~Section~~.**

Fees are outlined in ~~the~~ S.C. Regulation 61-30, Environmental Protection Fees~~, Regulation 61-30~~.

~~EE. Appeals.~~

~~(1)~~ ~~A Department decision involving the issuance, denial, renewal, suspension, or revocation of a permit, license, certificate, or certification may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.~~

~~(2)~~ ~~Any person to whom an order is issued may appeal pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.~~