

Document No. 4107
DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL
CHAPTER 61
Statutory Authority: 1976 Code Sections 44-93-10 *et seq.* and 44-1-60

R.61-105. Infectious Waste Management Regulations

Preamble:

1. The Department of Health and Environmental Control proposes to amend R. 61-105, South Carolina Infectious Waste Management Regulations. These Regulations were last amended June 24, 2005.

(1) Amendments would include the embalming process as a potential source of regulated infectious waste and set storage and treatment standards for this waste. Amendments would provide an exemption from treatment facility permitting requirements for facilities whose only treatment of infectious waste is related to the embalming process and is performed for the purposes of meeting this standard.

(2) Allowances for alternate recordkeeping and communication would be developed for generators and transporters in regards to weight, biohazard marking and manifesting.

(3) Duplicated requirements would be deleted, including a continual refrigeration requirement and radiological monitoring by transporters.

(4) New requirements would be added for situations that could create a public health risk that have not been addressed in the past, including unattended vehicles carrying infectious waste and the storage and disposal of infectious waste treatment residue.

(5) Additionally, clarifications would be made to the Regulation to address the handling and treatment of regulated infectious waste by small quantity generators and transporters.

(6) The proposed amendments would add or clarify definitions used in the Regulations.

(7) Stylistic changes that may include corrections for internal consistency, clarification, references, and spelling would be made to improve the overall text of the Regulation.

(8) Requirements in conflict with federal Department of Transportation regulations will be deleted or revised.

(9) Persons who meet the United States Postal Service Domestic Mail Manual packaging requirements will be exempted from obtaining a permit provided that only packages that meet this requirement are transported.

(10) Generator registration and fee requirements will be clarified.

(11) Facilities that close will be required to notify the Program.

(12) The Department also proposes to create an appeals section of R.61-105 to comply with statutory changes in the Administrative Appeals process pursuant to S.C. Code Section 44-1-60 (2006 S.C. Act 387).

2. A Notice of Drafting initiating the statutory process to amend R.61-105 was published in the *State Register* on June 27, 2008. Notice was also published on the Department's Regulatory Information internet site in its monthly *DHEC Regulation Development Update*, as well as on the DHEC Land and Waste Management Internet site.

3. Because of the complexity of the issues involved in these Regulatory amendments, more time was needed to craft the language of the amendments; therefore a second Notice of Drafting was published in the *State Register* on June 26, 2009. Notice was also published on the Department's Regulatory Information internet site in its monthly *DHEC Regulation Development Update*, as well as on the DHEC Land and Waste Management Internet site.

4. The proposed amendments were reviewed internally by appropriate staff prior to seeking Board initial approval to public notice them.

Section-by-Section Discussion of Revisions

R.61-105. Infectious Waste Management

D(1) Definitions - At D(1) five definitions are added in alphabetical order. Three existing definitions are revised.

New definitions include: “Generator registration status,” “Pump event,” “Site,” “Small quantity generator,” and “Treatment residue.”

The definitions for “Manifest,” “Storage,” and “Universal biohazard symbol” are revised.

E. Definition of Infectious Waste.

E(1) introduction and (1)(a) are expanded by adding the embalming process, revising paragraph E(1), and expanding the category of sharps at (1)(a). E(1)(b) will be revised to clarify that only waste culture media are to be regulated as infectious waste.

E(2)(c) is revised to match the EPA definition of mixed waste.

F. Generator Requirements.

F(1)(f) deletes the word “and” at the end.

F(1)(g) is revised to clarify generator registration requirements.

F(1)(h) adds: “the method of waste treatment and disposal; and”

F(1)(i) adds: “the Employer Identification Number (EIN).”

F(3) is revised to add requirements for records submitted as part of the registration requirements for facilities that store liquid treatment residue in holding tanks.

F(4) is revised to clarify generator fee requirements.

F(5) Language is revised to require generators to track infectious waste through transport instead of through disposal to be consistent with US DOT requirements. Statement is also clarified so that only generators who treat their own waste must develop a contingency plan and Quality Assurance program.

F(6)(c) Language is changed from “initiate the manifest” to “ensure a manifest is initiated” to clarify language outlining manifest form requirements for generators. Generators retain the responsibility to initiate a manifest but are allowed to delegate the initiation of a manifest.

F(6)(i) is revised to allow generators to offer waste to the U.S. Postal Service or a registered transporter.

F(6)(j) changes the requirements of generators from requiring the generator to actually weigh the waste at the time of the shipment to requiring the generator to obtain and record accurate weight of waste within

50 days of shipment. An exemption is provided for unabsorbed liquid waste produced during the embalming process.

F(7) adds a requirement that the Department must be notified in writing when a generator relocates, closes, or ceases to generate infectious waste or treatment residue. If a generator relocates, closes, or ceases to generate waste, all treatment residue must be disposed of in accordance with this regulation.

F(8) is a new section added to allow registered generators to accept non-regulated infectious waste generated in private residences and to specify how this waste must be handled, stored, transported, and treated.

G. Small Quantity Generators.

Revise paragraph G(1), G(1)(a) and (b); delete (b)(i) and (ii). New sections G(2)(b & c) are added to match US DOT requirements, and old G(2)(b & c) are renumbered. G(3) remains the same. G(4) is revised for clarity. Section G revisions define limits and inclusions for requirements of Small Quantity Generators.

I. Packaging Requirements.

I(1) This sentence sets standards for packaging of waste by generators and sets the transport standard for infectious waste if it is to be transported by the U.S. Postal Service as established in the Domestic Mail Manual.

I(2) Revise to include the responsibility of all potential parties for packaging sharps.

I(3) Revise language to be more realistic in Program expectations.

I(4) Revise to clarify container requirements.

I(5) This section sets the standards for how and when a container must be sealed to prevent facilities from holding a container indefinitely once it is full by volume or weight or putrescence. Once closed, containers are subject to the time limits in Section K(5)(a). Revise to indicate that containers must be sealed tightly and securely.

I(7) Revise the list of examples of containers and explicitly state that they are prohibited from use as rigid containment areas.

I(8) Revise to separate and clarify requirements.

I(9) Revise to clarify what kinds of containers are acceptable.

I(10) Revise to clarify the prevention of compaction.

I(12) After the words “or outer container,” add: “immediately after treatment” to require that treated containers whose appearance does not change due to treatment must be labeled with the word “treated” and date of treatment at the time of treatment.

J. Labeling of Containers.

J(1) This paragraph is revised to make sure the container is labeled once it is sealed.

J(2)(a) revises the cross reference for the requirements of the Universal biohazard symbol. The reference to “29CFR1910.1030(g)(1)(I)(B)” is deleted.

J(2)(b) is revised to eliminate the requirement for labeling a container with the name of the facility.

J(2)(c) and (f) are deleted to match US DOT regulations. J(2)(d) & (e) are renumbered to J(2)(c) & (d). New J(2)(c) is revised to add the word “and” at the end. J(2)(d) should be revised to delete the word “and.”

K. Storage of Infectious Waste.

K.(1) The revision of this paragraph adds the words: “Storage begins at the time the container is sealed.” to establish when storage begins. No changes are made to K(1)(a), (b), or (c).

K(2) revises list of the examples of outdoor storage to eliminate confusion.

K(4) revises the cross reference for the requirements of the Universal biohazard symbol. The reference to “29CFR1910.1030(g)(1)(I)(B)” and the requirement for other wording is deleted.

K.(5)(d) This paragraph is deleted to eliminate a requirement for continual refrigeration for generators, transporters, intermediate handling facility operators, and transfer facility operators.

M. Manifest Form Requirements For Generators.

This section has been substantially revised to break out lists of requirements into separate sections in an effort to state the requirements for generators more clearly.

M(1) Language is changed from “on a form approved by the Department” to “using DHEC Form 2116 or another Department approved form” to let generators and transporters know which DHEC form to use.

M(1)(a) through (m) have been reorganized and renumbered. M(1)(b) is revised to change when the requirements for a registration number on a manifest form is applicable. Delete M(1)(d), (i), (l), and (m) to match US DOT requirements. Revise the old (g) to include radioactive waste as well as radioactive material. Revise the old (j) and (k) to include the word “accept” instead of “receive” to be consistent with the language in the rest of the document. Revise old (e) to match US DOT requirements.

M(2) Language is changed from “initiate the manifest” to “ensure a manifest is initiated as” to clarify language outlining manifest form requirements for generators. Generators retain the responsibility to initiate a manifest but are allowed to delegate the initiation of a manifest.

M(3) Revise to match new numbering for M(1)(e), (f), and (g) and to add the option of a generator signing other than by hand.

M(4) Revise to delete reference to transporter signing manifest.

M(5) Delete to match US DOT standards.

N. Infectious Waste Transporter Requirements.

N(6) is revised to delete the redundant requirement for transporters to adhere to their waste management plan, as this is also in N(7).

N(6)(d) Paragraph (d) is removed to ease the burden on transporter requirements by not requiring transporters to do radiological monitoring. Generators are required to hold waste until it is indistinguishable from background and radiological monitoring of waste is required of treatment facilities rendering transporter monitoring redundant. Renumber old (6)(e) as (6)(d).

N(7) This paragraph is revised to clarify that transporters must submit a written infectious waste management plan annually with their registration and to separate clauses into different paragraphs.

N(9) This paragraph is revised to clarify potential ramifications if a discharge of infectious waste occurs during transport.

N(10) This paragraph is revised to assure that transporters no longer allow access to transport vehicles by unauthorized personnel.

O. Transporter Registration Requirements.

O(1) is reorganized to break down the requirements into individual sections for clarity.

O(2) Introductory paragraph language is changed from “as outlined in the Environmental Protection Fees, Regulation 61-30” to “as referenced in Section DD.” to reference a different section of the Regulation. Subsections (a), (b) and (c) remain the same.

O(6) After the first sentence, add the sentence “Transporters who only transport into or within this state regulated infectious waste packaged in accordance with United States Postal Service Domestic Mail Manual infectious waste packaging requirements are also exempt from registration.” This revision is reasonable because Domestic Mail packaging requirements are stringent enough to assure safety of the public health and the environment.

Q. Transport Vehicle Requirements.

Q(1)(a) Revise language to be more realistic in Program expectations.

Q(1)(g) The requirement that the cargo carrying body be labeled on the front is added to be consistent with U.S. DOT requirements.

Q(1)(g)(i) The word “registered” is added to clarify the transporter requirements.

Q(1)(g)(iii) Text is added to requirements for Transport Vehicle labeling: After the words “BIOHAZARDOUS WASTE” add the words: “and the universal biohazard symbol.”

Q(2) is revised to change which paragraphs of Section E are referred to.

R. Manifest Requirements for Transporters.

R(2)(a) remains the same. Delete (2)(b) to match US DOT standards. Renumber old (2)(c) as (2)(b).

R(2)(b) is revised to delete the reference to signing, as this is no longer required.

R(5)(a) Delete to match US DOT standards. Renumber old (5)(b) and (c) as (5)(a) and (b). New R(5)(a) is revised to delete signed and add completed, as signing is no longer required.

R(6) Revise to remove the language requiring the transporter to deliver waste to an entity listed on the manifest to match US DOT standards.

R(7) Delete paragraph to be consistent with other proposed changes in Section R. Renumber old R(8) as R(7).

Revise R(8)(a) to add the word “and” at the end.

R(8)(b) Delete paragraph to match US DOT standards, renumber old R(8)(c) as R(8)(b).

S. Storage Tank Requirements.

S. This reserved section is revised to add requirements for tanks used for storing treatment residue at generating facilities. Remove “Reserved” status and add requirements for tanks.

T. Infectious Waste Treatment.

T(1) The wording from T(4) is moved to this paragraph to indicate all possible disposition of waste and treatment residue. “Infectious waste must be treated prior to sanitary landfill disposition” is replaced with “After approved and adequate treatment, the treatment residue must be disposed of in accordance with state and federal solid waste requirements” and the second sentence “Any unused treatment media must be characterized, handled, and disposed of in accordance with applicable regulations.” is added.

T(2)(c) The “or” is deleted after the paragraph.

T(2)(d) A new paragraph is added to define the concentration levels of embalming fluid that is being regulated. Renumber old T(2)(d) as T(2)(e).

T(4) This paragraph is deleted since the language was moved to T(1).

Old T(5) through (10) are revised and renumbered for clarification and addition of requirements.

U. Infectious Waste Treatment Facility Standards

U(1) This paragraph is revised to clarify where exemptions are to be found for infectious waste treatment facilities standards by adding the words: “except as exempted in section T.” after the words: “as required by this regulation.”

U(7)(e) The paragraph is changed substantially for consistency to “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.”

U(8) Revise to clarify who must receive training at an infectious waste treatment facility.

U(10)(a) This paragraph revises language by changing “Division of Radioactive Waste Management” to “Department.”

U(10)(e) This paragraph revises language by changing “Division of Radioactive Waste Management” to “Department.”

U(13)(a) This paragraph is revised to assure that destruction of infectious waste includes the packaging by adding the words: “and packaging” after the words “of the waste.”

V. Intermediate Handling Facilities Standards

V(1) Add a paragraph to explicitly state that intermediate handling facilities must have a permit.

Renumber old V(1) through V(8) as V(2) through V(9).

V(5)(e) This revised paragraph changes the reporting requirement for consistency with other parts of this regulation.

V(6). Revise to clarify who must receive training at an infectious waste treatment facility.

X. Permit By Rule

X(1) Correct to clarify that infectious waste generators are the only facilities eligible to qualify for a Permit by Rule under this regulation.

X(2) No changes are made.

X(3) Revise to specify which facilities must apply for an infectious waste treatment permit.

Y. Manifest Form Requirements For Permitted Treatment Facilities

Y(2)(a), (d), (e), (f), and (g) These paragraphs are deleted to match US DOT standards. Renumber Y(2)(b), (c), and (h) as (a) (b) and (c); at the new (2)(b) change one percent to ten percent and add the word “and” at the end of the sentence; in the new (2)(c) change three years to two (2) years.

Y(3) Delete after combining requirements with those in Y(4) and Y(5).

Renumber old Y(4) and Y(5) as Y(3) and Y(4).

AA. Inspections and Record Keeping.

AA. This revision reorganizes the Regulation so that the authority for the Department to inspect facilities and check records are in one section and reorganizes the rest of the section accordingly. The title will be changed to “Inspections and Record Keeping.”

AA(1) Move language from BB(3) which provides authority to Departmental representatives to enter and inspect facilities to ascertain compliance with this regulation.

AA(2) Change three (3) years to two (2) years to match US DOT standards. Renumber original paragraph (1) as(2) Allow record storage as paper or electronically.

AA(3) Change three (3) years to two (2) years to match US DOT standards. Revise last sentence for clarity and to remove off-site manifest requirement. Renumber original paragraph (2) as (3). Allow record storage as paper or electronically.

AA(4) Add new paragraph at AA(4). The added paragraph sets requirements for record maintenance and retention and adds the requirements to the Regulations that authorizes the Department to inspect these records: "If the waste is no longer infectious because of treatment, and the treatment residue is stored onsite in a tank, the generator shall maintain a record of monitoring and pump events for two (2) years afterward to include the date and type of monitoring, who conducted the monitoring, date and amount of waste pumped, and the name of the business or person that provided the pumping service. Pump event data may be in the form of a manifest or log. Records shall be maintained by the generator for a minimum of two (2) years in a location easily accessible to the Department and shall provide these records to the Department upon request."

BB. Enforcement.

BB(1) and (2) are unchanged. BB(3) is deleted.

EE. Appeals

Add new section "EE. Appeals". Add new paragraph EE(1) and (2) to add provisions pursuant to Act 387 (2006) at SC. Section 44-1-60.

Notice of Staff Informational Forum and Public Comment Period:

Staff of the Department of Health and Environmental Control invites interested members of the public and regulated community to attend a staff conducted informational forum to be held on Wednesday, Dec 2, 2009 at 10:00 a.m. in Room 2102 at the Stern Building at 8911 Farrow Road, Suite 106. The purpose of the forum is to answer questions and to receive public comments from interested persons on the proposed amendment of R.61-105.

Interested persons are also provided an opportunity to submit written comments on the proposed Regulation at the forum or during a public comment period by writing to Richard Haynes, Director, Division of Waste Management, 2600 Bull Street, Columbia, SC 29201. To be considered, written comments must be received no later than 5:00 p.m. on December 2, 2009, the close of the public comment period.

Information or copies of the proposed text for public notice and comment may be obtained at http://www.scdhec.net/environment/lwm/public_notice.asp. Interested parties may also obtain a copy from the Department's Regulatory Development update at: <http://www.scdhec.gov/administration/regs/> or by calling Carolyn McLaughlin at: 803 896-4254.

Relevant public comments received at the Forum and during the above-noticed public comment period shall be submitted to the Board of Health and Environmental Control in a "Summary of Public Comments and Department Responses" for consideration at the public hearing as noticed below.

Notice of Public Hearing and Opportunity for Public Comment Pursuant to S.C. Code Sections 1-23-110 and 1-23-111:

Interested members of the public and regulated community are invited to make oral or written comments on the proposed amendment of R.61-105 at a public hearing to be conducted by the Board of Health and

Environmental Control at its regularly scheduled meeting on January 14, 2010. The public hearing will be held in the Board Room of the Commissioner's Suite, Third Floor, Aycock Building of the Department of Health and Environmental Control at 2600 Bull Street, Columbia, S.C. 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 Board's agenda will be published by the Department 24 hours in advance of the meeting. Persons desiring to make oral comments at the hearing are asked to limit their statements to five minutes and, as a courtesy, are asked to provide written comments of their presentations for the record.

Preliminary Fiscal Impact Statement:

There will be minimal cost to the state and its political subdivisions. See Statement of Need and Reasonableness below.

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 R.61-105 Infectious Waste Management Regulations.

Purpose: The Department of Health and Environmental Control proposes to amend Regulation 61-105 to include the handling of embalming waste as a regulated infectious waste, provide requirements for the use of formaldehyde as a disinfectant for bodily fluids during the embalming process, provide a method for the inspection, approval and use of holding tanks to hold the treatment residue created by the disinfection of bodily fluids with formaldehyde, and to clarify points in the Regulations for the regulated community. The proposed amendments would add or clarify definitions. Allowances for alternate recordkeeping and communication would be developed for generators and transporters in regards to weight, biohazard marking, and manifesting. Duplicated or outdated requirements would be deleted. New requirements would be added for situations that could create a public health risk that have not been addressed in the past. Clarifications would be made to the Regulation to address the handling and treatment of regulated infectious waste by generators and transporters. In response to comments, adjustments will be made to bring state transportation requirements in line with US Department of Transportation (DOT) requirements. Requirements for those utilizing the United States Postal Service to transport regulated infectious waste will be clarified. Generator registration and fee requirements will be revised and facilities that close will be required to notify the Program.

This revision will also create an appeals section of R.61-105 to comply with statutory changes in the Administrative Appeals process pursuant to S.C. Code Section 44-1-60 (2006 S.C. Act 387).

Legal Authority: South Carolina Infectious Waste Management Act, S.C. Code Sections 44-93-10 *et seq.* and 44-1-60

Plan for Implementation: Upon final approval by the Board of Health and Environmental Control, approval by the South Carolina General Assembly and publication in the *State Register* as a final Regulation, the amended Regulation will be provided in hard copy and electronic formats to the public at cost through the Department's Freedom of Information Office and at the Bureau web site.

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

This amendment is necessary and reasonable because it would update and clarify the Infectious Waste Management Regulation to protect public health and the environment in areas that are not currently addressed.

Proposed changes are necessary to add new amendments that would require the embalming process to be handled as a potential source of regulated infectious waste and to set storage and treatment standards for this waste and its residue that currently is not regulated under R.61-105.

The proposed revision is needed to include requirements to protect against potential hazards from leaking embalming fluid from tanks and to establish the proper procedures for storing and transporting these materials.

There are five potential methods for disposal of this treatment residue. The residue can be sent directly to a sanitary sewer for disposal at a regulated wastewater treatment facility or sent to an existing septic tank for bacterial decomposition and groundwater dispersal. The residue can be solidified and sent to a regulated solid waste landfill, or incinerated. The residue can be stored in a tank and then pumped out for further treatment and/or disposal.

The EPA has determined that it is not possible to meet the EPA Health Advisory Limit for formaldehyde utilizing a conventional septic system. Therefore, the Department will not issue any new septic tank permits to funeral homes for this embalming waste treatment residue. Facilities that do not have access to municipal wastewater systems must then apply to the Bureau of Water for a holding tank permit. However, facilities that are rural and do not have access to municipal wastewater systems are often small and do not have a large enough volume of waste to be regulated under the Standards for Wastewater Facility Construction regulations. As this waste could still be a risk to public health and the environment, the amendments to this Regulation would provide requirements for these generators to prevent such risk.

This amendment would provide a method for the approval, monitoring, and use of holding tanks to hold the treatment residue created by the disinfection of bodily fluids with formaldehyde. These amendments would apply to all storage tanks for embalming treatment residue installed after the amendments take effect. Tanks that have been installed prior to the time the amendments take effect would only have to meet certain of the requirements; they must meet the use, monitoring, record keeping, and disposal requirements. If discharge occurs, the generating facility may be required to clean up this discharge or take other action so that the discharge no longer presents a potential hazard to human health or the environment. Tanks with high pump-out frequency, or previously permitted septic tanks, would be subject to regulation by other Programs in the Department or on the federal level. Tanks would need to be pumped at a rate of greater than fifty (50) gallons per day or three hundred and fifty (350) gallons per week or one thousand five hundred (1500) gallons per month to be regulated by other parts of the Department as well as the Infectious Waste Program. Previously permitted septic tanks that contain embalming waste are regulated under R.61-56, Onsite Wastewater Systems or R.61-87, Underground Injection Control Regulations and would not be additionally regulated by these amendments.

Amendments would provide an exemption from treatment facility permitting requirements for facilities when the treatment of infectious waste is only related to the embalming process and is performed for the purposes of meeting this standard. The definitions of "Pump Event" and "Treatment Residue" are added to support these requirements.

Allowances for alternate record keeping and communication would make the requirements less burdensome for generators and transporters in regards to weighing waste, biohazard marking, and manifesting. Duplicated requirements would be eliminated. The requirement for radiological monitoring by transporters would be eliminated as well as the requirement for continual refrigeration for generators,

transporters, intermediate handling facility operators, and transfer facility operators. The definitions of “Generator registration status,” “Manifest,” “Site,” and “Small Quantity Generator” are added or revised to support these requirements. The definitions of “Storage” and “Universal Biohazard Symbol” are revised for clarification.

Proposed amendments would prevent situations that could create a public health risk that have not been addressed in the past, including a requirement that unattended vehicles carrying infectious waste must prevent access by unauthorized personnel and proposed amendments would provide for regulating the storage and disposal of infectious waste treatment residue. Additionally, clarifications are necessary to address the handling and treatment of sharps containers by small quantity generators.

Revision of the appeal provisions is necessary pursuant to State Law (Act 387 of 2006).

DETERMINATION OF COSTS AND BENEFITS:

Costs to the State or Political Subdivisions:

There will be no 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. Some of the changes in the Regulation stem from Department interpretation of the Regulations and incorporating them into Regulation gives the Department the authority to enforce the requirements. The proposed Regulation provides guidelines for the installation and monitoring of holding tanks for the residue resulting from embalming. This may require an insignificant increase in time spent by Department staff, but will provide direction to the regulated community in dealing with embalming waste treatment residue, which the regulated community has requested.

Generating facilities would be required to notify the Department when they close their businesses or stop generating infectious waste so that the Department would not waste resources attempting to contact facilities that have closed.

Costs to the Regulated Community:

Facilities that have chosen to delay the closing of containers prior to transport to defray costs could see an increase in their pick-up frequency. Depending on their financial arrangements with their transporters, this could increase costs. It has been the Department’s interpretation of the Regulations that once a container is full of waste, it should be closed for storage. Language supporting this interpretation would now be part of the Regulations.

The costs to facilities with existing tanks used to store embalming waste treatment residue could be as low as \$20 per facility for a monitor to measure the liquid in the tank. The monitor would aid in the detection of leaks that could potentially result in contamination of the environment. There are potential costs to the facilities for clean-up if contamination of any sort is detected. The facilities will also be responsible for a minimum level of processing required for treatment residue wastes. The treatment media itself, if unused, must be properly characterized, handled and disposed of. If facilities were not already handling treatment media properly, facilities may incur additional costs.

Due to the proposed requirement for labeling trucks with the biohazard symbol sign, if trucks were not already labeled, transporters may incur a small cost associated with purchasing and applying these labels.

There would be a savings to generators, transporters, intermediate handling facility operators, and transfer facility operators who would no longer have to refrigerate waste just because it was refrigerated at the generating facility or by the most recent handler. Transporters would no longer have to perform radiological monitoring, since treatment facilities are required to perform such monitoring and generating facilities are required to prevent radioactive waste from leaving the generating site. Overall, the proposed changes would provide for greater protection of the environment and public health with very little increase in cost to businesses. This may result in some cost savings for some facilities.

UNCERTAINTIES OF ESTIMATES:

No known uncertainties.

EFFECT ON ENVIRONMENT AND PUBLIC HEALTH:

The overall effect of these amendments is expected to be beneficial to the public health and environment by requiring monitoring of treatment residue from the embalming process that is no longer infectious by proposed regulatory definition but may contain formaldehyde, a potentially hazardous chemical.

If this waste is to be stored in a holding tank, the tank must be compatible with the material being stored, installed according to the manufacturer's instructions, at the same location as the generating facility, and must be used to store only treatment residue generated onsite. The tank must be monitored to be sure that it is not leaking.

Records must be retained for monitoring and pump events. If any contamination is suspected or confirmed, the Department must be notified and the generating facility is responsible for clean up.

There will now also be a minimum level of treatment required for liquid embalming waste, preventing human health risks. The treatment media itself, if unused, must be properly characterized, handled, and disposed of.

The proposed Regulation changes should also benefit public health by tightening control over storage of regulated infectious waste at generating facilities. The requirement that transporters must prevent unauthorized access to transport vehicles will help prevent risks to the public.

The amendment to update the regulatory appeal procedure is necessary to comply with the statutory changes in administrative law.

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

If these amendments are not implemented, any facility that generates only liquid waste during the embalming process will not be regulated, and some potential embalming waste storage and disposal practices may place the environment and public health at risk. Also, the risk to the public from transport vehicles carrying regulated infectious waste left unattended will continue.

Statement of Rationale:

A review of program regulatory interpretations, questions from the regulated community, and new issues brought to the attention of the Department led staff to propose revisions to this Regulation. These amendments will provide greater protections for the public, relieve undue stresses placed on the regulated

community, and clarify and strengthen regulatory interpretations of the Program by placing them in the Regulation.

See Statement of Need and Reasonableness above.

~~Indicates Matter Stricken~~

Indicates New Matter

Text:

The following sections have been added, deleted, or revised. All other sections of R.61-79 will remain. Deleted text is indicated by strikethrough; new text is indicated by underlining.

D(1) Definitions

Add five new definitions in alphabetical order: “Generator registration status;” “Pump event;” “Site;” “Small quantity generator;” and “Treatment residue.” Revise the definition for “Manifest,” “Storage,” and “Universal biohazard symbol.”

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

(bb) ~~(aa)~~ “Manifest” means the shipping document authorized ~~originated~~ and signed by the generator which contains the information required by this regulation.

(gg) “Pump Event” means any action where treatment residue is removed from a tank holding treatment residue.

(kk) “Site” means contiguous land, structures, and other appurtenances and improvements on the land used for generating, treating, storing, transferring or disposing of regulated infectious waste with the same ownership.

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

(oo) ~~(kk)~~ “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.

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

(xx) ~~(ss)~~ “Universal biohazard symbol” means the symbol design that conforms to the design shown in the federal Occupational Safety and Health Administration (OSHA) Standards. ~~29—CFR 1910.1030(g)(1)(I)(B)~~

E(1) Definition of Infectious Waste.

Amend E(1) introductory paragraph and E(1)(a). Other sub items remain the same:

(1) An infectious waste is any used material which is: generated in the health care community in the diagnosis, treatment, immunization, or care of human beings; generated in embalming, autopsy, or necropsy; generated in research pertaining to the production of biologicals which have been exposed to human pathogens; generated in research using human pathogens; and which is not excluded in two (2) below and which is listed in the categories below:

(a) Sharps.

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

(b) Microbiologicals.

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

Amend E(2)(c). Other sub items remain the same:

E(2)(c) Mixed waste containing regulated quantities of ~~either or both waste as defined in (a) or (b) immediately above~~ both RCRA hazardous waste and source, special nuclear, or byproduct material subject to the Atomic Energy Act of 1954, as amended, are to be managed pursuant to all applicable regulations.

F. Generator Requirements.

Amend F(1)(f) and (g); add new (h) and (i):

(f) a contact name of the infectious waste coordinator; ~~and~~

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

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

(i) the Employer Identification Number (EIN).

Revise paragraph F(3), (4) and (5) to read:

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

(4) Fees for registration will be due at the time of initial registration and ~~renewal annually thereafter~~. Fees will be assessed ~~as outlined in accordance with the Environmental Protection Fees, Regulation 61-30 Section DD based on generator's registration status.~~

(5) Each generator must have a designated infection control committee with the authority and responsibility for infectious waste management. This committee must develop or adopt a written protocol to manage the infectious waste stream from generation ~~to disposal 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 ~~if own~~ onsite treatment procedures. Small quantity generators are not required to have an infection control committee or a written protocol.

Revise F(6)(c), (i), and (j);

(6) Each generator must:

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

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

(j) ~~weigh waste prior to sending offsite for disposal and maintain monthly generation rates in the facility operating record.~~ 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.

Revise F(7); Add new F(8):

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

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

G. Small Quantity Generators.

Revise paragraph G(1), G(1)(a) and (b); delete (b)(i) and (ii). G(2) and G(3) remain the same. Revise paragraph G(4) as indicated

(1) All in-state generators must comply with the provisions of Section E; Section F, Parts 1-3, 6-8; and the following: All in-state generators that produce less than fifty (50) pounds of infectious waste per calendar month are small quantity generators and are exempt from the provisions of this regulation except they shall comply with the following:

(a) sharps, microbiological cultures, products of conception, and human blood and blood products must be managed pursuant to this regulation including but not limited to: packaging, treatment and weight generation rate requirements; and the provisions of Section E and F, except Section F(4), (5) and (6)(i).

(b) the management of the following infectious waste: 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.

~~(i) sharps, microbiological cultures, products of conception, and human blood and blood products must be managed pursuant to this regulation; and~~

~~(ii) all other infectious waste may be disposed of as other solid waste after being properly packaged to prevent exposure to solid waste workers and the public.~~

(2) Generators who qualify as small quantity generators, as defined above, may transport their own waste provided:

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

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

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

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

~~(e)(e)~~ (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.

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

I. Packaging Requirements.

Revise I(1) and (2); I(3) remains the same; revise I(4) and (5) as shown:

(1) Generators shall assure that infectious waste is ~~properly~~ packaged in accordance with the requirements of this section and to prevent any release of infectious waste from its packaging before storing, transporting, or offering for transport offsite. Absorbents may be used to aid in the prevention of releases. Waste transported by the U.S. Postal Service must meet the packaging requirements for infectious waste in the Domestic Mail Manual.

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

(3) All other types of infectious waste must be placed, stored, and maintained before and during transport in a rigid or semi-rigid, leak ~~proof~~ resistant container which is impervious to moisture.

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

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

I(6) remains the same; revise I(7), (8), (9) and (10) as indicated; I(11) remains the same; revise I(12):

(7) ~~Dumpsters, Roll-off containers, trailer bodies, or other vehicle containment areas do not constitute~~ cannot be used as rigid containment. ~~system but are only a transport mechanism.~~

(8) Infectious waste must be contained in ~~disposable or reusable~~ containers that are appropriate for the type and quantity of waste, ~~must withstand handling, transfer, and transportation without impairing the integrity of the container, must be closed tightly and securely,~~ and must be compatible with selected storage, transportation, and treatment processes.

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

(10) ~~Infectious~~ Compaction of waste shall not be compacted by any means shall be prevented prior to entering the containment of the treatment process.

(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.

Revise J(1) to read:

(1) Generators, and transporters must assure that once sealed, containers of infectious waste are properly labeled in English as outlined below.

Revise J(2)(a) and (b); delete J(2)(c) and (f); renumber (2)(d) and (e) to (2)(c) and (d); revise new J(2)(c) and (d) as indicated:

- (a) the universal biohazard symbol sign; ~~as specified in 29 CFR 1910.1030(g)(1)(I)(B);~~
- (b) the ~~name of~~ Department issued number of the in-state generator;
- (e) ~~the name, address, and phone number of the generator if the waste is generated outside of this state;~~
- (c)(~~d~~) a labeling process which is water-resistant and indelible; and
- (d)(~~e~~) the date the container was placed in storage or sent offsite, if not stored; ~~and,~~
- (f) ~~the words Infectious Waste, Biohazardous Waste, or Medical Waste.~~

K. Storage of Infectious Waste.

Revise K(1) introductory paragraph; sub items K(1)(a), (b), and (c) remain the same.

(1) Storage shall be in a manner and location which affords protection from animals, vectors, weather conditions, theft, vandalism and which minimizes exposure to the public. Storage begins at the time the container is sealed.

Revise K(2) ; K(3) remains the same; revise K(4); delete K(5)(d); K(5)introductory paragraph and (5)(a)-(c) remain the same.:

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

(4) Storage areas must be labeled with the universal biohazard symbol sign ~~as specified in 29 CFR 1910.1030(g)(1)(i)(B) and the words Infectious Waste, Medical Waste or Biohazardous Waste and the words Infectious Waste, Medical Waste, or Biohazardous Waste.~~

(5)(d) ~~Once infectious waste is stored in a refrigerated or frozen state by a generator, an intermediate handling facility operator, a transfer facility operator, or a transporter, the waste shall be maintained in that refrigerated or frozen state until treatment at a permitted treatment facility.~~

M. Manifest Form Requirements for Generators.

This section has been substantially revised.

Revise M(1) language. M(1)(a) through (m) have been reorganized and renumbered. Separate M(1)(a) into M(1)(a), (b) and (c). Separate the old (c) into two sections with the first section (e) requesting the number of containers of waste and the second section (f) designating the weight of the waste. Delete old (d). Old (e), (f), (g) and (h) are renumbered. Delete old (i). Renumber old (j) and (k). Delete old (l) and (m). Revise the old (g), (j), and (k).

(1) A generator who transports, or offers for transport, infectious waste for offsite treatment, storage, or disposal, must prepare a manifest ~~on a form approved by the Department~~ using DHEC Form 2116 or another Department approved form and filled out in a legible manner according to the instructions for that form. The manifest form must accompany the waste at all times after leaving the generator's facility. The manifest form will include, but is not limited to:

(a) ~~the name of the generator, the Department identification number (if located in S.C.), and address of the premises where the waste was generated;~~

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

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

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

(e) ~~(e)~~ the number of containers of waste and the weight (accurate to within one (1) percent);

(f) the weight or volume (accurate to within ten (10) percent);

~~(d) the name of the generator's designated treatment facility;~~

(g) ~~(e)~~ a certification by the generator stating "This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation" that the waste is packaged and labeled in accordance with this regulation, and that the description of the waste is accurate;

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

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

(j) ~~(h)~~ the name of the transporter who receives the waste from the generator or subsequent transporter and that transporter's Department issued transporter registration number;

~~(i) a certification by the transporter that the information required in (a), (b), (c) and (d) above is complete;~~

(k) ~~(j)~~ the date the transporter ~~received~~ accepted the shipment;

(l) ~~(k)~~ the date the treatment facility ~~received~~ accepted the shipment onsite;

~~(l) a certification by the treatment facility that the information required in (c) above is accurate with what was received, or the treatment facility must fill out a discrepancy report indicating the number of containers received and the weight received; and~~

~~(m) a certification by the treatment facility that the waste was adequately treated.~~

Revise language in M(2); revise reference in M(3); revise language in M(4); delete M(5).

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

(3) This generator shall sign by hand or other legally defensible signature where required in (1)(~~g~~) ~~(e)~~, (h) ~~(f)~~, and (i) ~~(g)~~

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

~~(5) The generator shall notify the Department in writing if he does not receive a completed manifest appropriately signed from the destination facility within fifty (50) days after offering for transport.~~

N. Infectious Waste Transporter Requirements.

Revise paragraph N(6); (6)(a) and (b) remain the same; add the word “and” at the end of (6)(c) and delete (6)(d); renumber (6)(e) to (6)(d).

(6) Transporters must develop ~~and adhere to~~ a written infectious waste management plan which must address at a minimum:

(c) handling and storage of waste; and

~~(d) radiological monitoring; and~~

(d) ~~(e)~~ personnel health and safety training.

Revise the first sentence of paragraph N(7); break the rest of the paragraph into (7)(a), (b) and (c) as shown:

(7) A draft of the plan required in Section N (6) must accompany the annual registration application.

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

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

(c) Changes in this plan must be made by submittal of a written request to the Department which may approve or deny such request.

Revise paragraph N(9) to read:

~~(9) In the event of a discharge of infectious waste during transportation or storage, the transporter must take appropriate and immediate action to prevent potential effects to human health or the environment, and must immediately telephone the Department's 24-hour emergency telephone number, (803) 253-6488, giving all requested information. 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.~~

Revise paragraph N(10) to read:

~~(10) No transport vehicle containing infectious waste may be left unattended for more than one (1) hour unless it is in a secured area not easily accessible to the general public. Transport vehicles containing infectious waste must be managed to prevent access by unauthorized persons.~~

O. Transporter Registration Requirements.

Reorganize paragraphs O(1)(a)-(c) as indicated; delete subparagraphs (c)(i)-(iii); revise O(d); add new paragraphs (e), (f) and (f)(i) - (iii); add new (g):

(a) the transporter's name and mailing address;

(b) the ~~transporter's mailing address~~ name, address, and telephone number for each intermediate handling facility, transfer facility, or transportation related site that the transporter will operate at in South Carolina;

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

~~(d) the address for each intermediate handling facility, transfer facility, or transportation related site that the transporter will operate at in South Carolina this statement signed by hand by the owner or his authorized agent: "I certify, under penalty of criminal and/or civil prosecution for making or submission of false statements, representations, or omissions, that I have read, understand, and will comply with the South Carolina Infectious Waste Management Regulation R.61-105.";~~

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

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

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

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

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

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

Revise O(2) introductory paragraph;(2)(a), (b) and (c) remain the same.

(2) No person shall engage or continue to engage in transportation of infectious waste (except as outlined in Section N (2)) in South Carolina unless they register annually with the Department as an infectious waste transporter, and pay applicable fees as outlined in ~~the Environmental Protection Fees, Regulation 61-30~~ Section DD.

Revise section O(6) to read:

(6) Transporters which neither pick up infectious waste nor deliver infectious waste within this state are exempt from registration. Transporters who only transport into or within this state regulated infectious waste packaged in accordance with United States Postal Service Domestic Mail Manual infectious waste packaging requirements are also exempt from registration.

Q. Transport Vehicle Requirements.

Revise Q(1)(a), Q(1)(g), and Q(1)(g)(i); (g)(ii) remains the same; revise (g)(iii) as shown:

Q(1) Each vehicle used to transport infectious waste must meet at a minimum these requirements:

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

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

(i) the registered name of the transporter;

(iii) the words INFECTIOUS WASTE, MEDICAL WASTE, or BIOHAZARDOUS WASTE and the universal biohazard symbol sign.

Revise Q(2) to read:

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

R. Manifest Requirements for Transporters.

R(2)(a) remains the same; delete (2)(b); renumber (2)(c) as (2)(b) and revise new (2)(b) as shown;

~~(b) certify that the manifest accurately reflects the number of containers being transported by signing and dating the manifest; and~~

~~(b)~~ (e) return a ~~signed and dated~~ copy of the manifest form to the generator before leaving the site.

Delete R(5)(a); renumber (5)(b) and (c) as (5)(a) and (b); revise new (5)(a)

~~(a) obtain a copy of the manifest signed and dated by the authorized representative of the treatment facility;~~

~~(b)~~ (a) retain a copy of the ~~signed~~ completed manifest for his records; and

~~(c)~~ (b) turn the remaining copies of the manifest over to the treatment facility.

Revise R(6) to read:

(6) The transporter shall deliver the entire quantity represented on the manifest that he accepted from the generator or another transporter to another ~~the next~~ transporter or a ~~the~~ destination facility ~~listed on the manifest~~.

Delete R(7), delete old R(8)(b); renumber old R(8) as R(7); revise new R(7)(a); renumber old R(8)(c) as R(7)(b).

~~(7) If the infectious waste cannot be delivered in accordance with (6) above, the transporter shall contact the generator for further lawful instructions, revise the manifest according to the instructions received from the generator and deliver the entire quantity of infectious waste from that generator in accordance with those lawful instructions.~~

~~(7)~~ (8) All transporters and/or management companies which list themselves as the generator on the manifest or a consolidated manifest must assume full responsibility of the generator(s) and must:

(a) attach a copy of the completed new manifest form to the original manifest form and retain a copy of the new and original manifest form; and

~~(b) return a copy of each manifest form to the original generator(s) within seven (7) days of receipt of the new manifest form (copy 1) from the destination facility; and~~

~~(b)~~ (c) maintain a transporter consolidation log indicating all shipments that have been consolidated.

S. Storage Tank Requirements

Remove [Reserved] status in Section Title. Add new section S to read:

S. [Reserved] Storage Tank Requirements.

(1) Liquid treatment residue generated during the embalming process may be stored in an underground or above ground storage tank located onsite at the generating facility. Tanks in operation at the time this regulation takes effect must meet the use, monitoring, record keeping, disposal, and clean-up requirements of this Section. Tanks installed after the date this regulation becomes effective must meet all requirements of these regulations.

(2) Storage tanks must meet the following conditions:

(a) A facility must notify the Department in writing before installing a tank to be used for storage of treatment residue. Notification should include facility name and address, number of tanks, and storage capacity;

(b) Tank materials of construction must be compatible with treatment residue to be stored;

(c) Tank must be installed and maintained in accordance with manufacturer's instructions;

(d) When treatment residue is removed from the tank, it must be pumped by a person licensed by the Department for the cleaning of disposal systems and sent directly to a regulated facility for further treatment or disposal;

(e) Tank must be monitored following pump events and with a frequency sufficient to demonstrate it is not leaking. Monitoring may be performed utilizing a dipstick, however monitoring must be performed when tank contents are sufficiently settled;

(f) The facility generating waste that is treated and stored in the tank must maintain a record of tank monitoring and pump events;

(g) Tank must be used exclusively for treatment residue storage; and

(h) Tank and records must meet all applicable state and federal requirements, including Industrial Wastewater and Disposal System Clean-out requirements.

(3) The Department may require the generating facility to clean up any treatment residue discharge that occurs during storage or take such action as may be required by state, federal, or local officials so that the treatment residue discharge no longer presents a potential hazard to human health or the environment.

T. Infectious Waste Treatment.

Revise section T(1) introduction to read:

(1) Infectious waste must be treated prior to ~~sanitary landfill disposition~~ disposal except as indicated in Section G. After approved and adequate treatment, treatment residue must be disposed of in accordance with state and federal solid waste requirements. Any unused treatment media must be characterized, handled, and disposed of in accordance with applicable regulations.

T(2) introduction and (2)(a) and (b) remain the same; revise (T)(2)(c) and (d) as shown; renumber old (2)(d) as (e).

(2) (c) chemical disinfection; ~~or~~

(d) embalming fluid containing at least two (2) percent formaldehyde; or

(e) ~~(d)~~ any other Department approved treatment method.

T(3) remains the same; delete T(4); renumber old T(5) and (6) as T(4) and (5); old T(5)(a) and (b) remain the same.

~~(4) After approved and adequate treatment, the waste residue may be disposed of in accordance with state and federal solid waste requirements.~~

~~(5)~~ (4) The following infectious waste may be disposed of before treatment:

~~(6)~~ (5) Storage of infectious waste prior to treatment must be in accordance with Section K of this regulation.

Revise T(7), (8), (9) and (10) as shown and renumber as T(6) through T(9).

~~(7)~~ (6) It is unlawful for any person to discharge infectious waste or ~~treated infectious waste~~ treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment.

~~(8)~~ (7) Facilities that only treat liquid embalming waste with at least a two (2) percent formaldehyde solution and sSmall quantity generators may that treat, by an approved method onsite, infectious waste which they generate onsite without being are not required to be permitted as a treatment facility.

~~(9)~~ (8) Treatment of infectious waste must be monitored by use of biological indicators or laboratory culture of the treatment residue to ensure that pathogens have been adequately treated. Frequency of this testing shall be determined by the Department on a case-by-case basis or as outlined in this regulation.

~~(10)~~ (9) Products of conception must be incinerated, cremated, interred, or donated for medical research.

U. Infectious Waste Treatment Facility Standards.

Revise U(1), U(7)(e), U(8), U(10)(a), U(10)(e), and U(13)(a) to read:

(1) No person may operate an infectious waste treatment or disposal facility or generator facility without first obtaining a permit as required by this regulation except as exempted in section T. A separate permit shall be required for each site or facility although the Department may include one or more different types of facilities in a single permit if the facilities are collocated on the same site.

~~(7)(e)~~ It is unlawful for any person to discharge infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment. ~~report to~~

~~the Department any spill greater than one gallon or one cubic foot of dry waste immediately by calling the 24 Hour Emergency Spill Telephone Number, (803) 253-6488.~~

(8) All ~~employees~~ individuals involved with handling and management of waste shall receive thorough training in their responsibilities and duties. A training protocol shall be submitted to the Department at the time of application for a permit. Training documentation for ~~employees~~ individuals shall be submitted to the Department within thirty (30) days of completion.

(10)(a) use instrumentation which is approved by the ~~Division of Radioactive Waste Management Department~~ for this purpose;

(10)(e) report any and all incidents when radioactive materials are detected to the ~~Department Division of Radioactive Waste Management~~ for guidance in dealing with the radioactive materials. The Department may allow a treatment facility to hold containers of waste containing radioactive material for radioactive decay after the facility has submitted procedures for appropriately managing the containers and has received approval from the Department. However, under no circumstance may a treatment facility solicit the receipt of radioactive material.

(13)(a) provide complete combustion of the waste and packaging to carbonized or mineralized ash;

V. Intermediate Handling Facilities Standards

Insert the following as paragraph V(1). Renumber the old V(1) through V(8) as V(2) through V(9). Revise new paragraph V(5)(e).

V(1) No person may operate an infectious waste intermediate handling facility without first obtaining a permit as required by this regulation. A separate permit shall be required for each site or facility although the Department may include one or more different types of facilities in a single permit if the facilities are co-located on the same site.

(2) (4) All intermediate handling facilities must develop and submit to the Department for approval a standard operating procedure manual which will include at a minimum:

(3) (2) Approval for acceptance of infectious waste at an intermediate handling facility may be withdrawn by the Department for noncompliance with the standard operating procedure manual.

(4) (3) When a facility ceases infectious waste management activities, it shall notify the Department in writing, immediately, and it shall thoroughly clean and disinfect the facility and all equipment used in the handling of infectious waste. All untreated waste shall be disposed of in accordance with the requirements of this regulation.

(5) (4) In the event of an accidental spill of infectious waste, the designated personnel at the facility shall:

(e) It is unlawful for any person to discharge infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment. ~~report to the Department any spill greater than one gallon or one cubic foot of dry waste immediately by calling the 24 Hour Emergency Spill Telephone Number, (803) 253-6488.~~

~~(6)~~ ~~(5)~~ All ~~employees~~ individuals involved with handling and management of waste shall receive thorough training in their responsibilities and duties. A training protocol shall be submitted to the Department at the time of application for a permit. Training documentation for employees shall be submitted to the Department within thirty (30) days of completion.

~~(7)~~ ~~(6)~~ Permittee shall notify the Department in writing within thirty (30) days prior to any changes in ownership, operating control, name, or location. The Department may upon written request transfer a permit to a new owner or operator where no other change in the permit is necessary provided that a written agreement containing a specific date for transfer of permit responsibility and financial assurance between the current and new owner has been submitted to the Department.

~~(8)~~ ~~(7)~~ 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)~~ ~~(8)~~ A facility receiving waste generated offsite must log-in transport vehicles as they arrive at the facility in a bound log book and note in this book if any shipments are rejected. The intermediate handling facility must:

- (a) disinfect the cargo-carrying compartment(s) immediately after unloading the waste; and
- (b) clean out visible debris and immediately put debris into the treatment system.

X. Permit By Rule

Revise X(1) and X(3) as shown; X(2) remains the same.

(1) All ~~Infectious waste treatment facilities~~ generators which comply with the conditions of (2) below shall be deemed to have a permit by rule.

(3) All ~~other facilities~~ infectious waste generators who treat infectious waste and are not exempted in Section T and not meeting the requirements of (2) above shall apply for an infectious waste treatment permit as outlined in Section W.

Y. Manifest Form Requirements For Permitted Treatment Facilities.

Delete Y(2)(a); renumber Y(2)(b) and (c) as (a) and (b); revise new (b) as shown. Delete Y(2)(d)-(g); revise old Y(2)(h) as shown and renumber as Y(2)(c).

(2) The owner or operator or his authorized agent of a treatment facility when accepting a manifested shipment shall:

- ~~(a) sign and date each copy of the manifest to certify that the infectious waste was accepted;~~
- (a)~~(b)~~ write on the manifest the number of containers accepted and the total weight;
- (b)~~(c)~~ note any discrepancies greater than ten ~~one~~ (10) percent of the container count on the manifest;
and
- ~~(d) give the transporter at least one copy of the signed manifest;~~

~~(e) sign a certification that the information required in (2) (e) above is accurate with what was received, or complete and submit the discrepancy report required by subparagraph (3) below;~~

~~(f) sign and date each copy of the manifest certifying when the waste was adequately treated;~~

~~(g) send a copy of the completed manifest to the generator (as stated on the manifest), within twenty-one (21) days of delivery; and~~

~~(c) (h)~~ retain a copy of the completed manifest form for ~~two~~ three (3) years.

Delete Y(3) and renumber old Y(4) and Y(5) as (3) and (4). Y(5)(a)-(g) remain the same.

(3) Discrepancy reports as required by (2) (c) must include:

~~— (a) any variation in piece count such as a discrepancy greater than one (1) percent of the box, pail, drum, or container count on a manifest;~~

~~— (b) identification of packaging that is broken, torn, or leaking; and~~

~~— (c) identification of infectious waste that arrives at a treatment facility which is not accompanied by a manifest, or which is accompanied by a manifest which is incorrect, incomplete, or not signed.~~

(3) (4) When any variation in piece count greater than one (1) percent or in weight greater than ten (10) percent discrepancies are is discovered, the owner or operator shall attempt to resolve the discrepancy with the waste generator or the transporter. If the discrepancy is not resolved, the owner or operator shall submit a letter to the Department, within five (5) days, of receipt of the waste, describing the nature of the discrepancy and the attempts the owner or operator has undertaken to reconcile it. The owner or operator shall include with this letter a legible copy of the manifest in question.

(4) (5) If a facility receives any infectious waste from offsite which is not accompanied by a manifest, or which is accompanied by a manifest which is incorrect, incomplete, or not signed, the owner/operator must prepare and submit to the Department a written copy of a report within fifteen (15) days after receiving the waste. The "Unmanifested Waste Report" must include the following information:

AA. Record Keeping.

Revise title to Part AA to read:

AA. Inspections and Record Keeping.

Add new AA(1); renumber and revise old AA(1) and (2) as AA (2) and (3); add new AA(4)

(1) Department representatives are authorized to enter and inspect any property or premises for the purpose of ascertaining compliance or noncompliance with this regulation.

(2) (4) All generators, transporters, transfer facilities, intermediate handling facilities and treatment facilities handling infectious waste generated, treated, transported, or otherwise managed in the State shall maintain all records and manifest copies required by this regulation for a minimum of ~~three-two~~ (3) years in a location within South Carolina easily accessible to the Department during regular business hours and shall provide these records to the Department upon request. Records may be maintained in paper form or electronically.

(3) (2) If the waste is no longer infectious because of treatment, the generator or permitted facility shall maintain a record of the treatment for ~~three-two~~ (3) years afterward to include the date and type of

treatment, amount of waste treated, and the individual operating the treatment. Records for onsite treatment ~~and manifests from transporters for offsite treatment~~ shall be maintained by the generator for a minimum of ~~three~~ two (32) years in a location easily accessible to the Department and shall be provided these records to the Department upon request. Records may be maintained in paper form or electronically.

(4) If the waste is no longer infectious because of treatment, and the treatment residue is stored onsite in a tank, the generator shall maintain a record of monitoring and pump events for two (2) years afterward to include the date and type of monitoring, who conducted the monitoring, date and amount of waste pumped, and the name of the business or person that provided the pumping service. Pump event data may be in the form of a manifest or log. Records shall be maintained by the generator for a minimum of two (2) years in a location within South Carolina easily accessible to the Department and shall be provided to the Department upon request. Records may be maintained in paper form or electronically.

BB. Enforcement

Delete BB(3)

~~BB (3) Department representatives are authorized to enter and inspect any property or premises for the purpose of ascertaining compliance or noncompliance with this regulation.~~

Add new section “EE. Appeals”; add new paragraph EE(1) and (2) to add provisions pursuant to Act 387 (2006) at SC. Section 44-1-60.

EE. Appeals

(EE)(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.