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Document No. 4107

**DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL**

CHAPTER 61

Statutory Authority: 1976 Code Sections 44-1-60 and 44-93-10 et seq.

61-105. Infectious Waste Management

**Synopsis:**

 The Department of Health and Environmental Control has amended R. 61-105, South Carolina Infectious Waste Management Regulations. These Regulations were previously amended June 24, 2005. Amendments include:

 (1) The embalming process as a potential source of regulated infectious waste and set storage and treatment standards for this waste. Amendments 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 have been developed for generators and transporters in regards to weight, biohazard marking and manifesting.

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

 (4) New requirements have been 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 have been made to the Regulation to address the handling and treatment of regulated infectious waste by small quantity generators and transporters.

 (6) The amendments add or clarify definitions used in the Regulation.

 (7) Stylistic changes include corrections for internal consistency, clarification, references, and spelling in an effort to improve the overall text of the Regulation.

 (8) Requirements were brought into compatibility with federal Department of Transportation regulations.

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

 (10) Generator registration and fee requirements have been 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).

 A Notice of Drafting for this amendment was published in the *State Register* on June 26, 2009.

**Below are changes made to the proposed regulation during the legislative review**

**process, as requested by the Senate Medical Affairs Committee**

**by its letter dated March 25, 2010:**

61-105.D. Definitions.

The section outline enumeration at D(1) was reorganized from existing definition “(w).”

61-105.J. Labeling of Containers.

At 61-105.J(3), a cross reference was corrected from (a) and (d) to (a) and (c).

61-105.N. Infectious Waste Transporter Requirements.

The enumeration as proposed was corrected and changed from N(10) to N(11).

61-105.O. Transport Registration Requirements.

At 61-105.O(3), a cross reference was corrected from O(1)(c) to O(1)(f).

61-105.Q. Transporter Vehicle Requirements.

The proposed changes at 61-105.Q(1)(g) introductory paragraph and Q(1)(g)(iii) were removed and the text was returned to the existing text of R.61-105. Subitem 61-105.Q(1)(h) was added for clarification that the biohazardous symbol sign must appear on four sides of the transporter vehicle to meet the US Department of Transportation requirements.

**Below is DHEC’s Section-by-Section Discussion of Revisions**

**as submitted to the General Assembly for review on January 28, 2010:**

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) 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 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.

Revises paragraph G(1), G(1)(a) and (b); deletes (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.SectionG revisions define limits and inclusions for requirements of Small Quantity Generators.

I. Packaging Requirements.

I(1) 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) is revised to include the responsibility of all potential parties for packaging sharps.

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

I(4) is revised to clarify container requirements.

I(5) 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) revises the list of examples of containers and explicitly state that they are prohibited from use as rigid containment areas.

I(8) is revised to separate and clarify requirements.

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

I(10) is revised 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) 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) adds: “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) 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) is revised 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) is revised 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) 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) 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) is revised to clarify potential ramifications if a discharge of infectious waste occurs during transport.

N(10) 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: “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) adds: “registered” to clarify the transporter requirements.

Q(1)(g)(iii) after the words “BIOHAZARDOUS WASTE” add: “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) is revised 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) is revised 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) “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) 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) 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) 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) is revised to clarify who must receive training at an infectious waste treatment facility.

U(10)(a) language is changed from “Division of Radioactive Waste Management” to “Department.”

U(10)(e) language is changed from “Division of Radioactive Waste Management” to “Department.”

U(13)(a) 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) adds 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) 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. 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) moves language from BB(3) which provides authority to Departmental representatives to enter and inspect facilities to ascertain compliance with this regulation.

AA(2) changes 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) changes 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) adds 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

“EE. Appeals” is added; EE(1) and (2) add provisions pursuant to Act 387 (2006) at South Carolina Code of Laws, Section 44-1-60.

**Instructions:** Amend R.61-105 using each individual instruction provided with the text below.

**Text:**

The following sections have been added, deleted, or revised. All other sections of R.61-105 will remain. Deleted text is indicated by strikeout; 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 definitions for “Manifest,” “Storage,” and “Universal biohazard symbol.” Reorganize Section D(1) outline from existing definition “(w).**

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

 (x) “Hazardous waste” means a Resource Conservation and Recovery Act (RCRA) hazardous waste as defined in R.61‑79.261.3 of the S. C. Hazardous Waste Management Regulations.

 (y) “Infectious waste” or “waste” means a material as defined in Section E of this regulation.

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

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

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

 (cc) “Offsite” means not onsite.

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

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

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

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

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

 (ii) “Release” means to set free from restraint or confinement.

 (jj) “Secured area” means an area which is fenced with a locking gate or which is regularly patrolled by security personnel which prevents access by the general public. An area which has controlled access and barriers to prevent exposure of the general public.

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

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

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

 (nn) “State” means the State of South Carolina.

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

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

 (qq) “Transfer facility” means any transportation related facility where shipments of infectious waste are held during the normal course of transportation, but are not off loaded or on loaded into fixed storage areas.

 (rr) “Transport” means the movement of infectious waste from the generation site to a treatment facility or site for intermediate storage and/or disposal.

 (ss) “Transporter” means a person engaged in the offsite transportation of infectious waste by air, rail, highway, or water.

 (tt) “Transport vehicle” means a method used for the transportation of cargo by any mode. Each cargo‑carrying body (trailer, railroad freight car, etc.) is a separate transport vehicle.

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

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

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

 (xx) “Universal biohazard symbol” means the symbol design that conforms to the design shown in the Federal Occupational Safety and Health Administration (OSHA) Standards .

**E(1) Definition of Infectious Waste.**

**Amend E(1) introductory paragraph and E(1)(a) and (b). 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 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;

 (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 annually thereafter. Fees will be assessed in accordance with Section DD based on generator’s registration status.

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

**Revise F(6)(c), (i), and (j):**

 (6) Each generator must:

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

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

**G. Small Quantity Generators.**

**Revise paragraph G(1), G(1)(a) and (b); delete (b)(i) and (ii). Revise G(2)(b) as indicated and G(3) remains 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:

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

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

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

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

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

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

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

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

 (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), (2), (3), (4), and (5) as shown:**

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

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

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

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

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

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

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

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

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

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

 (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;

(b) the Department issued number of the in-state generator;

 (c) a labeling process which is water-resistant and indelible; and

 (d) the date the container was placed in storage or sent offsite, if not stored.

**Revise J(3) to read:**

(3) Each bag used to line the inside of an outer container shall be labeled with indelible ink or imprinted as outlined in (a) and (c)immediately above.

**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, sheds, trailers, van bodies, or any other storage area).

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

**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 using DHEC Form 2116 or another Department approved form and filled out in a legible manner according to the instructions for that form. The manifest form must accompany the waste at all times after leaving the generator’s facility. The manifest form will include, but is not limited to:

 (a) the name of the generator;

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

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

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

 (e) the number of containers of waste;

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

 (g) a certification by the generator stating “This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation”;

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

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

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

 (k) the date the transporter accepted the shipment;

 (l) the date the treatment facility accepted the shipment onsite;

**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 ensure a manifest is initiated as required in (1) above.

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

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

**N. Infectious Waste Transporter Requirements.**

**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 a written infectious waste management plan which must address at a minimum:

 (c) handling and storage of waste; and

 (d) 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) 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(11) to read:**

 (11) 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;

 (b) the transporter’s mailing address;

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

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

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

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

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

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

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

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

**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 Section DD.

**Revise O(3) to read:**

 (3) The financial responsibility required in section O(1)(f) above must be maintained. If any change occurs in a registered transporter’s financial responsibility, he must cease to transport infectious waste and notify the Department immediately to determine when and how transportation may be resumed.

**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)(b), (c), (d), (e) and (f) remain the same.**

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

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

**Revise Q(1)(g)(i). Q(1)(g) introductory, Q(1)(g)(ii) and (iii) remain the same.**

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

 (i) the registered name of the transporter;

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

 (iii) the words INFECTIOUS WASTE, MEDICAL WASTE, or BIOHAZARDOUS WASTE .

**Add Q(1)(h) to read:**

 (h) the biohazard symbol sign must be permanently affixed to the cargo-carrying body on two sides and the front and back.

**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) return a 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) retain a copy of the completed manifest for his records; and

 (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 transporter or a destination facility.

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

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

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

**S. Storage Tank Requirements.**

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

S.Storage Tank Requirements.

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

 (2) Storage tanks must meet the following conditions:

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

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

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

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

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

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

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

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

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

**T. Infectious Waste Treatment.**

**Revise section T(1) introduction to read:**

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

**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;

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

 (e) 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) The following infectious waste may be disposed of before treatment:

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

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

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

 (7) Facilities that only treat liquid embalming waste with at least a two (2) percent formaldehyde solution and small quantity generators that treat, by an approved method onsite, infectious waste which they generate onsite are not required to be permitted as a treatment facility.

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

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

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

**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.

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

 (10)(a) use instrumentation which is approved by the Department for this purpose;

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

 (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):**

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

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

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

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

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

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

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

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

 (8) Facilities shall schedule shipments of waste to prevent a backlog of loaded transportation vehicles at the facility or offsite. The number of loaded and unloaded transport vehicles stored onsite will be controlled by permit conditions.

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

 (a) disinfect the cargo-carrying compartment(s) immediately after unloading the waste; and

 (b) clean out visible debris and immediately put debris into the treatment system.

**X. Permit By Rule.**

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

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

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

**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) write on the manifest the number of containers accepted and the total weight;

 (b) note any discrepancies greater than ten (10) percent of the container count on the manifest; and

 (c) retain a copy of the completed manifest form for two (2) years.

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

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

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

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

 (3) If the waste is no longer infectious because of treatment, the generator or permitted facility shall maintain a record of the treatment for two (2) years afterward to include the date and type of treatment, amount of waste treated, and the individual operating the treatment. Records for onsite treatment shall be maintained by the generator for a minimum of two (2) years in a location easily accessible to the Department and shall be provided to the Department upon request. Records may be maintained in paper form or electronically.

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

**BB. Enforcement.**

**Delete BB(3):**

**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.

**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 has amended 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 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.

The 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 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 amendment 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.

These amendments will 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 amendments will 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 changes in the Regulation affect operational procedures by regulated facilities and will 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 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 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 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.