

Regulation 61-105

Infectious Waste Management Regulation

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S.C. Code Sections 44-93-10 et seq. and 44-93-100

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A.Purpose and Scope.

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

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

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

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

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

B.Severability.

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

C.Use of Number and Gender.

As used in this regulation:

- (1) Words in the masculine gender also include the feminine and neuter genders; and
- (2) Words in the singular include the plural; and
- (3) Words in the plural include the singular.
- (4) Words have common dictionary meaning unless otherwise specified.

D.Definitions.

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

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

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

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

- (d) “CFR” means the Code of Federal Regulations.
- (e) “Closure” means the point in time at which facility owners or operators discontinue operation by ceasing to accept, treat, store, or dispose of infectious waste.
- (f) “Commissioner” means the Commissioner of the Department or his authorized agent.
- (g) “Container” means any portable device in which a material is stored, transported, treated, disposed of, or otherwise managed.
- (h) “Containment” means the packaging of infectious waste or the containers in which infectious waste is placed.
- (i) “Contingency Plan” means a document setting out an organized, planned and coordinated course of action to be followed in case of a fire, explosion, or release of infectious waste or infectious waste constituents, or interruption of normal procedures of infectious waste management.
- (j) “Department” means the South Carolina Department of Health and Environmental Control, including personnel of the Department authorized by the Board to act on behalf of the Department or Board.
- (k) “Destination facility” means an infectious waste treatment facility which has received a permit from the Department in accordance with this regulation or an appropriate out-of-state facility and which is the facility designated by the generator to which waste is to be transported.
- (l) “Discharge” or “infectious waste discharge” means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of infectious waste into or onto any land or waters of the State, including groundwater.
- (m) “Dispose” means to discharge, deposit, inject, dump, spill, leak, or place any waste into or on any land or water, including groundwater, so that the substance may enter the environment or be emitted into the air or discharged into any waters, including groundwater.
- (n) “EPA” means the U. S. Environmental Protection Agency.
- (o) “EPA identification number” means the EPA assigned Medical Waste Identification Number.
- (p) “Existing facility” means a facility which was in operation under permits issued by the Department on June 8, 1989.
- (q) “Expand” means an increase in the capacity of the facility or an increase in the quantity of infectious waste received by a facility that exceeds a permit condition.
- (r) “Facility” means a location or site within which infectious waste is treated, stored, and/or disposed of.
- (s) “Final closure” means the closure of all infectious waste management units at the facility in accordance with all applicable closure requirements so that infectious waste management activities are no longer conducted at the facility.

(t) “Free liquids” means liquids which separate readily from the portion of a waste under ambient temperature and pressure.

(u) “Generator” means the person producing infectious waste except waste produced in a private residence.

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

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

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

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

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

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

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

(cc) “Offsite” means not onsite.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

E. Definition of Infectious Waste.

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

(a) Sharps.

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

(b) Microbiologicals.

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

(c) Blood and Blood Products.

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

(d) Pathological Waste.

All tissues, organs, limbs, products of conception, and other body parts removed from the whole body, excluding tissues which have been preserved with formaldehyde or other approved preserving agents, and the body fluids which may be infectious due to bloodborne pathogens. These body fluids are: cerebrospinal fluids, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, semen, and vaginal/cervical secretions.

(e) Contaminated Animal Waste.

Animal carcasses, body parts and bedding when the animal has been intentionally exposed to human pathogens in research or the production of biologicals.

(f) Isolation Waste.

All waste generated from communicable disease isolation of the Biosafety Level 4 agents, highly communicable diseases, pursuant to the ‘Guidelines for Isolation Precautions in Hospitals’, published by the Centers For Disease Control.

(g) Other Waste.

Any other material designated by written generator policy as infectious, or any other material designated by a generator as infectious by placing the material into a container labeled infectious as outlined in Section J. Any solid waste which is mixed with infectious waste becomes designated as infectious and must be so managed unless expressly excluded in 2 (c) below.

(h) Infectious Waste Residues Resulting from Discharges.

Any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any infectious waste.

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

(a) Hazardous waste which is to be managed pursuant to the Hazardous Waste Management Regulations, R. 61-79, as amended, et seq.

(b) Radioactive material which is managed pursuant to the Department Regulation 61-63, Radioactive Material (Title A).

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

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

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

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

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

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

F. Generator Requirements.

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

(a) name of the business;

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

(c) physical location of the site of waste generated (each site of waste generated must apply separately);

- (d) mailing address of the site of generation;
- (e) telephone number of the site;
- (f) a contact name of the infectious waste coordinator;
- (g) the categories and corresponding amount of infectious waste generated annually (estimated within plus or minus (+ or -) twenty (20) percent).
- (h) the method of waste treatment and disposal; and
- (i) the Employer Identification Number (EIN).

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

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

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

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

(6) Each generator must:

- (a) segregate infectious waste from other waste at the point of generation;
- (b) assure proper packaging and labeling of waste to be transported offsite as required in Section I and J, respectively, of this regulation;
- (c) ensure a manifest is initiated if waste is to be transported offsite as outlined in Section M of this regulation;
- (d) prevent infectious waste containing radioactive material which is distinguishable from background from leaving the site of generation when the material is under the jurisdiction of the United States Nuclear Regulatory Commission or an Agreement State;
- (e) maintain records as required by this regulation in Section AA;
- (f) store waste as outlined in Section K of this regulation;

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

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

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

(j) Obtain and record accurate weight of waste within fifty (50) days of shipment. Unabsorbed liquid waste produced during the embalming process is exempt from this requirement.

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

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

G. Small Quantity Generators.

(1) All in-state generators must comply with the provisions of Section E; Section F, Parts 1-3, 6-8; and the following:

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

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

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

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

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

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

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

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

(3) If a small quantity generator offers infectious waste for transport offsite for treatment at a destination facility, the waste must be managed pursuant to Sections H through DD of this regulation.

(4) If in any calendar month fifty (50) pounds of infectious waste or more is produced, the generator must notify the Department in writing; manage infectious waste pursuant to the entire regulation; and pay

the annual fee as outlined in Section DD of this regulation. A generator will be able to claim designation as a small quantity generator after submitting documentation demonstrating twelve (12) consecutive calendar months of waste production less than fifty (50) pounds, or if at the time of registration, the generator estimates that less than fifty (50) pounds a month will be generated.

H. Segregation Requirements.

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

I. Packaging Requirements.

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

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

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

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

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

(6) Plastic bags used inside of containers shall be a red or orange color and have sufficient strength to prevent tearing.

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

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

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

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

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

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

J. Labeling of Containers.

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

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

- (a) the universal biohazard symbol sign;
- (b) the Department issued number of the in-state generator;
- (c) a labeling process which is water-resistant and indelible; and
- (d) the date the container was placed in storage or sent offsite, if not stored.

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

(4) Transporters must label each outer container at the time it is accepted as specified in Section P (2).

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

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

K. Storage of Infectious Waste.

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

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

(b) The waste must be protected to maintain the integrity of the packaging and provide protection from weather conditions such as water, rain, and wind.

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

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

(3) Storage areas must allow access to authorized personnel only.

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

(5) Infectious waste must be maintained in a nonputrescent state using refrigeration when necessary.

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

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

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

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

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

L. Disinfection Standards.

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

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

(b) Vehicle bodies which have been used to store or transport infectious waste must be disinfected immediately after unloading.

(c) Spillage of infectious waste must be disinfected immediately.

(2) Disinfection can be accomplished by appropriate use of an EPA registered disinfectant used according to the label instructions at the tuberculocidal strength.

(3) Drainage from decontamination processes shall discharge to a Department approved sanitary sewer system or be transported to a Department approved sewerage treatment facility or permitted infectious waste treatment facility.

M. Manifest Form Requirements For Generators.

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

- (a) the name of the generator;
 - (b) the Department identification number (if applicable);
 - (c) the address of the site where the waste was generated;
 - (d) a general description of the nature of the waste being shipped;
 - (e) the number of containers of waste;
 - (f) the weight or volume (accurate to within ten (10) percent);
 - (g) a certification by the generator stating “This is to certify that the above-named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation”;
 - (h) a certification by the generator that the shipment does not contain regulated quantities of hazardous waste as defined by the S.C. Hazardous Waste Management Regulations;
 - (i) a certification by the generator that the shipment does not contain radioactive material or waste above levels determined in Section F(6)(d) of this Regulation;
 - (j) the name of the transporter who receives the waste from the generator or subsequent transporter and that transporter’s Department issued transporter registration number;
 - (k) the date the transporter accepted the shipment;
 - (l) the date the treatment facility accepted the shipment onsite;
- (2) The generator who offers regulated infectious waste for transport offsite shall ensure a manifest is initiated as required in (1) above.
- (3) This generator shall sign by hand or other legally defensible signature where required in (1)(g), (h), and (i).
- (4) The generator shall retain one copy of the manifest after the transporter has accepted the shipment.

N. Infectious Waste Transporter Requirements.

- (1) Transporters of infectious waste which is generated, stored, transferred or treated within South Carolina must be registered with the Department prior to such activity unless otherwise provided by this regulation.
- (2) Generators who transport their own infectious waste offsite, except those generators who qualify as small quantity generators in Section G of this regulation, must also comply with all applicable transporter requirements of this regulation.
- (3) Transporters of infectious waste must comply with all applicable requirements of this regulation during transportation and when the waste is at a transfer facility.

(a) infectious waste may be transferred from one vehicle to another only at a designated transfer facility; and

(b) infectious waste may not be unloaded into fixed storage at a transfer facility.

(4) Transporters must also comply with the requirements of Sections I and J when they repack defective boxes of infectious waste.

(5) Transporters must also comply with applicable requirements of this regulation when they:

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

(b) remove infectious waste from reusable containers; or

(c) repackage or modify packaging of infectious waste.

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

(a) a spill plan;

(b) contingency plans for alternate treatment, storage and/or disposal sites;

(c) handling and storage of waste; and

(d) personnel health and safety training.

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

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

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

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

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

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

(10) The Department may require transporters to clean up and/or disinfect any infectious waste discharge that occurs during transportation or take such action as may be required by state, federal, or local officials

so that the infectious waste discharge no longer presents a potential hazard to human health or the environment.

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

(12) Reserved.

O. Transporter Registration Requirements.

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

(a) the transporter's name;

(b) the transporter's mailing address;

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

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

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

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

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

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

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

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

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

(a) Transporters must notify the Department in writing within thirty (30) days if any changes occur in the information required for registration as outlined in (1) above or if they terminate their business; and

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

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

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

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

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

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

P. Transporter Acceptance of Infectious Waste.

Transporter acceptance of infectious waste occurs when the waste is loaded onto the transport vehicle.

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

(a) packaged as required in Section I;

(b) labeled as required in Section J; and

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

(2) Transporters must attach a waterproof identification label to the outside of each container of infectious waste they accept for transport. The label must be affixed in a manner which does not cover any other required labels or markings. This identification label must include but is not limited to:

(a) the transporter's Department issued identification number, or the transporter's name, address, and phone number; and

(b) Reserved.

(3) If the transporter accepts loaded and sealed trailers from a broker or generator, that transporter does not have to assure proper packaging as required in Section I or proper labeling as required in Section J. However, the transporter must:

(a) assure that the load is accompanied by a properly completed manifest; and

(b) prevent discharges of infectious waste, especially fluids, from the cargo-carrying body.

Q. Transport Vehicle Requirements.

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

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

(b) the containers of waste shall be loaded and unloaded so that no compaction or mechanical stress of the waste occurs during handling or during transit;

(c) the cargo-carrying body shall be maintained in a sanitary condition and disinfected immediately after each unloading and as spills are detected;

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

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

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

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

(i) the name of the transporter;

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

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

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

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

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

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

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

(c) and meet the requirements of Section K.

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

R. Manifest Requirements For Transporters.

(1) No transporter shall accept a shipment of infectious waste which is to be transported within South Carolina unless it is accompanied by an infectious waste manifest which has been completed according to the instructions for the Department approved form and signed by the generator.

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

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

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

(3) The transporter, transfer facility operator, and/or intermediate handling facility operator shall ensure that the manifest form accompanies the infectious waste at all times until unloaded for treatment.

(4) The transporter who delivers infectious waste within or into South Carolina must ensure delivery to a registered or properly permitted infectious waste management transporter, transfer facility, intermediate handling facility or treatment facility.

(5) The transporter, upon delivery of infectious waste to a permitted treatment facility, shall:

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

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

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

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

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

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

S. Storage Tank Requirements.

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

(2) Storage tanks must meet the following conditions:

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

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

- (c) Tank must be installed and maintained in accordance with manufacturer's instructions;
 - (d) When treatment residue is removed from the tank, it must be pumped by a person licensed by the Department for the cleaning of disposal systems and sent directly to a regulated facility for further treatment or disposal;
 - (e) Tank must be monitored following pump events and with a frequency sufficient to demonstrate it is not leaking. Monitoring may be performed utilizing a dipstick, however monitoring must be performed when tank contents are sufficiently settled;
 - (f) The facility generating waste that is treated and stored in the tank must maintain a record of tank monitoring and pump events;
 - (g) Tank must be used exclusively for treatment residue storage; and
 - (h) Tank and records must meet all applicable state and federal requirements, including Industrial Wastewater and Disposal System Clean-out requirements.
- (3) The Department may require the generating facility to clean up any treatment residue discharge that occurs during storage or take such action as may be required by state, federal, or local officials so that the treatment residue discharge no longer presents a potential hazard to human health or the environment.

T. Infectious Waste Treatment.

- (1) Infectious waste must be treated prior to disposal except as indicated in Section G. After approved and adequate treatment, treatment residue must be disposed of in accordance with state and federal solid waste requirements. Any unused treatment media must be characterized, handled, and disposed of in accordance with applicable regulations.
- (2) Treatment must be by one of the following treatment methods in accordance with this regulation and other applicable state and federal laws and regulations:
- (a) incineration;
 - (b) steam sterilization;
 - (c) chemical disinfection;
 - (d) embalming fluid containing at least two (2) percent formaldehyde; or
 - (e) any other Department approved treatment method.
- (3) Approval for other forms of treatment must be obtained from the Department and meet standards set at that time by the Department.
- (4) The following infectious waste may be disposed of before treatment:
- (a) an approved liquid or semi-liquid waste other than microbiological cultures and stocks may be discharged directly into a Department approved wastewater treatment disposal system; and

(b) recognizable human anatomical remains may be disposed of by interment or donated for medical research.

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

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

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

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

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

U. Infectious Waste Treatment Facility Standards.

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

(2) All treatment facilities must treat the waste as indicated in Section T.

(3) Infectious waste treatment residue must not be disposed of until or unless Department approved monitoring methods confirm effectiveness of the treatment process.

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

(a) unloading and handling procedures;

(b) safety procedures;

(c) emergency preparedness and response plans;

(d) receiving, record keeping, and reporting procedures;

(e) remedial action plans;

(f) quality assurance plans for treatment methods;

(g) radiological and hazardous waste monitoring procedures;

- (h) procedures for identifying types and quantities of infectious waste received;
- (i) contingency plans for use of alternate facilities; and
- (j) procedures for disposition of treatment residues.

(5) Approval for acceptance of infectious waste at a treatment or disposal facility may be withdrawn by the Department for noncompliance with the standard operating procedure manual.

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

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

- (a) contain the spill to the area immediately affected;
- (b) immediately disinfect the area which is contaminated;
- (c) pick up, repackage as required or otherwise immediately remove the spilled material into the treatment system;
- (d) record the incident in a bound log book, including the quantity spilled, personnel involved, and the nature and consequences of the event; and

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

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

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

(10) A facility receiving waste generated in a hospital or other generator which uses radioactive material must screen incoming waste for radioactivity as they arrive at the treatment facility. Such facilities must:

- (a) use instrumentation which is approved by the Department for this purpose;
- (b) have the operator properly trained on such equipment;

(c) have such equipment calibrated at least once a year by an authorized calibrator;

(d) maintain a log of quality assurance testing and calibration of such instrumentation; and

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

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

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

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

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

(13) Incinerators must, in addition to items (1) through (12) above:

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

(b) comply with all applicable regulations issued by the Department; and

(c) receive authorization for disposal of treatment residue from the Department prior to disposition into a landfill located in this state, and said authorization shall be based on relevant analyses and requirements deemed necessary by the Department. Such authorization may be incorporated into a landfill permit.

(14) All steam sterilizers must, in addition to items (1) through (12) above.

(a) use Department approved indicator organisms in test runs to assure proper treatment of the waste. Indicator organisms must be used daily at a commercial facility and monthly at a generator facility in each steam sterilizer;

(b) record the temperature and time during each complete cycle to ensure the attainment of a temperature of 121 degrees Centigrade (250 degrees Fahrenheit) for 45 minutes or longer at fifteen (15) pounds pressure, depending on quantity and density of the load, in order to achieve sterilization of the entire load; (Thermometers shall be checked for calibration at least annually.)

(c) have a gauge which indicates the pressure of each cycle;

(d) use heat sensitive tape or other device for each container that is processed to indicate that the steam sterilization temperature has been reached. The waste will not be considered appropriately treated if the indicator fails;

(e) use the biological indicator *Bacillus stearothermophilus* placed at the center of a load processed under standard operating conditions to confirm the attainment of adequate sterilization conditions;

(f) maintain records of the procedures specified in (b), and (e) above for period of not less than three (3) years; and

(g) assure that treatment residues are disposed of in accordance with applicable State and Federal Requirements.

V. Intermediate Handling Facilities Standards.

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

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

(a) unloading and handling procedures;

(b) safety procedures;

(c) emergency preparedness and response plans;

(d) receiving, record keeping, and reporting procedures;

(e) remedial action plans;

(f) procedure for treatment of spills;

(g) radiological and hazardous waste monitoring procedures;

(h) procedures for identifying types and quantities of infectious waste received;

(i) contingency plans for use of alternate facilities; and

(j) procedures for disposition of treatment residues.

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

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

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

(a) contain the spill to the area immediately affected;

- (b) immediately disinfect the area which is contaminated;
- (c) immediately pick up and repackage as required or treat the spilled material;
- (d) record the incident in a bound log book, including the quantity spilled, personnel involved, and the nature and consequences of the event; and
- (e) It is unlawful for any person to discharge infectious waste or treatment residue into the environment of this State except as permitted by the Department. If a release of infectious waste or treatment residue to the environment is known or suspected, the facility must report to the Department within twenty-four (24) hours and immediately investigate and confirm all suspected releases. Action may then be required by local, state, or federal officials so that the infectious waste or treatment residue discharge no longer presents an actual or potential hazard to human health or the environment.
- (6) All individuals involved with handling and management of waste shall receive thorough training in their responsibilities and duties. A training protocol shall be submitted to the Department at the time of application for a permit. Training documentation for employees shall be submitted to the Department within thirty (30) days of completion.
- (7) Permittee shall notify the Department in writing within thirty (30) days prior to any changes in ownership, operating control, name, or location. The Department may upon written request transfer a permit to a new owner or operator where no other change in the permit is necessary provided that a written agreement containing a specific date for transfer of permit responsibility and financial assurance between the current and new owner has been submitted to the Department.
- (8) Facilities shall schedule shipments of waste to prevent a backlog of loaded transportation vehicles at the facility or offsite. The number of loaded and unloaded transport vehicles stored onsite will be controlled by permit conditions.
- (9) A facility receiving waste generated offsite must log-in transport vehicles as they arrive at the facility in a bound log book and note in this book if any shipments are rejected. The intermediate handling facility must:
 - (a) disinfect the cargo-carrying compartment(s) immediately after unloading the waste; and
 - (b) clean out visible debris and immediately put debris into the treatment system.

W. Permit Applications and Issuance.

- (1) No person may expand or construct a new treatment facility without obtaining an Infectious Waste Management permit issued by the Department. To obtain a permit, the applicant shall demonstrate the need for such a facility or expansion. To determine if there is a need, infectious waste generated outside of the state may not be considered without Department approval.
- (2) The Department will determine and publish annually an estimate of the amount of infectious waste to be generated in South Carolina during the ensuing twelve months.
- (3) The demonstration of need does not apply to:
 - (a) facilities owned by counties, municipalities, or public service districts which accept only infectious waste generated in this state;

(b) facilities that are owned or operated by the generator of the waste and this waste is generated in this state;

(c) generator facilities; or

(d) facilities currently operated under permits issued by the Department, or to the renewal of existing permits issued by the Department if there is no expansion of the capacity as prescribed in the conditions of the permit.

(4) No person may expand or construct a new intermediate handling facility without an Infectious Waste Management permit issued by the Department. Intermediate handling facility permit applicants do not have to demonstrate a need.

(5) To obtain an Infectious Waste Management Permit, the person must complete a permit application as designed by the Department. Permit applications will not be processed until they are deemed complete by the Department.

(6) A draft of the manual required in Section U (4) must accompany the permit application. The manual must meet the approval of the Department or be modified so that it will meet approval. After approval by the Department, the standard operating procedure manual shall become part of the permit and must be adhered to by the permittee. Changes in this manual must be made by submittal of a written request to the Department which may approve or deny such request.

(7) In addition to other requirements, a permit application for a treatment facility or intermediate handling facility must include at a minimum:

(a) an engineering report which, at a minimum, contains a description of the facility, the process and equipment to be used, the proposed service area, and storage of the waste;

(b) engineering plans and specifications which must, at a minimum, describe the architectural, mechanical, electrical, plumbing, heating, ventilating, process equipment, instrumentation and control diagrams, and performance specifications for all major equipment and control centers;

(c) the latitude and longitude of the facility;

(d) a topographic map (or similar map) extending one mile beyond the property boundaries of the source, depicting the facility and each of its intake and discharge structures; each of its infectious waste management, treatment, storage, or disposal facilities; those wells, springs, other surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant within the quarter-mile of the facility property boundary; and the 100-year flood plain;

(e) a written acknowledgment from the governing body of the city or town, and/or county in which the facility is to be located that the location and operation of the facility are consistent with all applicable ordinances;

(f) a description of the process to be used for treating, storing, handling, transporting and disposing of infectious waste, and the design capacity of these items;

(g) a description of the type of the infectious waste to be treated, stored, transported or disposed at the facility, an estimate of the quantity of such wastes to be treated, stored, transported, and disposed annually;

(h) a quality assurance and quality control report;

(i) a contingency plan describing a technically and financially feasible course of action to be taken in response to contingencies which may occur during construction and operation of the facility to include a description of how the waste will be managed to protect the waste from flood waters.;

(j) an identification of possible air releases and groundwater or surface water discharges;

(k) a waste control plan describing the manner in which waste will be received, stored, and otherwise managed;

(l) a plan outlining the flow of traffic associated with the facility;

(m) a closure plan which includes the estimated cost of closure;

(i) a closure cost estimate which must be based on the cost of hiring a third party to close the facility; and

(ii) a cost estimate which may not include any salvage value from the sale of any structures, equipment, and other assets.

(n) other information as may be required by the Department.

(8) The Permittee shall notify the Department in writing within thirty (30) days of any changes of the information required in (7) above or changes which would require modifications of the permit as issued.

(9) A permit may be terminated or a new or renewal application may be denied by the Department for noncompliance by the permittee with any conditions of the permit, requirements of this regulation, or the Act.

(10) In addition to conditions required in all permits, the Department shall establish conditions as required on a case-by-case basis, for the duration of the permits, schedules of compliance, monitoring, and to provide for and assure compliance with all applicable requirements of this regulation.

(11) Permits will be valid for the period stated on the permit. If the application for renewal is received as above, the permit will continue in force until the Department makes a permit decision.

(12) As a condition of approval for an Infectious Waste Management Permit, any person who owns or operates a facility or group of facilities for the treatment, storage, or disposal of infectious waste must demonstrate financial responsibility for bodily injury and property damage to third parties caused by sudden accidental occurrences arising from the operation of the facility or group of facilities and assure the satisfactory maintenance, closure, and postclosure care of any facility or group of facilities, and to carry out any corrective action which may be required by the Department. Such form and amount of financial responsibility shall be a permit condition specified by the Department. At any time, should the Department determine that the levels of financial responsibility required are not consistent with the degree and duration of risk associated with treatment, storage, or disposal at the facility or group of facilities, the Department may adjust the level of financial responsibility required as may be necessary to protect human health and

the environment. This adjusted level will be based on the Department's assessment of the degree and duration of risk associated with the ownership or operation of the facility or group of facilities.

(13) The permittee must immediately notify the Department upon loss of the financial responsibility coverage. A permittee shall cease to treat or store infectious waste upon loss of financial responsibility coverage.

(14) A facility may receive only those waste streams for which it is permitted; however, a facility may request in writing to receive new waste streams which are subject to Department approval or denial.

X. Permit By Rule.

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

(2) To qualify for permit by rule the owner and/or operator of the facility shall:

(a) comply with all parts of the Act and this regulation except permitting procedures of Section W.

(b) demonstrate that more than seventy-five (75) percent (by weight, in a calendar year) of all infectious waste that is stored, treated or disposed of by the facility is generated onsite.

(c) assure that no activities at the facility involve the placing of infectious waste directly into the environment.

(d) notify the Department in writing that the facility is operating under a permit by rule and supply the following information:

(i) the name, mailing address, location address, and phone number of the facility;

(ii) type of businesses served;

(iii) the type of facility; and

(iv) the principal officer; and

(e) notify the Department in writing before onsite treatment activities begin.

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

(4) Any facility deemed to have a permit by rule which fails to satisfy any of the conditions set forth in (2) above or this regulation may have its permit by rule revoked and must obtain a permit as outlined in Section W to continue to store, treat, or dispose of infectious waste.

Y. Manifest Form Requirements For Permitted Treatment Facilities.

(1) Treatment facilities must not accept infectious waste to be treated, stored, or otherwise managed unless accompanied by a Department approved manifest form if the waste is generated offsite.

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

- (a) write on the manifest the number of containers accepted and the total weight;
- (b) note any discrepancies greater than ten (10) percent of the container count on the manifest; and
- (c) retain a copy of the completed manifest form for two (2) years.

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

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

- (a) the name and address of the facility;
- (b) the date the facility received the waste;
- (c) the identification number or name and address of the generator and the transporter if available;
- (d) a description and the quantity of the waste;
- (e) the method of treatment, storage, or disposal of the waste;
- (f) a certification signed by the owner operator of the facility or his authorized representative; and
- (g) a brief explanation of why the waste was unmanifested, if possible.

Z. Reporting For Permitted Treatment Facilities.

(1) All commercial treatment facilities are required to submit the monthly fees and reports as required by the Act.

(2) All treatment facilities are required to submit an annual report to the Department, covering the period from January 1 through December 31 of each calendar year which shall be submitted to the Department by February 15 of the subsequent year. The report shall include but is not limited to:

- (a) a description of the sources by state, and amounts of infectious waste treated;
- (b) the method used to treat the waste; and
- (c) the amount and disposition of the residue.

AA. Inspections and Record Keeping.

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

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

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

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

BB. Enforcement.

(1) Any person who violates any of the provisions of this regulation or any permit issued pursuant hereto, or any order issued by the Department or Board shall be subject to applicable civil, administrative, and criminal penalties as provided for in the Infectious Waste Management Act.

(2) Any registered generator or transporter, or permitted intermediate handling facility or treatment facility is subject to having its registration or permit suspended or revoked upon finding by the Department that:

- (a) false or inaccurate information has been submitted in the application process;
- (b) laws, Department orders, regulations, or registration or permit conditions have been violated;
- (c) reports or other information required by the Department have not been submitted or inaccurately submitted; and/or
- (d) lawful inspection has been refused.

CC. Variances.

(1) The Department may, upon written petition from any person who is subject to this regulation, grant a variance from one or more specific provisions of this regulation under the following conditions. The petitioner shall:

(a) identify the specific provisions of this regulation from which variance is sought;

(b) demonstrate that compliance with the identified provision would, on the basis of conditions unique and peculiar to the applicant's particular situation, tend to impose a substantial financial, technological, or safety burden on the petitioner or the public; and

(c) demonstrate that the proposed activity will have no significant adverse impact on the public health, safety, or welfare, the environment or natural resources and will be consistent with the provisions of the Infectious Waste Management Act.

(2) In granting any variance hereunder the Department may impose specific conditions reasonably necessary to assure that the subject activity will have no adverse impact on the public health, safety, or welfare, the environment or natural resources.

(3) Any variance granted by the Department may be immediately withdrawn when the Department finds on the basis of complaints, noncompliance with conditions of the variance or other information that the variance is not in the public interest or protective of human health and/or the environment, or that the petitioner has provided false or inaccurate information on which the variance was granted.

(4) Nothing herein shall be construed as a waiver of the Department's right to deny any petition for a variance.

DD. Fees Section.

Fees are outlined in the Environmental Protection Fees, Regulation 61-30.

EE. Appeals

(1) A Department decision involving the issuance, denial, renewal, suspension, or revocation of a permit, license, certificate, or certification may be appealed by an affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.

(2) Any person to whom an order is issued may appeal pursuant to applicable law, including S.C. Code Title 44, Chapter 1 and Title 1, Chapter 23.