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TITLE 250 – DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

CHAPTER 140 – WASTE AND MATERIALS MANAGEMENT

SUBCHAPTER 15 – MEDICAL WASTE

PART 1 – Medical Waste Regulations

1.1 Authority

These Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste in Rhode Island are promulgated pursuant to the requirements and provisions of R.I. Gen. Laws Chapters 42-17.1, "Department of Environmental Management," 42-17.6 "Administrative Penalties for Environmental Violations," and 23-19.12 in accordance with the provisions of R.I. Gen. Laws Chapter 42-35, "Administrative Procedures Act."

1.2 Purpose, Scope, and Applicability

A. Purpose- These Rules and Regulations serve the following purposes:

1. To protect the public health and the environment from the effects of improper management of medical waste through the assurance of proper, adequate and sound management of regulated medical waste.

2. To establish comprehensive standards and procedures governing the generation, transportation, storage, treatment, destruction and disposal of regulated medical waste.

3. To establish a program for tracking medical waste shipments pursuant to R.I. Gen. Laws Chapter 23-19.12.

4. To establish a program for permitting, licensing, and/or registration of persons who generate, transport, store, treat, destroy, and/or dispose of regulated medical waste.

5. To establish a program for evaluating technologies for treating and/or destroying regulated medical waste.

B. Scope and Applicability:

1. These regulations shall apply to persons who generate, transport, store, treat, manage and/or dispose of regulated medical waste as defined in § 1.5 of this Part.

2. Generators, transporters, and owners or operators of intermediate handling facilities or destination facilities who transport, offer for transport, or otherwise manage regulated medical waste within Rhode Island shall comply with these regulations.

3. Regulated medical waste becomes subject to these regulations at the time and in the location that the material becomes waste and shall remain subject to these regulations until such time as the regulated medical waste has been both treated and destroyed.

4. These regulations shall supplement and not replace all other environmental statutes both State and Federal. In cases of regulation under more than one environmental statute the administrative authority shall determine the order and manner of compliance in the fashion that most fully effectuates the requirements and policies of the statutes involved.

5. In certain situations involving outbreaks, or suspected outbreaks, of certain highly communicable diseases (either human or animal) the Director, in consultation with the Rhode Island Department of Health as appropriate, may issue a written order requiring a different standard of treatment for regulated medical waste associated with the outbreak.

6. The terms and provisions of these Rules and Regulations shall be liberally construed to permit the Department to effectuate the purposes of state law, goals and policies.

C. Regulated Medical Waste: Means a special category of solid waste (including solid, semisolid, or liquid materials) that includes specific types of medical waste subject to the handling and tracking requirements of these regulations. A regulated medical waste is any waste, as defined in these regulations, generated in the diagnosis (including testing and laboratory analysis), treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the preparation of human remains for burial or cremation, or in the production or testing of biologicals, or in the development of pharmaceuticals, that is listed in this Part but is not excluded or exempted in § 1.2(D) of this Part. Regulated medical waste shall also include certain waste, as listed in this section that is generated in any process where it is likely to have come in contact with human blood or body fluids. Regulated medical wastes mixed with non-hazardous solid wastes shall be considered regulated medical wastes. For the purposes of these regulations, the following categories of medical wastes are regulated medical waste:

1. Cultures and Stocks: Cultures and stocks of infectious agents and associated biologicals, including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals;

discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

2. Animal Pathological Waste: Contaminated animal carcasses, body parts, and bedding of animals that were known to have either:

   a. Been exposed to infectious agents during research, including research in veterinary hospitals, production of biologicals, or testing of pharmaceuticals; or,

   b. Been infected with highly communicable endemic diseases that are indicated in § 1.22 of this Part, Appendix II to require special handling of carcasses and other materials.

3. Human Pathological Wastes: Tissues, organs, and body parts of humans that are removed during surgery or autopsy, or other medical procedures (e.g., obstetrical procedures).

4. Human Blood, Body Fluids and Blood Products:

   a. Liquid waste human bloods or body fluids;

   b. Products of blood;

   c. Items saturated and/or dripping with human blood or body fluids;

   d. Items that were saturated and/or dripping with human blood or body fluids that are caked with dried human blood or body fluids; including, but not limited to, serum, plasma, and other blood components, and their containers (e.g., blood bags and blood vials) and body fluids as defined in these regulations; or,

   e. Specimens of body fluids and their containers.

5. Sharps: Objects including, but not limited to, hypodermic needles, syringes with or without the attached needle, Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, glass carpules, and glass culture dishes regardless of presence of infectious agents. Also included are other types of broken or unbroken glassware that have been used in animal or human patient care or treatment, such as used slides and cover slips. For the purpose of these regulations, disposable syringes and needles are considered regulated medical waste after one use. The following categories of wastes are considered sharps:

   a. Medical and Veterinary Sharps: Sharps that have been used in animal or human patient care or treatment, including sharps generated from the preparation of human and animal remains for

burial or cremation, or in medical, research, or industrial laboratories.

b. Unused Sharps: Unused, discarded hypodermic needles or other sharps as described above with the exception that if the unused sharp is in its original sealed packaging, it is not by definition Regulated Medical Waste.

c. Other Sharp Waste: This category of waste shall also include sharps used on human beings or animals for other than medical procedures, such as sharps used for cosmetic treatment, training purposes, circumcision or embalming procedures.

d. Body Art Waste: any waste produced in the course of injecting or physically altering a human being or animal including tattooing, ear piercing or any other process where a foreign object is used to cut or pierce the skin. Waste generated in this manner meeting the definition of sharps must be handled accordingly.

6. Isolation Wastes: Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from isolated animals known to be infected with highly communicable diseases. A list of these diseases may be found in § 1.21 of this Part, Appendix I. The Director may update this list as new diseases are identified.

7. Spill/Cleanup Material: Any material collected during or resulting from the cleanup of a spill of regulated medical waste.

8. Mixtures and Waste in Medical Waste Containers: Any waste which is a mixture of regulated medical waste and some other type of waste that is neither radioactive nor a hazardous waste of a type other than regulated medical waste shall be considered a regulated medical waste. Also, any waste, when placed in a sharps container, bag with a biohazard symbol, or other container labeled and/or designed for the packaging of regulated medical waste, must be handled and treated as a regulated medical waste, even if the contents may not have previously met the definitions in this section. If the waste is a radioactive and/or a hazardous waste it must also be handled in accordance with Regulations appropriate for radioactive and/or hazardous wastes.

9. Crime Scene/Accident Cleanup Waste: Any waste generated by commercial entities hired to clean crime scenes or accidents that are saturated with human blood or are sharps or sharp objects contaminated with human blood.

D. Regulated Medical Waste - Exclusions and Exemptions: The following categories of medical waste are specifically excluded from the definition of regulated medical waste:

1. Hazardous Waste

   Materials identified or listed under DEM Rules and Regulations for Hazardous Waste Management (Subchapter 10 Part 1 of this Chapter). Regulated medical waste that is mixed with hazardous waste shall be defined as hazardous waste and shall be regulated in accordance with DEM Rules and Regulations for Hazardous Waste Management (Subchapter 10 Part 1 of this Chapter).

2. Household Medical Waste

   a. Medical waste generated by individuals on the premises of a single family home or single family dwelling unit or by members of households residing in single and multiple residences, hotels, and motels which serve as a residence for individuals, provided the dwelling is not serving as a commercial or professional office where individuals who are not members of the family residing at such dwelling are receiving medical care by a health care professional.

   b. This exemption also includes the wastes generated by health care providers in private homes where they provide medical services to individuals residing in said homes; and,

   c. Medical waste generated and disposed of with residential solid wastes from a single family residential premises or single family dwelling unit shall be exempt from these regulations except where such medical waste is generated from commercial or professional offices.

   d. Household medical waste, once it is accepted at a collection center, shall become regulated medical waste, and the person responsible for the collection center shall be regulated as a generator in accordance with the requirements of these regulations. Similarly, household medical waste shall become regulated medical waste when accepted by a Health Care Professional.

3. Incinerator Ash and Treatment/Destruction Residue: Regulated medical waste that has been both treated and destroyed is no longer regulated medical waste; this includes ash from incineration of regulated medical waste provided the ash meets the definition for treated regulated medical waste and destroyed regulated medical waste, and residues from wastes that have been both treated and destroyed (e.g., waste that has been subjected to decontamination and grinding, or chemical disinfection followed by grinding, or steam sterilization followed by shredding). Notwithstanding this exemption, incinerator ash and treatment/destruction residue may be a hazardous waste and shall be handled in accordance with the provisions of § 1.2(D)(1) of this Part.

4. Human Remains: Human remains (e.g., corpses and anatomical parts) that are stored, transported, or otherwise managed for purposes of interment or cremation. However, regulated medical waste attached to, or within, a corpse is not exempt from these regulations and shall be removed and then managed as regulated medical waste according to these regulations.

5. Etiologic Agents: Etiologic agents that are being transported intrastate and/or interstate between facilities pursuant to regulations set by the U.S. Department of Transportation, the U.S. Department of Health and Human Services, and all other applicable shipping requirements.

6. Enforcement Samples: Enforcement samples, including samples of regulated medical waste obtained during enforcement procedures by authorized U.S. Environmental Protection Agency personnel and the State of Rhode Island.

7. Vaccination and Pharmaceutical Vials: Containers for commercially available vaccines or other pharmaceuticals that do not have an attached needle, and that have not contacted blood or body fluid.

1.3 Enforcement and Inspections

A. Failure to comply with any of the provisions of these regulations or of the terms and conditions of any permit, license or registration granted or order issued hereunder constitutes a violation of the Rhode Island Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste Act, R.I. Gen. Laws Chapter 23-19.12.

B. Upon a determination by the Director that a violation of R.I. Gen. Laws Chapter 23-19.12, or this Part, has occurred or is about to occur, the Director shall initiate one or more of the actions set forth in R.I. Gen. Laws § 42-17.1-2(21).

C. A violation of R.I. Gen. Laws Chapter 23-19.12 or this Part may give rise to civil or administrative penalties as set forth in R.I. Gen. Laws § 23-19.12-15.

D. Pursuant to R.I. Gen. Laws § 23-19.12-7, the Director is authorized to conduct such inspections of facilities, as he or she deems necessary or desirable, where regulated medical waste is generated, stored, treated, destroyed, transferred, or otherwise managed. The Director is also authorized to conduct inspections of any vehicles used to transport regulated medical waste and any records required pursuant to the authority granted under R.I. Gen. Laws Chapter 23-19.12. Inspections shall be conducted during the facility's normal business hours unless the Director determines that an immediate inspection is necessary.

1.4 Effective Dates

A. This Part (Medical Waste Regulations) shall be effective twenty (20) days after they are filed with the Secretary of State.

B. The length of time parties shall keep records required under this Part is automatically extended in the case where Rhode Island initiates an enforcement action, for which those records are relevant. For the purpose of these regulations, relevant records are those records, which reference or refer to the matter, which is the subject of the enforcement action. In such cases, the parties shall keep relevant records until the conclusion of the enforcement action.

1.5 Definitions

A. Wherever used in these regulations the following terms shall have the following meanings:

1. "Biologicals" means preparations made from living organisms and their products, including vaccines, cultures, etc., intended for use in diagnosing, immunizing or treating humans or animals or in research pertaining thereto.

2. "Blood products" means any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon, etc.

3. "Body fluids" means liquid emanating or derived from humans and limited to blood; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; dialysate and amniotic fluids; and semen and vaginal secretions but excluding feces, urine, nasal secretions, sputum, sweat, tears, vomitus, saliva, and breast milk, unless any such excluded substance contains visible blood or is isolation waste.

4. "Building" means any structure used or intended for supporting or sheltering any use or occupancy subject to these regulations.

5. "Central collection point" means a location where a generator consolidates regulated medical waste brought together from original generation points prior to its transport off-site to a transfer facility, an intermediate handler, or a destination facility. A storage facility shared by small quantity generators within a building is considered a central collection point.

6. "Decontamination" means the process of substantially reducing or eliminating the presence of harmful substances, such as infectious agents, so as to substantially reduce the likelihood of disease transmission from those substances.

7. "DEM" means the Rhode Island Department of Environmental Management.

8. "Department" means the Rhode Island Department of Environmental Management.

9. "Destination facility" means the disposal facility, the incineration facility, or any other type of facility that both treats and destroys regulated medical waste, to which a consignment of such is intended to be shipped. A destination facility is subject to the Rhode Island Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter) if the facility is located within the State of Rhode Island.

10. "Destroyed regulated medical waste" means regulated medical waste that has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing or breaking, so that it is no longer generally recognizable as medical waste. Encapsulation or compaction of regulated medical waste does not render such waste destroyed regulated medical waste. To be generally unrecognizable, all waste must be shredded such that the majority of waste is of a size of less than 1 inch and all sharps are ground to less than one half an inch.

11. "Destruction facility" means a facility that destroys regulated medical waste by ruining or mutilating it, or tearing it apart and may include a transfer station, a solid waste management facility, or any other facility that destroys regulated medical waste. A destruction facility is subject to the Rhode Island Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter) if the facility is located within the State of Rhode Island.

12. "Director" means the Director of the Rhode Island Department of Environmental Management or his or her designee. Said designee may be an employee of the Rhode Island Department of Environmental Management or from the Rhode Island Department of Health.

13. "Disposal" means the discharge, deposit, injection, dumping, spilling, leaking, abandoning, or placing of any regulated medical waste in, on, into, or onto any land, other surface, or building or vehicle, or trailer, or other containment structure, or into any water, watercourse, stormwater system or sewer system.

14. "Domestic sewage" means any human excremental liquid or substance, any putrescible vegetable matter, garbage and filth, including, but not limited to, the discharge of toilets, laundry tubs, washing machines, sinks,

and dishwashers, which is disposed of by means of a septic system or sanitary sewer.

15. "Encapsulation" means the application of a substance that either creates a membrane over the surface and/or penetrates the material or binds its components together.

16. "EPA" means the United States Environmental Protection Agency.

17. "Facility" means all land and structures, other appurtenances, and improvements on the land, used for generating, handling, storing, treating, destroying, or disposing of regulated medical waste; provided that all land and structures are under the control of a single person or legal entity. A facility may consist of several generating, handling, storage, treatment, destruction, or disposal operation units.

18. "FIFRA" means the Federal Insecticide, Fungicide and Rodenticide Act.

19. "Generator" means any person whose act or process produces regulated medical waste as defined in these regulations, or whose act first causes a medical waste to become subject to regulation. In the case where more than one person (e.g., doctors with separate medical practices) is located in the same building, each individual business entity shall be considered a separate generator for purposes of these regulations.

20. "Hazardous waste" means any waste meeting the definition of a hazardous waste under DEM's Rules and Regulations for Hazardous Waste Management (Subchapter 10 Part 1 of this Chapter) that includes both those wastes defined under the Resource Conservation and Recovery Act as well as Rhode Island Wastes in DEM Rules and Regulations for Hazardous Waste Management (Subchapter 10 Part 1 of this Chapter).

21. "Health care professional" means any person required to be licensed by this state (or the state where he/she practices) to provide health care services, including, but not limited to, a physician, hospital, intermediate care facility or other health care facility, dentist, nurse, optometrist, emergency medical technician, podiatrist, physical therapist, psychiatric social worker, pharmacist, or psychologist, and any officer, employee or agent of that provider acting in the course and scope of his or her employment or agency related to or supportive of health services.

22. "Incineration" means the treatment and destruction of regulated medical waste using controlled flame combustion in an arrangement of chambers and equipment designed for burning solid, semi-solid or gaseous combustible waste to a gas and residue.

23. "Infectious agent" means any organism, such as a virus or a bacterium, that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

24. "Intermediate handler" means a facility that either treats regulated medical waste or destroys regulated medical waste but does not do both. The term, as used in these regulations, does not include transporters. An intermediate handler shall obtain a license for a Solid Waste Management Facility from DEM, Office of Land Revitalization and Sustainable Materials Management, as per the Rhode Island Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter).

25. "Laboratory" means any research, analytical, or clinical facility that performs health care related analysis or service. This includes, but is not limited to, medical, pathological, pharmaceutical, and other research, commercial, or industrial laboratories.

26. "Landfill" means a disposal facility or part of a facility where regulated medical waste is placed in or on the land and which is not a land treatment facility, a surface impoundment, or an injection well.

27. "Medical waste tracking form" means the form used for identifying the quantity, composition, and the origin, routing, and destination of regulated medical waste during its transportation from the facility of generation to the point of transfer, disposal, treatment, destruction, or storage. Such a tracking form may mean a paper form or its digital counterpart that is functionally equivalent to the form. Digital formats must be approved by the Department in writing prior to use. A medical waste tracking form must include the following fields:

    a. A unique Tracking Form Number, Generator's Name and Mailing Address, RI medical waste generator registration number, and telephone Number

    b. Transporter's Name and Mailing Address, Telephone Number and RI Regulated Medical Waste Transporter Permit Number

    c. Destination Facility Name and Address, telephone Number, State Permit or ID Number

    d. Waste Description, Total Number Containers, Total Quantity and unit of measure

    e. Special Handling Instructions and Additional Information

f. Generator's Certification, transporter 1 Certification of Receipt, transporter 2 or Intermediate Handler Certification of Receipt, destination facility certification of receipt, New Tracking Form Number and destination facility (if applicable), and discrepancy item

28. "Off-site" means a facility or area for the storage, treatment, and/or disposal of regulated medical waste which is not on the generator's site (i.e., "on-site") or a facility or area which receives regulated medical waste for storage or treatment which has not been generated "on-site" at that facility.

29. "On-site" means land area and appurtenances thereon and thereto used for the collection, storage, processing, treatment, and/or disposal of regulated medical waste on the same or geographically contiguous property at which regulated medical waste is generated. Two or more pieces of property either owned or operated by a single person or legal entity are considered a single site.

30. "Original generation point" means the location where regulated medical waste is generated. Waste may be taken from original generation points to a central collection point prior to off-site transport or on-site treatment.

31. "Person" means an individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, any interstate body, or any department, agency or instrumentality of the United States.

32. "Private courier service" means an entity whose primary business is the interstate and/or intrastate transport of packages, parcels and similar items for commercial purposes, and which transports regulated medical waste as less than ten percent (10%) of their total activity in Rhode Island, both in terms of volume and revenue.

33. "Regulated medical waste" means defined in § 1.2(C) of this Part.

34. "Sanitary sewer" means the collection system which transports domestic sewage and waste waters to a municipal wastewater treatment facility. Said treatment facility shall include primary and secondary wastewater treatment.

35. "Small quantity generator" means a generator of regulated medical waste who generates, transports, or offers for transport less than fifty (50) pounds of regulated medical waste in a calendar month.

36. "Solid waste" means garbage, refuse, and other discarded solid materials generated by residential, institutional, commercial, industrial and agricultural sources but does not include solids or dissolved solids in domestic sewage sludge, nor does it include hazardous waste. For the

purpose of these regulations, solid waste shall also include non-hazardous liquid, semi solid, and containerized gaseous waste.

37. "Spill" means any planned or unplanned release, leaking, pumping, pouring, emitting, or depositing of regulated medical waste in violation of the requirements of these regulations.

38. "Steam sterilization" means a treatment method for regulated medical waste utilizing saturated steam within a pressure vessel (known as steam sterilizer, autoclave, or retort) at time lengths and temperatures sufficient to kill infectious agents within the waste.

39. "Storage" means the temporary holding of regulated medical wastes at a designated accumulation area before treatment, destruction, disposal, or transport to another location.

40. "Tracking form" means Medical Waste Tracking Form

41. "Transfer facility" means any transportation related facility including loading docks, parking areas, storage areas and other similar areas where shipments of regulated medical waste are held during the course of transportation. A transfer facility shall obtain a license for a Solid Waste Management Facility from DEM, Office of Land Revitalization and Sustainable Materials Management, as per the Rhode Island Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter).

42. "Transportation" means the movement of regulated medical waste on a public way to any destination. However, movement on a public way entirely contiguous to the facility's property shall not be considered transportation.

43. "Transporter" means a person engaged in transportation of regulated medical waste.

44. "Treated regulated medical waste" means regulated medical waste that has been treated to substantially reduce or eliminate its potential for causing disease, but which has not yet been destroyed.

45. "Treatment" means when used in the context of regulated medical waste management means any method, technique, or process designed to:

    a. Completely and reliably inactivate *Geobacillus stearothermophilus* spores or *Bacillus atrophaeus* spores at a 4 Log_{10} reduction or greater.

    b. Technologies not based on thermal or chemical treatment must also demonstrate the ability to completely and reliably inactivate

vegetative bacteria, fungi, viruses, parasites, and mycobacterium at a 6 Log_{10} reduction or greater.

46. "Treatment facility" when used in the context of medical waste refers to any facility that accepts regulated medical waste and changes its biological character or composition so as to substantially reduce or eliminate its potential for causing disease, but does not destroy the medical waste. A treatment facility may include a transfer station, a solid waste management facility, or any other facility that treats regulated medical waste. A treatment facility is also subject to the Rhode Island Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter) if the facility is located within the State of Rhode Island.

47. "Universal biohazard symbol" means the biohazard marking conforming to 29 C.F.R. § 1910.1030(g)(1)(i).

48. "Untreated regulated medical waste" means regulated medical waste that has not been treated to substantially reduce or eliminate its potential for causing disease.

1.6 Identification and Segregation of Regulated Medical Wastes

A. Applicability

1. Generators shall comply with the requirements of this section from the time and location that an item becomes regulated medical waste.

2. Generators shall comply with § 1.8 of this Part for on-site storage.

3. Training/Notification Requirement: Generators shall notify in writing all employees involved with the identification and segregation of regulated medical wastes of the provisions in § 1.6 of this Part. This training/ notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

B. Identification

1. A person who generates a medical waste within the State of Rhode Island shall determine if that waste is a regulated medical waste. Any wastes that contain regulated medical waste mixed with general solid waste shall be managed as regulated medical wastes.

2. Any regulated medical wastes which meet the definition of "hazardous waste", or which are mixed with hazardous wastes shall be managed as hazardous waste in accordance with the most current DEM Rules and Regulations for Hazardous Waste Management (Subchapter 10 Part 1 of this Title).

C. Segregation

Generators shall segregate regulated medical waste from the general waste stream to the maximum extent practicable to ensure the special handling and treatment required by these regulations. Separation from the general waste stream shall occur at the point at which the regulated medical waste is generated.

1. Generators shall segregate regulated medical wastes into the following groups:

   a. Sharps and unused sharps, including sharps containing residual fluid;

   b. Fluids in bulk quantities (quantities greater than twenty cubic centimeters (20 cm^3));

   c. Human Pathological wastes as defined in § 1.2(C) of this Part.

   d. Other regulated medical wastes.

2. Regulated medical wastes shall be placed in suitable containers, according to the requirements of § 1.7 of this Part, at the source of origin (e.g., patient room, operating room, etc.).

3. If other solid waste is placed in the same container(s) as regulated medical waste, then the entire contents of the container(s) shall be managed as regulated medical waste and shall meet all the requirements of these regulations.

4. If a generator manages all solid waste as regulated medical waste, the identification and segregation requirements of § 1.6 of this Part need not be met. However, the entire solid waste stream of this generator shall then be managed as regulated medical waste and shall meet all remaining handling and management requirements of these regulations.

1.7 Packaging and Containment of Regulated Medical Wastes

A. General Packaging and Containment Requirements

Regulated medical waste shall be properly packaged to assure effective containment throughout the handling, storage, transport, and treatment process. In addition to the specific packaging and containment requirements for each category of regulated medical waste contained in §§ 1.7(B) and (C) of this Part, the following general requirements shall be met before transporting or offering for transport such waste off-site or within the generating facility:

1. Generators shall ensure that all regulated medical waste is placed in a container or containers that are:

    a. Rigid;

    b. Leak resistant;

    c. Impervious to moisture;

    d. Of a strength sufficient to prevent tearing or bursting under normal conditions of use and handling; and,

    e. Sealed to prevent leakage during transport.

2. Materials for packaging shall be strong enough to remain intact during whatever type of handling, storage, and transport the container(s) may undergo.

3. Mechanical compaction of regulated medical waste shall not be conducted prior to treatment and/or disposal, unless the mechanical compaction and treatment are part of a single, self-contained process that does not place employees or the public at risk of exposure to untreated regulated medical waste.

4. Training/Notification Requirement: Generators shall notify in writing all employees involved with packaging and containment of regulated medical wastes of the provisions in § 1.7 of this Part. This training/ notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

B. Packaging Requirements for Sharps

1. In addition to the general packaging and containment requirements for regulated medical wastes in § 1.7(A) of this Part, all sharps and unused sharps, including sharps with residual fluids, shall be packaged in containers that are puncture resistant. Any sharps placed into such a container shall not be manipulated inside the container and/or shall not be removed from said container under any circumstances. The sharps shall be placed directly into the container without recapping, clipping, bending, or breaking unless one of the following criteria are met:

    a. The employer can demonstrate that the requirements of this section are not feasible for a specific medical procedure; or,

    b. Such recapping or needle removal is accomplished through the use of a mechanical device or one-handed technique specifically approved in writing by the Director.

2. Sharps containers shall be assembled and utilized as intended by the manufacturer at all times while in use. Sharps containers with openings large enough to allow entry of any human hand shall also be subject to any additional physical and/or administrative controls necessary to prevent access by the public during normal conditions of use.

3. The container shall be sealable in a manner that prevents spillage of contents during transport. The container shall identify the contents as regulated medical waste by displaying the Universal Biohazard Symbol on the outside of the container.

C. Packaging Requirements for Fluids in Bulk Quantities

In addition to the general packaging and containment requirements for regulated medical wastes in § 1.7(A) of this Part, human blood and blood products and body fluids in quantities greater than twenty cubic centimeters (20 cm^3) shall be packaged in containers that are break resistant and tightly lidded or stoppered. The container shall identify the contents as regulated medical waste by displaying the universal biohazard symbol on the outside of the container.

D. Packaging Requirements for Human Pathological Wastes

In addition to the general packaging and containment requirements for regulated medical wastes contained in § 1.7(A) of this Part, pathological wastes shall be placed in a container marked or labeled with the words “pathological waste”, “path waste”, “pathology waste” or “incinerate only” or other labels approved by the Department on the lid or on the sides. Any waste placed in a container so marked must be managed as pathological waste in accordance with the requirements of these regulations.

E. Packaging Requirements for Animal Pathological Waste

In addition to the general packaging and containment requirements for regulated medical wastes contained in § 1.7(A) of this Part, Carcasses of animals contaminated with highly communicable endemic animal diseases listed in § 1.22 of this Part, shall be handled in accordance with special handling instruction in § 1.22 of this Part.

F. Packaging and Containment Requirements for Other Regulated Medical Wastes

In addition to the general packaging and containment requirements for regulated medical wastes in § 1.7(A) of this Part, those regulated medical wastes which are not sharps or fluids in bulk quantities, (including, but not limited to, cultures and stocks, non-liquid pathological wastes, non-liquid animal wastes (where the waste presents a risk of zoonotic disease), non-liquid isolation wastes, materials saturated with blood) shall be packaged in either rigid containers that are designed to be tightly sealable or in plastic bags that meet the following requirements:

1. The plastic bags shall be impervious to moisture and be tear resistant;

2. The plastic bags shall be a distinctive red or orange color, or clear (i.e., without color). If a clear bag is used then the universal biohazard symbol shall be appropriately displayed on the bag;

3. In order to allow the use of "single plastic bags", the bags shall be constructed of material of sufficient single thickness strength to pass the 165 gram dropped dart impact resistance test as prescribed by the American Society for Testing and Materials (ASTM) Dart Test (ASTM Standard #D 1709 91) and certified by the manufacturer. Otherwise, "double bagging" (i.e., the use of two plastic bags, one inside the other) is required.

4. A container (e.g., a step can) used on-site to hold regulated medical waste shall have either a red or orange plastic bag plainly visible; or if a clear bag is used then the universal biohazard symbol shall be displayed on the container as well as on the bag.

1.8 Storage of Regulated Medical Wastes

A. Applicability

1. Any person who stores regulated medical waste prior to treatment or disposal on-site or transport off-site shall comply with the storage requirements of this section.

2. Training/Notification Requirement: Generators shall notify in writing all employees involved with the storage of regulated medical wastes of the provisions in § 1.8 of this Part. This training/notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

B. Exemptions

Sharps containers, currently in use, are exempt from the generator storage requirements provided they meet all the requirements in §§ 1.7(A) and (B) of this Part.

C. General Storage Requirements

1. The regulated medical waste shall be stored in a manner and location which maintains the integrity of the packaging and provides protection from flooding and from adverse weather conditions such as rain, snow, ice, sleet, hail, and wind. All areas used for the storage of regulated medical waste shall be constructed of finished materials that are impermeable to moisture and capable of being easily maintained in a sanitary condition.

2. On-site storage areas shall be restricted to authorized personnel. Outdoor storage areas, such as dumpsters, sheds, tractor-trailers, or other storage areas, that contain regulated medical waste shall be securely locked in order to prevent unauthorized access.

3. The regulated medical waste shall be stored in a manner that prevents access by, and does not provide a breeding place or a food source for, insects, rodents, or other animals.

4. The storage area shall be clearly identified as containing regulated medical waste through the posting of universal biohazard signs or signs containing the following wording: "medical waste" or "regulated medical waste."

5. The regulated medical waste shall be maintained in a non-putrescent state. Total storage of regulated medical waste shall not exceed fifty (50) pounds or seven (7) calendar days, whichever condition shall allow storage for the longer period of time. The seven-day storage period shall not include legal holidays and begins on the date the container was filled or was no longer used for collection at the point of generation. Storage of regulated medical waste at a licensed treatment, storage and disposal facility shall be governed by the applicable requirements for those facilities in these regulations and/or the facility's permit conditions.

6. Regulated medical waste shall not be compacted, undergo grinding, or be subject to violent mechanical stress on-site unless the regulated medical waste has been treated prior to compaction, grinding, or other mechanical stress; or, unless the compaction, grinding, or mechanical stress and the treatment are part of a single, self-contained process that does not place employees or the public at risk of exposure to untreated regulated medical waste.

1.9 Decontamination Standards for Reusable Containers

A. Applicability

1. Generators, transporters, intermediate handlers, and destination facility owners and operators shall comply with the requirements of this section with respect to reusing containers.

2. Training/Notification Requirement: Generators shall notify in writing all employees involved with the decontamination of reusable containers for regulated medical wastes of the provisions in § 1.9 of this Part. This training/notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

B. Standards

1. All non-rigid packaging and inner liners used for the packaging of medical waste shall be managed as regulated medical waste and shall not be reused.

2. Any container used for the storage and/or transport of regulated medical waste and designated for reuse once emptied shall be decontaminated after each use. Decontamination can be accomplished by chemical disinfection, steam sterilization, thermal inactivation, or other suitable process that is appropriates both for the type of container to be decontaminated and for the type of contamination present. The facility or generator responsible for decontamination must submit sampling protocols and results to demonstrate the technology, as installed, is providing adequate decontamination.

3. If any container used for the storage and/or transport of regulated medical waste is for any reason not capable of being rendered free of contamination in accordance with the requirements of § 1.9(B)(2) of this Part, the container shall be managed (i.e., labeled and treated and/or disposed of) as regulated medical waste.

1.10 On-Site Transport of Regulated Medical Wastes

A. To ensure the safe transport of regulated medical wastes within the generating facility (on-site), generators shall comply with the following requirements:

1. The regulated medical waste shall be properly packaged to ensure containment of the waste as described in § 1.7 of this Part; all containers and packages containing regulated medical wastes shall be sealed to prevent leakage or spillage while in transport.

2. The handling, transfer, and loading of packages and containers of regulated medical wastes shall be performed in a manner that does not destroy the integrity of the packaging.

3. The regulated medical waste shall not be subjected to violent mechanical stress during on-site transport.

4. Wheeled carts shall be used for the transport of packages or containers of regulated medical wastes if these packages or containers will be moved more than a short distance or if these packages or containers cannot be easily handled by one person (due to weight, size, shape, bulkiness, etc.) regardless of the distance to be moved.

5. Any regulated medical waste that is contained in plastic bags shall not be moved or transported in mechanical devices, dumb waiters, or chutes, unless the chutes are designed to prevent accumulation of wastes in

corners and edges and are lined with materials which can be easily cleaned (e.g., stainless steel).

6. Carts used for the transport of packages and containers of regulated medical wastes shall be sturdy and shall be constructed of finished materials that are impermeable to moisture and capable of being easily maintained in a sanitary condition. Carts shall be routinely cleaned and disinfected, and immediately cleaned and disinfected after use if the cart has been contaminated by medical waste.

7. Items other than regulated medical waste shall not be placed in the same cart with regulated medical waste at any point during on-site transportation.

8. The compaction of packages and containers of regulated medical wastes prior to or during on-site transport is prohibited.

9. Training/Notification Requirement: Generators shall notify in writing all employees involved with the on-site transport of regulated medical wastes of the provisions in § 1.10 of this Part. This training/notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

1.11 Labeling and Marking Regulated Medical Waste for Off-Site Transport

A. Applicability

1. All containers used for the packaging and containment of regulated medical wastes shall be labeled with the universal biological hazard symbol or shall be clearly labeled as containing regulated medical waste. In addition, all packages or containers which will be transported or offered for transport off-site shall meet the labeling and marking requirements of § 1.11 of this Part.

2. Training/Notification Requirement: Generators shall notify in writing all employees involved with the labeling and marking of regulated medical waste for off-site transport of the provisions in § 1.11 of this Part. This training/notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

B. Labeling Requirements

Generators shall label each package or container of regulated medical waste with a water-resistant label affixed to or printed on the outside of the container. The label shall include the words "medical waste," or display the universal

biohazard symbol. Red plastic bags used, as inner packaging need not display a label.

C. Marking (Identification) Requirements

Generators and intermediate handlers shall mark each package or container of regulated medical waste according to the following marking requirements before the waste is transported or offered for transport off-site:

1. The outermost surface of each package or container prepared for shipment shall be marked or labeled with water-resistant paint/labels of sufficient dimension and contain the following information:

   a. Generator's or intermediate handler's name;

   b. Generator's or intermediate handler's address;

   c. Transporter's name (if applicable);

   d. Transporter's Rhode Island regulated medical waste transporter permit number (if applicable);

   e. Date of shipment (date of off-site transport); and,

   f. Identification of contents as medical waste.

2. When regulated medical waste is transported by more than one transporter, each transporter other than the transporter who accepted the waste from the generator shall affix a water-resistant identification tag on the outside of the secondary container. Such tag shall be at least three inches by five inches and shall be affixed in such manner as not to obscure previously affixed identification tags. Such tag shall indicate in indelible writing the name, address, business location, and Rhode Island regulated medical waste transporter permit number of the transporter affixing the tag and the date such transporter accepted the waste.

1.12 On-Site Treatment and/or Destruction of Regulated Medical Waste

A. Applicability

1. The regulations in this section apply to generators of regulated medical waste that conduct on-site treatment and/or destruction of regulated medical waste, and to generators that accept regulated medical waste for treatment and/or destruction.

2. Generators that accept regulated medical waste from other generators for treatment and/or destruction shall apply for a license, in accordance with

the requirements contained in § 1.17 of this Part, from: Rhode Island Department of Environmental Management, Office of Land Revitalization and Sustainable Materials Management, 235 Promenade Street, Providence, RI 02908.

3. Generators are also subject to the requirements of all applicable State solid waste and air emission regulations.

4. Training/Notification Requirement: Generators shall notify in writing all employees involved with on-site treatment and/or destruction of regulated medical wastes of the provisions in § 1.12 of this Part. This training/notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

B. Recordkeeping Requirements for On-Site Incineration

1. Generators shall keep an operating log at their incineration facility that includes the following information:

   a. The date each incineration cycle began;

   b. The length of the incineration cycle;

   c. The total quantity of waste incinerated per incineration cycle;

   d. An estimate of the quantity of regulated medical waste incinerated per incineration cycle;

   e. Generators shall compile the operating log required by § 1.12(B)(1) of this Part from the effective date of these regulations;

   f. Generators shall retain the operating log for at least three (3) years from the date of the last entry in the log.

2. Generators with on-site incinerators that accept regulated medical waste from generator(s) subject to § 1.13(B)(2) of this Part shall maintain the following information for each shipment of regulated medical waste accepted:

   a. The date the waste was accepted;

   b. The name and address of the generator who originated the shipment;

   c. The total quantity and unit of measure of the regulated medical waste accepted from the originating generator;

   d. The signature of the individual accepting the waste.

3. Generators with on-site incinerators that accept regulated medical waste from generators subject to the tracking form requirements shall keep copies of all tracking forms for a period of three (3) years from the date they accepted the waste.

C. Reporting Requirements for On-Site Incineration

1. General: The owner or operator of an on-site incinerator shall prepare and submit copies of the on-site incinerator report to: Rhode Island Department of Environmental Management, Office of Land Revitalization and Sustainable Materials Management, 235 Promenade Street, Providence, RI 02908. The reports shall summarize information collected in the operating log and shall contain the following information:

   a. Facility name, mailing address, and location;

   b. Facility type (e.g., hospital, laboratory);

   c. Contact person;

   d. Waste feed information;

   e. The total number of incinerators at the facility that incinerate regulated medical waste and information concerning each incinerator.

2. Each report shall contain the following certification, signed by the facility owner or by owner's designee:

   a. "I certify that I have personally examined and am familiar with the information submitted in this and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete."

3. Generators shall retain a copy of the on-site incinerator report form required under § 1.12(C) of this Part for three (3) years from the date of submission. Reports shall cover the period of January 1 to June 30 of each year and from July 1 to December 31 of each year. These reports are due forty-five (45) days after the end of the reporting period.

D. On-Site Steam Sterilization Standards

A steam sterilizer used to convert untreated regulated medical waste into treated regulated medical waste shall be operated in accordance with the following requirements. In addition, operators of steam sterilizers shall be familiar with autoclaving techniques and hazards (i.e., burn protection and aerosol minimization).

1. The sterilizers shall be dedicated for waste only. The sterilizers shall be operated in accordance with the manufacturer's specifications for waste in regard to time, temperature, pressure, and capacity, provided that these specifications change the biological character or composition of the regulated medical waste so as to substantially reduce or eliminate its potential for causing disease.

2. If no manufacturer's specifications for waste exist, or if another combination of time, temperature, pressure and capacity is used, such combination shall be proven, on the basis of thorough tests, to render the regulated medical waste treated. These tests shall include a test to determine the capacity of this combination to completely and reliably inactivate *Geobacillus stearothermophilus* spores at a 4 Log_{10} reduction or greater. Testing must demonstrate that inactivation is uniform and within containers reasonably likely to be treated in the system.

3. Regulated medical waste shall be steam sterilized in its primary container. The primary container shall be placed in the sterilization chamber so that sufficient space is provided between the chamber walls and the container to allow the steam to surround the container. The primary container shall be sealed loosely enough to allow the steam to penetrate the contents of the container, unless a self-venting bag is used.

4. Unless a steam sterilizer is equipped to continuously monitor and record temperatures during the entire length of each sterilization cycle, the operator of such sterilizer shall affix to the primary container temperature sensitive tape, which will indicate when the desired temperature is reached.

    a. Regulated medical waste shall not be considered treated regulated medical waste unless:

        (1) The temperature sensitive tape indicates that a temperature of at least 250 degrees F (121 degrees C) was reached during the sterilization process; or,

        (2) A temperature determined in accordance with § 1.12(D)(2) of this Part was reached during the sterilization process; or,

        (3) A temperature recommended by the manufacturer of the sterilizer that is sufficient enough to render the infectious agents within the waste treated, was reached during the sterilization process; and,

        (4) In addition to attaining the specific temperature determined in accordance with §§ 1.12(D)(4)(a)((1)), ((2)) and ((3)) of this Part, said temperature shall be maintained for a period of time sufficient to completely and reliably inactivate

Geobacillus stearothermophilus spores at a 4 Log_{10} reduction or greater. Testing must demonstrate that inactivation is uniform and within containers reasonably likely to be treated in the system.

b. A record of this temperature shall be kept as explained in § 1.12(D)(7) of this Part.

c. A steam sterilizer purchased after the effective date of this section, and used for waste sterilization, shall automatically and continuously monitor and record temperatures throughout the entire length of each steam sterilization cycle. This record shall be kept for three (3) years from the date the waste was treated.

5. Spore tests shall be conducted, at a minimum either once every forty (40) hours of operation or weekly, whichever allows for a greater length of time between tests. These tests shall be conducted to evaluate the effectiveness of the sterilization process, including tests of the capacity of such process to completely and reliably inactivate *Geobacillus stearothermophilus* spores at a 4 Log_{10} reduction or greater. Each test shall include at least three (3) samples of test organisms placed in the medical waste load. One sample shall be placed approximately one-third of the way from the top of the load, one sample in the center of the load, and one sample approximately one-third of the way from the bottom of the load. A log shall be maintained recording the dates and results of such tests, and shall be kept for at least three (3) years from the date of the last entry in the log.

6. At least once during every forty (40) hours of operation, a sterilization unit shall be evaluated to determine whether it is operating properly with respect to temperature and pressure. A log shall be maintained recording the dates and results of such evaluations and the dates of calibration. The log shall be kept for at least three (3) years from the date of the last entry in the log.

7. For each sterilization unit, a log shall be maintained which contains, at a minimum, the following information for each use:

a. Date;

b. Time;

c. Operator;

d. Type and approximate amount of regulated medical waste treated;

e. Sterilization pressure reading;

f. Maximum temperature obtained during the sterilization process; and,

g. The length of time that the sterilization pressure and temperature determined in accordance with §§ 1.12(D)(1) through (2) of this Part were maintained.

8. The log required by § 1.12(D)(7) of this Part shall be kept at least three (3) years from the date the waste was treated.

E. Recordkeeping for Alternate On-Site Treatment and/or Destruction Methods

Any method or process other than incineration or steam sterilization used by a generator for treatment and/or destruction of regulated medical waste on-site shall be approved by the Director in accordance with § 1.15(G)(5) of this Part. Each generator shall maintain the following records:

1. The approximate quantity and unit of measure of regulated medical waste that is subject to the treatment and/or destruction process(es);

2. Approximate percent of total waste treated and/or destroyed that is regulated medical waste;

3. For regulated medical waste accepted from generators meeting the exemption conditions in §§ 1.13(B)(2) and 1.13(B)(4) of this Part, information identifying the generator, the date the waste was accepted, the quantity and unit of measure of waste accepted, and the date the waste was treated and/or destroyed;

4. Results of all required quality assurance monitoring/procedures conducted to demonstrate compliance with the conditions of the approval granted by the Director in accordance with §1.15(G)(5) of this Part; and,

5. Records shall be maintained by the generator for a period of at least three (3) years from the date the waste was treated and/or destroyed.

1.13 Generator Requirements for Off-Site Transportation of Regulated Medical Waste

A. Applicability

1. A person who generates regulated medical waste and whose generating facility is located in Rhode Island shall determine if that waste is a regulated medical waste (as defined in §§ 1.2(C) and 1.5 of this Part).

2. Any generator that transports off-site or offers for transport off-site any regulated medical wastes shall comply with all requirements for such transport set forth in §§ 1.6 through 1.9, and 1.11 of this Part.

3. A generator of regulated medical wastes shall determine the quantity of regulated medical wastes generated in a calendar month, and the quantity transported or offered for transport off-site for treatment, destruction, or disposal.

4. Vessels at port in Rhode Island are subject to the requirements of this section for those regulated medical wastes that are transported ashore in Rhode Island. The owner or operator of the vessel and the person(s) removing or accepting waste from the vessel are considered co-generators of the waste.

5. A generator that treats and destroys or disposes of regulated medical waste on-site (e.g., incineration, burial or sewer disposal covered by § 307(b) through (d), of the Clean Water Act) is not subject to tracking requirements for that waste. However, generators of regulated medical waste with on-site incinerators are subject to DEM on-site incinerator requirements.

6. Generators of regulated medical waste with on-site treatment and/or destruction system(s) are subject to the requirements of § 1.12 of this Part. In addition, generators who treat and destroy regulated medical waste are subject to §§ 1.6 through 1.10 of this Part. Generators who treat or dispose of regulated medical waste on-site may also be subject to additional Federal, State, or local laws and regulations.

7. Training/Notification Requirement: Generators shall notify in writing all employees involved with the off-site transportation of regulated medical wastes of the provisions in § 1.13 of this Part. This training/notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

B. General Requirements

Generator shall send regulated medical waste only to a permitted facility. Except as provided below, he/she shall not offer regulated medical waste to a medical waste transporter that does not have a medical waste transporter permit number and a valid RI medical waste transporter permit as indicated by an official sticker on each transportation unit. Generators shall use transporters who have been issued a Rhode Island regulated medical waste transporter permit number by the Rhode Island Department of Environmental Management,

1. Generators of fifty (50) pounds or more of regulated medical waste per calendar month: Generators who generate, transport, or offer for transport off-site fifty (50) pounds or more of regulated medical waste in a calendar month are subject to the requirements of §§ 1.6 through 1.11 of this Part and all requirements of this Section for each shipment of regulated medical waste.

2. Small Quantity Generator(s): Small quantity generators are subject to the requirements of §§ 1.6 through 1.11 of this Part and are exempt from:

   a. The requirement to use a transporter who has been issued a Rhode Island regulated medical waste transporter permit; and,

   b. The requirement to use a tracking form; and,

   c. The requirements of § 1.13(C) of this Part;

   d. The exemption(s) contained in §§ 1.13(B)(2)(a) through (c) of this Part shall only be applicable if the following conditions are met:

      (1) The regulated medical waste is transported from the original generation point to a satellite facility or central collection point owned by the generator.

      (2) From the time the waste is received at the central collection point, the generator must store and ship the waste in accordance with all other generator requirements of these regulations, including requirements to use a medical waste tracking form.

      (3) Small quantity generators and crime scene cleanup contractors that transport regulated medical waste between satellite facilities or to a central collection point shall apply to the Department for a Letter of Authorization. This authorization shall last for a period of three (3) years, after which time the generator must reapply.

      (4) Notwithstanding the requirements of § 1.13(B)(2)(d)((1)) of this Part, small quantity generators in the same building may share a common storage facility within the building (before the waste is transported off-site), without applying for a letter of authorization; provided that the appropriate logs are kept at both the original generation point and the central collection point, as described in § 1.13(E)(2) of this Part; and,

      (5) Prior to utilization of a common storage facility pursuant to § 1.13(B) of this Part, all participating small quantity generators shall be signatories to a written agreement which describes, at a minimum, the person(s) responsible for preparing the medical waste tracking form, the person(s) responsible for arranging off-site transportation of regulated medical waste, and the person(s) assuming legal responsibility for any violation of these regulations. Notwithstanding the foregoing, any written agreement must

be approved in advance by the Director if the average total regulated medical waste generated per month is in excess of two hundred (200) pounds; and,

(6) Other than small quantity generators may act as the manager/agent for agreements pursuant to §§ 1.13(B) through (C) of this Part provided that: they are located in the same building as the participants; all regulated medical waste received under the agreement is segregated from their own regulated waste; and all regulated medical waste received under the agreement is transported off-site under a separate medical waste tracking form; and,

(7) The regulated medical waste is transported by the generator, or an authorized employee, in a vehicle owned by the generator or authorized employee; and,

(8) The generator shall compile a shipment log and maintain records as required in § 1.13(E)(2) of this Part.

3. Shipments Between Generator's Facilities: Generators are exempt from the requirement to use transporters that have a Rhode Island regulated medical waste transporter permit number when transporting regulated medical waste from the original generation point to a central collection point, or between satellite facilities, provided they meet all of the following conditions:

a. The regulated medical waste is transported by the generator, or the generator's authorized employee, in a vehicle owned by the generator or the employee; and,

b. The regulated medical waste is brought to a central collection point or treatment facility owned or operated by the generator.

(1) Small quantity generators who transport regulated medical waste between satellite facilities shall apply for a letter of authorization from: Rhode Island Department of Environmental Management, Office of Land Revitalization and Sustainable Materials Management, 235 Promenade Street, Providence, RI 02908.

(2) Other generators (i.e., those who generate and transport or offer for transport more than fifty (50) pounds of regulated medical waste in a calendar month) with multiple locations shall apply for a transporter permit and letter of authorization as per § 1.14 of this Part from: Rhode Island Department of Environmental Management, Office of Land Revitalization

and Sustainable Materials Management, 235 Promenade Street, Providence, RI 02908;

c. The original generation point and the central collection point or treatment facility are located in the State of Rhode Island; and,

d. The generator compiles and maintains a shipment log at each generation point and each central collection point as required by § 1.13(E) of this Part.

4. Shipments of Sharps and Unused Sharps through the U.S. Postal Service: small quantity generators who transport regulated medical waste (sharps and unused sharps) by the U.S. Postal Service are exempt from the requirement to use a transporter that has a Rhode Island regulated medical waste transporter permit number provided that the following conditions are met:

a. The package is sent by first class or priority mail in accordance with § 1.10(Q) of this Part (Infectious Substances) of the United States Postal Service Domestic Mail Manual.

b. The generator compiles a shipment log and maintains the original shipping papers as required by § 1.13(E) of this Part;

c. Reports shall be submitted to the Director for the periods of January 1 to June 30 and July 1 to December 31 of each year. These reports shall be received by the Director within forty-five (45) days of the end of each reporting period.

5. Transportation of sharps from residences by health care professionals: Health care professionals and veterinarians who generate medical waste that would otherwise be classified as household medical waste, may transport the waste back to their offices without a medical waste tracking form, provided the waste is properly packaged in accordance with § 1.7 of this Part and that the waste is properly handled as regulated medical waste upon arrival at the central collection point.

C. Use of the Tracking Form

1. Except as otherwise exempted in § 1.13(B) of this Part, a generator that transports or offers for transport regulated medical waste for off-site treatment or disposal shall prepare a tracking form according to this section.

2. Generators may obtain samples of the Rhode Island Medical Waste Tracking Form from: Rhode Island Department of Environmental Management, Office of Land Revitalization and Sustainable Materials Management, 235 Promenade Street, Providence, RI 02908.

3. The generator shall prepare the number of tracking form copies that will provide the generator, each transporter(s), and each intermediate handler with one copy, and the owner or operator of the destination facility with two copies.

4. The generator shall also:

   a. Sign the certification statement on the tracking form by hand;

   b. Obtain the signature of the initial transporter and include the date of acceptance on the tracking form; and,

   c. Retain one copy, in accordance with § 1.13(E) of this Part.

5. For rail shipments of regulated medical waste within the United States that originate at the site of generation, the generator shall send at least three (3) copies of the tracking form dated and signed in accordance with § 1.13(C) of this Part to:

   a. The next non-rail transporter, if any; or,

   b. The intermediate handler or destination facility if transported solely by rail; or,

   c. The last rail transporter to handle the waste in the United States if exported by rail.

D. Generators Exporting Regulated Medical Waste

Generators, including transporters and intermediate handlers that initiate tracking forms, which export regulated medical waste to a foreign country for treatment and destruction, or disposal, shall request the destination facility to provide written confirmation that the waste was received. If the generator does not receive written confirmation from the destination facility within forty-five (45) days from the date of acceptance of the waste by the first transporter, the generator shall submit an exception report as required under § 1.13(F) of this Part.

E. Recordkeeping

1. Except as provided in § 1.13(E)(2) of this Part, each generator shall:

   a. Retain both the original generator receipt [yellow-copy, page 4] and the completed generator copy [white-copy, page 1] of each tracking form signed in accordance with § 1.13(C) of this Part, for at least three hundred and seventy-five (375) days from the date the waste was accepted by the initial transporter; and,

b. Retain for a period of three hundred and seventy-five (375) days a copy of all exception reports required to be submitted under § 1.13(F) of this Part.

2. Generators that are exempt from using the medical waste tracking form, as specified in § 1.13(B) of this Part, shall meet the following requirements:

a. A shipment log shall be maintained at the original generation point for a period of three hundred and seventy-five (375) days from the date the waste was shipped. The log shall contain the following information:

(1) Date of shipment;

(2) Quantity and unit of measure of regulated medical waste transported, by waste category (i.e., untreated and treated);

(3) Address or location of central collection point;

(4) Signature of generator's employee who is transporting the waste, to signify delivery has been completed.

b. A shipment log shall be maintained at each central collection point for a period of three hundred and seventy-five (375) days from the date that regulated medical waste was accepted from each original generation point and shall contain the following information:

(1) Date of receipt;

(2) Quantity (and unit of measure) of regulated medical waste accepted, by waste category (i.e., untreated and treated);

(3) Address or location of original generation point; and,

(4) Signature of generator or generator's representative who operates the central collection point, to signify acceptance of the waste.

3. Generators that meet the conditions of § 1.13(B)(2) of this Part and do not voluntarily comply with the use of the medical waste tracking form are subject to the following recordkeeping requirements:

a. Generators that use a transporter that holds a valid Rhode Island regulated medical waste transporter permit shall maintain a log for a period of three hundred and seventy-five (375) days from the date of shipment that contains the following information for each shipment or pickup:

(1) Transporter's name and address;

(2) Transporter's regulated medical waste transporter permit number;

(3) Quantity and unit of measure of regulated medical waste transported, by waste category (i.e., untreated and treated);

(4) Date of shipment; and,

(5) The signature of the transporter's representative accepting the regulated medical waste for transport.

b. Generators who transport their own regulated medical waste to a treatment, destruction, or disposal facility as specified in § 1.13(B)(2)(d) of this Part shall compile and maintain a log for a period of three hundred and seventy-five (375) days from the date of the last shipment entered into the log. The log shall contain the following information:

(1) Name and address of the intermediate handler, destination facility, or health care facility to which the generator has transported the shipment of regulated medical waste;

(2) Quantity and unit of measure of regulated medical waste transported, by waste category (i.e., untreated and treated);

(3) Date of shipment; and,

(4) Signature of the generator or his authorized representative who transported the waste.

c. Generators that transport regulated medical waste by the U.S. Postal Service § 1.13(B)(4) of this Part shall retain the original shipping papers and a shipment log for a period of three hundred and seventy-five (375) days from the date of shipment. The log shall contain the following information:

(1) Quantity and unit of measure of regulated medical waste transported, by waste category (i.e., untreated and treated);

(2) Date of shipment; and,

(3) Name and address of each intermediate handler or destination facility to which the generator has transported the regulated medical waste by the U.S. Postal Service.

F. Exception/Discrepancy Reporting

1. A generator that meets the conditions of § 1.13(B)(1) of this Part or initiates a tracking form voluntarily shall contact the owner or operator of the destination facility, transporter(s), and intermediate handler(s), as appropriate, to determine the status of any tracked waste if he does not receive a copy of the completed tracking form with the signature of the owner or operator of the destination facility within thirty-five (35) days of the date the waste was accepted by the initial transporter.

2. A generator shall submit an exception report, as described below, to the Director if he has not received a completed copy of the tracking form signed by the owner or operator of the destination facility within forty-five (45) days of the date the waste was accepted by the initial transporter. The exception report shall be postmarked on or before the forty-sixth (46th) day and shall include:

    a. A legible copy of the original tracking form for which the generator does not have confirmation of delivery; and,

    b. A cover letter signed by the generator or his authorized representative explaining the efforts taken to locate the regulated medical waste and the results of those efforts.

    c. The generator shall keep a copy of the exception report for a period of at least three hundred and seventy-five (375) days from the due date of the report.

3. A generator shall also submit a discrepancy report, as described below, to the Director if there are any discrepancies between the information contained on the original generator receipt [yellow-copy, page 4] and the signed/completed generator copy [white-copy, page 1] that are not documented in block 23 of the medical waste tracking form. This discrepancy report shall be postmarked no later than five (5) working days from the date that the signed/completed generator copy [white-copy, page 1] is received from the owner or operator of the destination facility and shall include:

    a. A legible copy of both the original generator receipt and the signed/ completed generator copy received from the owner or operator of the destination facility; and,

    b. A cover letter signed by the generator or his authorized representative identifying the discrepancies that were not documented in block 23 of the medical waste tracking form;

    c. The generator shall keep a copy of this discrepancy report for a period of at least three hundred and seventy-five (375) days from the date of the report.

1.14 Transporter Requirements for Off-Site Transportation of Regulated Medical Waste

A. Applicability

1. These requirements apply to persons who engage in transportation of regulated medical waste in Rhode Island. No person or other legal entity shall engage in the transportation of regulated medical waste on a public way in the State of Rhode Island unless such person or entity shall first have been issued a permit by the Director for this purpose.

2. Notwithstanding the requirements of § 1.14(B)(1) of this Part, the following are exempt from the requirements of this section:

   a. Generators of regulated medical waste that transport regulated medical waste but are exempt under § 1.13(B) of this Part from the requirement for initiating a medical waste tracking form; and,

   b. Persons transporting household medical waste; and,

   c. On-site transportation of regulated medical waste; and,

   d. Wildlife rehabilitators authorized by DEM/Division of Fish and Wildlife transporting regulated medical waste to a veterinarian that actively supervises their activities.

3. A transporter of regulated medical waste shall also comply with § 1.13 of this Part when the transporter consolidates two or more shipments of regulated medical waste onto a single tracking form.

4. Transporters shall also comply with §§ 1.6, 1.7, 1.8, 1.9 and 1.11 of this Part if the transporters:

   a. Store regulated medical waste in the course of transport; or,

   b. Remove regulated medical waste from a reusable container; or,

   c. Modify packaging of regulated medical waste.

5. Transporters shall not accept regulated medical waste from a generator unless and until said generator has a valid regulated medical waste generator registration number issued pursuant to § 1.16 of this Part.

6. Training/Notification Requirement: Transporters and owners and operators of transfer facilities shall notify in writing all employees involved with off-site transportation of regulated medical waste of the provisions in this § 1.14 of this Part. Generators shall notify in writing all employees involved with the off-site transportation of regulated medical waste of the provisions

of §§ 1.6, 1.7, 1.8, 1.9, 1.11 and 1.14 of this Part. This training/notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

B. Regulated Medical Waste Transporter Permit Requirements

1. Exemption: The requirements of this Section shall not be applicable to use of vehicles to collect and transport regulated medical waste in emergency situations which present a threat to public health and safety. In the event of an emergency, the Director shall be immediately notified of each vehicle used for the cleanup and transportation of regulated medical waste. Notwithstanding this exemption, all collected regulated medical waste shall be managed in accordance with all applicable regulations at all times subsequent to this notification.

2. Contents of Application: A transporter shall submit an application for a regulated medical waste transporter permit on a form prescribed by the Director. Such application shall include, as a minimum, the following:

a. Name under which the application is being made;

b. Applicant's business location(s) and mailing address if different from business location(s);

c. Applicant's business phone number;

d. Name, address and phone number of the owner of the applicant company;

e. The name(s), address(es) and phone number(s) of the applicant's personnel who can be reached in case of an emergency;

f. The name(s) and signature(s) of all company personnel who are authorized to sign medical waste tracking forms;

g. A list of all employees authorized to transport or otherwise handle Regulated Medical Waste and a certification that these employees have been trained in the hazards of blood borne pathogens. This list must be amended when new individuals are hired.

h. The following information for each vehicle that may be used to transport regulated medical waste:

(1) The manufacturer;

(2) Model;

(3) Year of manufacture;

(4) Vehicle Identification Number (VIN);

(5) Cargo carrying capacity;

(6) Proof of ownership of each vehicle; and,

(7) Proof of current registration for each vehicle with the appropriate state motor vehicle agency;

i. The address of any transfer station(s) and/or vehicle parking area(s) used by the applicant for storing or parking vehicles identified in § 1.14(B)(2)(g) of this Part;

j. Location(s) to be used, pursuant to § 1.14(K) of this Part, for temporary storage of regulated medical waste in vehicles;

k. The specific location(s) and/or person(s) to which the transporter delivers or intends to deliver regulated medical waste, and a signed notarized statement from each person and/or location which certifies that said person/location is in compliance with all applicable licensing/permitting requirements for the jurisdiction(s) to which regulated medical waste will be transported;

l. A copy of the applicant's spill management plan prepared in accordance with the requirements of § 1.14(G) of this Part;

m. The permit application fee specified by § 1.14(B)(6)(a) of this Part;

n. The signature of the applicant or a person duly authorized to act on behalf of the applicant; and,

o. Any other information reasonably required by the Director to demonstrate that the applicant can safely transport regulated medical waste and comply with all applicable provisions of § 1.14 of this Part.

3. Notification of Changes: A transporter who has been issued a regulated medical waste transporter permit shall notify the Director, in writing, of any change(s) in the information required by the permit application. Such notification shall be provided in advance whenever possible. However, in no case shall the notification be postmarked later than five (5) business days after the effective date of the change(s). Notwithstanding the foregoing, the Director shall be notified, in writing, of the name(s) and signature(s) of additional company personnel authorized to sign medical waste tracking forms before the employee(s) may sign the tracking forms.

4. Vehicle Requirements

a. Vehicles used to transport regulated medical waste in Rhode Island shall, as a minimum, meet the following requirements:

(1) The vehicle shall have a fully enclosed, leak resistant cargo carrying body;

(2) The transporter shall maintain the cargo carrying body in good sanitary condition;

(3) The cargo carrying body shall be secured if left unattended; and,

(4) The regulated medical waste shall not be subject to mechanical stress or compaction during loading and unloading or during transit.

b. Vehicles used to transport regulated medical waste shall have the following identification in letters no less than three (3) inches in height on both sides and the back of the cargo carrying body:

(1) The name of the transporter;

(2) The transporter's regulated medical waste transporter permit number; and,

(3) A universal biohazard sign or the following words imprinted: "medical waste" or "regulated medical waste."

c. A transporter shall not transport regulated medical waste in the same container with other solid waste unless the transporter manages both as regulated medical waste in compliance with these regulations; and,

d. The transporter shall not use the cargo carrying compartment of the vehicle to co-mingle anything with regulated medical waste. Hazardous waste may be transported with regulated medical waste if the following criteria are met:

(1) The transporter vehicle is permitted to carry hazardous waste;

(2) The regulated medical waste and the hazardous waste are packaged separately;

(3) The hazardous waste is properly labeled, marked, packaged, and handled in accordance with all applicable laws and regulations; and,

(4) The transporter vehicle is identified, in accordance with all applicable regulations, as carrying both regulated medical waste and hazardous waste.

5. Vehicle Inspection Requirements: Each vehicle identified in § 1.14(B)(4) of this Part shall be inspected by the applicant prior to application for a medical waste transporter permit or application to add an additional vehicle to an existing permit. The applicant must complete the Department's vehicle checklist certifying the vehicle meets the Department's standards prior to the permitting of any vehicles. All equipment listed in the checklist shall be kept on the vehicle at all times.

6. Regulated Medical Waste Transporter Permit Fees: Pursuant to R.I. Gen. Laws § 23-19.12-9, the Director has established the following fee schedule for regulated medical waste transporter permits:

   a. A permit application fee of one hundred twenty-five dollars ($125) per vehicle identified on the permit application;

   b. An annual registration fee of one hundred twenty-five dollars ($125) per vehicle, or a monthly fee of twenty-five dollars ($25) per vehicle identified on the permit application or on subsequent amendments;

   c. No permit fee adjustments shall be made for vehicles that are removed from the permit and not replaced.

   d. In the case of a tractor/trailer combination, the power unit (tractor) is the vehicle that is required to have a permit. The non-powered unit (trailer) is not required to possess a permit.

7. Insurance: The holder of a regulated medical waste transporter permit shall maintain liability insurance sufficient to provide coverage of one million dollars ($1,000,000.00) per incident involving the transport of regulated medical waste.

8. Expiration of regulated medical waste transporter permits: Upon approval by the Director, a regulated medical waste company's registration shall expire three (3) years from the date of issuance, unless sooner modified, suspended or revoked. However, the transporter permits shall expire annually and the transporter must pay the annual registration fee of $125 for each vehicle that carries waste.

9. Renewal of Regulated Medical Waste Transporter Permits

   a. Requests for renewal of a regulated medical waste transporter permit shall contain all the information required by § 1.14(B) of this Part without reference to any previously submitted material.

b. In any case in which a holder of a regulated medical waste transporter permit has filed an application in proper form for renewal not less than thirty (30) days prior to expiration of his/her existing permit, the existing permit shall not expire until final action on the application has been taken by the Director.

C. Accepting Regulated Medical Waste for Transport

1. Transporters shall not accept for transport within Rhode Island any regulated medical waste unless the regulated medical waste is packaged in accordance with § 1.7 of this Part and labeled/marked in accordance with § 1.11 of this Part.

2. Transporters shall not accept regulated medical waste for transport within Rhode Island unless it is accompanied by a properly completed tracking form as required under § 1.13(C) of this Part unless the generator is exempt from the use of the tracking form under § 1.13(B) of this Part.

3. Notwithstanding § 1.14(C)(2) of this Part, a non-rail transporter may accept from a rail transporter regulated medical waste that is not accompanied by a tracking form, provided that such non-rail transporter:

   a. Signs and dates all copies of the medical waste tracking form which has been forwarded by the generator or the first non-rail transporter to the accepting non-rail transporter, or, if the tracking form has not been received by the accepting non-rail transporter, on the shipping paper;

   b. Leaves a copy of the signed and dated shipping paper with the rail transporter, if applicable; and,

   c. Retains a copy of the signed and dated shipping paper or tracking form, as applicable.

4. Before accepting regulated medical waste that is accompanied by a tracking form, a transporter shall:

   a. Verify that the tracking form accurately reflects the number of containers and quantity of all treated and untreated regulated medical waste accepted;

   b. On all copies of the tracking form, sign and indicate the date the waste was accepted from the generator or prior transporter, as applicable; and,

   c. If the transporter is the first transporter of the waste, return a copy of the signed and dated tracking form to the generator before accepting the waste, or if the transporter is a subsequent

transporter of the waste, return a copy of the signed and dated tracking form to the prior transporter before accepting the waste; and,

d. Return a signed copy of the tracking form to the generator before leaving the generator's site.

e. Retain one copy of the signed and dated tracking form.

D. Use of the Medical Waste Tracking Form

1. A transporter, other than a rail transporter, shall ensure that the tracking form accompanies the regulated medical waste during transport.

2. When a transporter, other than a rail transporter, delivers regulated medical waste to another transporter or a destination facility, the delivering transporter shall:

a. On all copies of the tracking form, obtain the date of delivery and the signature of the accepting transporter or the operator of the destination facility;

b. Retain one copy of the signed and dated tracking form; and,

c. Give the remaining copies of the signed and dated tracking form to the accepting transporter or to an authorized facility representative.

3. When a transporter other than a rail transporter delivers regulated medical waste to a transporter outside Rhode Island or facility outside Rhode Island, the delivering transporter shall:

a. Verify that the waste has been delivered to the accepting transporter or operator of the facility;

b. On all copies of the tracking form, have the accepting transporter or facility operator write his signature and the date accepted;

c. Retain one copy of the signed and dated tracking form; and,

d. Give the remaining copies of the tracking form to the accepting transporter, intermediate handler, or destination facility.

4. Delivery of Regulated Medical Waste Outside the United States: Any transporter who transports regulated medical waste across an international border, or who delivers regulated medical waste to a transporter or treatment, destruction, or destination facility located in a foreign country shall:

a. Sign the tracking form and verify that the waste has been delivered to the next transporter, or treatment, destruction, or destination facility;

b. Retain one copy of the signed tracking form for his records; and

c. Return all remaining copies of the tracking form by mail to the generator.

5. Consolidating or Re-manifesting Waste to a New Tracking Form

a. A transporter may choose to consolidate or re-manifest to a single tracking form all shipments of regulated medical waste transported in a single vehicle.

b. When a transporter consolidates wastes on to a manifest, he/she shall:

(1) Indicate on the original tracking form that the waste was reconsolidated with the new tracking form number.

(2) Retain a copy of each tracking form in accordance with § 1.14(L) of this Part; and,

(3) Return a copy of each tracking form to the generator within thirty-five (35) days of the date that the generator offered the documented regulated medical waste for transport;

c. For each consolidated tracking form initiated, a transporter shall maintain a consolidation log indicating all shipments consolidated or re-manifested on that form. The log shall accompany the tracking form and include the following information:

(1) Name of each generator;

(2) The generator's address;

(3) Date the regulated medical waste was originally shipped by the generator;

(4) Quantity of regulated medical waste (i.e., number of containers and quantity and unit of measure) by waste category (i.e., "untreated" or "treated") shipped by each generator; and,

(5) The names, regulated medical transporter permit or identification numbers of all previous transporters or, if not applicable, the transporters' addresses.

6. When a transporter receives from a treatment, destruction or destination facility a copy of a tracking form which he initiated pursuant to § 1.14(D)(5) of this Part, and which the operator of such facility signed and dated in accordance with § 1.14(D)(3)(b) of this Part, such transporter shall:

   a. Attach a copy of the tracking form received from the treatment, destruction, or destination facility to the copy of the tracking form originally prepared by the generator;

   b. Retain a copy of the tracking form received from said facility; and,

   c. Return a copy of the tracking form received from the facility, together with a copy of the tracking form originally prepared by the generator, to the generator so that the generator receives these tracking forms within thirty-five (35) days of the date that the generator offered the documented regulated medical waste for transport.

7. When a non-rail transporter accepts regulated medical waste from a rail transporter, such non-rail transporter shall:

   a. Write his signature and the date he accepts the waste on all copies of the tracking form which was forwarded by the generator or first non-rail transporter to the accepting non-rail transporter, or, if the tracking form has not been received by the accepting non-rail transporter, on the shipping paper;

   b. Leave a copy of the signed and dated shipping paper with the rail transporter, if applicable; and,

   c. Retain a copy of the signed and dated shipping paper or tracking form, as applicable.

E. Marking (Identification)

When regulated medical waste is handled by more than one transporter, each subsequent transporter shall attach a water resistant identification tag below the generator's marking on the outer surface of the packaging, so that it does not obscure the generator's or previous transporter's markings. The transporter taking possession of the shipment shall ensure that the tag contains the following information:

1. Name of transporter taking possession (receiving) of the regulated medical waste;

2. Transporter regulated medical waste transporter permit number; and,

3. Date of receipt.

F. Delivery of Regulated Medical Waste

1. A transporter shall deliver the entire quantity of regulated medical waste that he accepts from a generator or prior transporter to:

   a. The destination facility identified on the tracking form; or,

   b. The next transporter, if any.

2. If regulated medical waste cannot be delivered in accordance with § 1.14(F)(1) of this Part, a medical waste transporter shall:

   a. Contact the generator for further directions;

   b. Revise the tracking form according to the generator's instructions; and,

   c. Deliver the entire quantity of regulated medical waste according to the generator's instructions.

3. No transporter shall deliver regulated medical waste or cause regulated medical waste to be delivered to any treatment, destruction or destination facility, whether located inside or outside of Rhode Island, unless such treatment and/or destruction facility complies with all applicable law.

4. If any vehicle owned or operated by a medical waste transporter is involved in a spill of regulated medical waste or if the vehicle is involved in an accident which renders the vehicle in non-compliance with § 1.14 of this Part, such transporter shall immediately notify the Director of DEM.

G. Management of Spills

1. Spill Management Plan: All transporters, intermediate handlers, and destruction facilities shall adopt and adhere to a written procedure developed by the transporter and approved by the Department, to govern the management and decontamination of regulated medical waste spills.

2. Cleanup Equipment and Supplies: All transporters, intermediate handlers, and destruction facilities shall have at each site, including each vehicle used to transport regulated medical waste, appropriate equipment and supplies for cleaning up a spill of regulated medical waste. Equipment and supplies shall include, but are not limited to, the following:

   a. Spill Containment and Cleanup Kit: A spill containment and cleanup kit shall be kept in each area utilized for the collection, transfer, storage, treatment, packaging or other such handling of regulated medical wastes. All vehicles operating under a Rhode Island regulated medical waste transporter permit shall carry a spill

containment and cleanup kit in the vehicle whenever regulated medical waste is transported. Personnel shall be trained in the use of the kit and the kit shall contain at least the following items:

(1) Absorbent material for spilled liquids. The absorbent material shall have a rated capacity of one gallon of liquid for every cubic foot of regulated medical waste that is normally managed in that area for which the kit is provided or ten (10) gallons, whichever is less;

(2) One gallon of disinfectant in a sprayer capable of dispersing its charge in a mist and in a stream. The disinfectant shall be of hospital grade and of a formulation described in § 1.14(G)(3) of this Part and be effective against mycobacteria;

(3) Fifty (50) plastic infectious waste bags that meet the requirements of § 1.7(E) of this Part, accompanied by sealing tape (or devices for sealing), and appropriate labels as required by § 1.11 of this Part. These bags shall be large enough to overpack any box or other container normally used for regulated medical waste handling by the facility;

(4) Two (2) sets of overalls, gloves, boots, caps and protective eye covering, all of which shall be disposable and impermeable to liquids. Overalls, boots and caps shall be oversized or fitted to medical waste handlers and be made of a moisture resistant or moisture proof material. Gloves for handling regulated medical waste where sharps are not present shall be durable and moisture resistant or moisture proof. Gloves for handling sharps shall be puncture resistant or puncture proof in addition to liquid resistant. Boots shall be of durable moisture resistant or moisture proof material, which will not tear under the stress of walking. At a minimum, protective-breathing devices shall include surgical masks. The kit shall also contain tape for sealing wrists and ankles;

(5) Scoop shovels, push brooms, and buckets;

(6) A first aid kit, fire extinguisher, lights, and other appropriate safety equipment;

(7) A suitable means of communication for summoning aid in an emergency; and,

(8) An approved copy of the spill management plan as described in § 1.14(G) of this Part.

3. Disinfectants and Decontamination Procedures

a. Approved routine decontamination procedures for soiled surfaces include, but are not limited to:

(1) Exposure to hot water of at least 82°C (180°F) for a minimum fifteen (15) seconds; or,

(2) Rinsing with or immersion in a chemical disinfectant; or,

(3) Rinsing with or immersion in a one-to-ten (1:10) dilution of five percent (5%) sodium hypochlorite solution.

b. Any chemical disinfectant used for decontamination shall be registered with the U.S. EPA as hospital disinfectants that are tuberculocidal, fungicidal, virucidal and effective against HIV 1.

4. The transporter shall make provisions for prompt control of spills and other emergencies, as set forth in the spill management plan required by § 1.14(G)(1) of this Part.

5. Reporting of Medical Waste Spills

a. In the event of a spill of regulated medical waste by the transporter, the transporter shall notify the Department immediately of the spill. In all cases of spills, the transporter shall immediately take steps to contain and clean up the regulated medical waste.

b. In addition to the immediate notification requirement of § 1.14(G)(5)(a) of this Part, the transporter shall, within forty-eight (48) hours of a spill of regulated medical waste, submit an accident report to the Director. A copy of the report shall be kept on file for a minimum of three (3) years at the same location as the regulated medical waste transporter permit. The three (3) year period for retention shall start from the date of report. Record retention periods shall be extended during the course of any unresolved litigation, or when so requested by the Director or by EPA.

H. Other Inspections and Department Actions

Upon request of the Department, a medical waste transporter shall:

1. Permit the Department to inspect Tracking forms, shipment logs, reports, permits, licenses, billing records, or other documents related to the transportation or other handling of regulated medical waste.

2. Permit the Department to inspect any vehicle or related equipment or any vehicle parking area used by the transporter involved in the handling, transporting, storing or transferring regulated medical waste.

3. Decontaminate, utilizing procedures described in § 1.14(G) of this Part, or permit the Department to decontaminate at the owner's expense, any vehicle or section of a facility that has been in contact with regulated medical waste, or take or allow the Department to take any other measures necessary to make such vehicle or facility safe.

I. Personnel/Equipment

1. The transporter of regulated medical waste shall provide a sufficient number of personnel with the skills necessary to comply with all applicable laws and regulations.

2. All equipment shall be maintained in such a manner that it shall be fit for the purposes for which it was intended by the manufacturer.

J. Containerization of Regulated Medical Waste

The transporter of regulated medical waste shall not handle containerized regulated medical waste unless the containers are constructed and maintained in accordance with these regulations and the medical waste is properly segregated, packaged, labeled, and marked in accordance with §§ 1.6 and 1.7 of this Part.

K. Temporary Storage

A medical waste transporter may store regulated medical waste in the same vehicle used to pick up and transport such waste from a generator only if:

1. Such vehicle is parked at a location that:

   a. Is under the direct control of the transporter; and,

   b. Has been approved for such use by the Director in the transporter's regulated medical waste transporter permit;

2. The location where such vehicle is parked is secured to prevent access thereto by any person other than the transporter and the transporter's employees;

3. Regulated medical waste is stored in the vehicle for a period not to exceed one week, not including legal holidays;

4. The regulated medical waste is stored in accordance with the provisions of § 1.8 of this Part;

5. Such vehicle complies with the provisions of § 1.14(B)(5) of this Part;

6. No regulated medical waste is loaded on to or off of such vehicle during storage of regulated medical waste;

7. Temporary storage of regulated medical waste shall only be allowed in locations approved by the Director and included on the application for a regulated medical waste transporter permit;

8. Temporary storage in the transporting vehicle at the location of a breakdown of the vehicle shall only be allowed if the transporter notifies the Department of the location of the vehicle and the estimated time for repairs. During the period of the breakdown, the cargo body of the vehicle shall be locked and shall not be accessible to anyone except authorized personnel;

9. Temporary storage facilities shall keep an accurate log of all regulated medical waste shipped in and out of the facility; and,

10. Medical waste transfer stations shall be in accordance with R.I. Gen. Laws Chapter 23-19.12 and these regulations, and be licensed in accordance with all applicable Rules and Regulations.

L. Recordkeeping

1. A transporter of regulated medical waste shall keep a copy of the tracking form signed by the generator, the previous transporter (if applicable), and the next party, which may be one of the following: another transporter; or the owner or operator of an intermediate handling facility; or destination facility. The transporter shall retain a copy of this form for a period of three hundred and seventy-five (375) days from the date the waste was accepted by the next party.

2. For regulated medical waste that is not accompanied by a generator-initiated tracking form, the transporter shall retain a copy of all transporter-initiated tracking forms and consolidation logs for a period of three (3) years from the date the waste was accepted by the transporter.

3. For any regulated medical waste that was received by the transporter accompanied by a tracking form and consolidated or re-manifested by the transporter to another tracking form, the transporter shall:

   a. Retain a copy of the generator-initiated tracking form signed by the transporter for a period of three hundred and seventy-five (375) days from the date the waste was accepted by the transporter; and,

   b. Retain a copy of the transporter-initiated tracking form signed by the intermediate handler or destination facility for a period of three

hundred and seventy-five (375) days from the date the waste was accepted by the intermediate handler or destination facility.

4. Retain a copy of each transporter report required by § 1.14(M) of this Part for a period of three (3) years from the date of submission.

M. Reporting

A transporter that accepts regulated medical waste generated in Rhode Island shall submit reports describing the source and disposition of the waste. In addition, transporters that accept regulated medical waste generated in another state shall submit reports describing the source and disposition of the waste if such waste is being transported to a destination facility, intermediate handler, or transfer facility located in Rhode Island. The reports shall be submitted in electronic format as described below.

1. One copy of the report described in § 1.14(M)(3) of this Part shall be submitted to: Rhode Island Department of Environmental Management, Office of Land Revitalization and Sustainable Materials Management, 235 Promenade Street, Providence, Rhode Island 02908.

2. Each report shall contain the following information:

   a. The transporters name, address, and RI regulated medical waste transporter permit number;

   b. The name and telephone number of a contact person;

   c. Total number of generators from whom the transporter accepted regulated medical waste;

   d. The name, addresses, and type of each generator from whom the transporter accepted regulated medical waste;

   e. The amount, unit of measure and waste category (i.e., untreated or treated) of regulated medical waste accepted from each generator;

   f. The total quantity and waste category, of regulated medical waste from all generators in Rhode Island that the transporter delivered to an intermediate handler or to a destination facility;

   g. The total and waste category of regulated medical waste from all generators in Rhode Island that the transporter delivered to a second transporter or to a transfer facility; and,

   h. The certification signed by the owner or operator, or his authorized representative.

4. Transporters that transport or deliver regulated medical waste to an intermediate handler or to a destination facility shall also provide the following information:

   a. The name and address of each intermediate handler and destination facility to which waste from Rhode Island was delivered;

   b. The amount, by waste category, that was delivered;

   c. The total number of intermediate handlers and destination facilities to which waste was delivered.

5. The transporter shall submit reports for the periods of January 1 to June 30 and July 1 to December 31 of each year.

6. Transporters shall submit the reports required in § 1.14(M)(5) of this Part on or before the date forty-five (45) days after the end of the reporting period.

7. Each transporter that initiates a tracking form shall meet the requirements of § 1.13(F) of this Part (Exception Reporting), except that the thirty-five (35) and forty-five (45) day periods commence on the day the transporter accepted the waste from the generator.

N. Rail Shipments of Regulated Medical Waste

1. Applicability: These requirements apply to persons engaged in rail transportation of regulated medical waste generated in Rhode Island.

2. Rail transporters of regulated medical waste shall also comply with all other parts of § 1.14 of this Part, except as otherwise noted in these regulations.

3. General Requirements: The following requirements apply to all shipments of regulated medical waste involving rail transport:

   a. When accepting regulated medical waste generated in Rhode Island from a non-rail transporter, the initial rail transporter shall:

      (1) Sign and date the tracking form acknowledging acceptance of the regulated medical waste;

      (2) Return a signed copy of the tracking form to the non-rail transporter;

      (3) Forward at least three copies of the tracking form to: The next non-rail transporter, if any; the intermediate handler or destination facility, if the shipment is delivered to that facility

by rail; or the last rail transporter designated to handle the waste in the United States; and,

(4) Retain one copy of the tracking form and rail shipping paper in accordance with § 1.14(D) of this Part.

b. A rail transporter shall ensure that a shipping paper accompanies each shipment of regulated medical waste during transport and contains all the information required on the tracking form, other than that required by boxes 7, 10, and 15. A rail transporter that accepts regulated medical waste from a prior rail transporter and delivers such waste to a subsequent rail transporter is not required to sign the shipping paper relating to such shipment of waste.

c. When a rail transporter delivers regulated medical waste to a treatment or destination facility in Rhode Island, such transporter shall:

(1) Have the operator of the destination facility who has accepted the regulated medical waste sign and date all copies of the tracking form which was forwarded by the generator or the first non-rail transporter to the destination facility, or, if the tracking form has not been received by the treatment or destination facility, on the shipping paper; and,

(2) Retain a copy of the signed and dated tracking form or shipping paper, as applicable.

d. When delivering regulated medical waste to a non-rail transporter, a rail transporter shall:

(1) Obtain the date of delivery and the signature of the next non-rail transporter on the tracking form; and,

(2) Retain a copy of the tracking form in accordance with § 1.14(L) of this Part.

e. Upon accepting regulated medical waste generated in Rhode Island from a rail transporter, a non-rail transporter shall sign and date the tracking form (or the shipping papers if the tracking form has not been received by the transporter) and provide a copy to the rail transporter.

1.15 Treatment, Destruction and Destination Facilities

A. Applicability

The provisions of this Section apply to owners and operators of facilities that treat, destroy, and/or dispose of regulated medical waste as follows:

1. Destination facilities;

2. Intermediate handlers;

3. Generators that receive regulated medical waste accompanied by a tracking form.

4. Persons that treat and/or destroy regulated medical waste that has been generated on-site, and do not treat and/or destroy regulated medical waste that has been generated off-site, shall only be exempt from the provisions of §§ 1.15(B)(1) and (2), 1.15(C), (D) and (F) of this Part.

B. Requirements for Treatment, Destruction, and Destination Facilities

1. A treatment, destruction, or destination facility shall not accept regulated medical waste which is not packaged, labeled, and marked in accordance with §§ 1.7 and 1.11 of this Part.

2. A treatment, destruction or destination facility shall not accept regulated medical waste that is not accompanied by a tracking form that complies with §§ 1.13 and 1.14 of this Part.

3. No person shall operate a treatment, destruction, or destination facility at which regulated medical waste is burned or otherwise treated and/or destroyed unless such treatment, destruction, or destination facility complies with all applicable laws and regulations.

4. All treatment, destruction, or destination facilities shall keep a spill containment and cleanup kit in or near any storage area, loading and unloading area, decontamination area, and treatment area where regulated medical waste is managed. The location of the kits shall provide for rapid and efficient cleanup of spills anywhere within these areas. The kit shall consist of at least the following items:

   a. Absorbent material for spilled liquids. The absorbent material shall have a rated capacity of one gallon of liquid for every cubic foot of regulated medical waste that is normally managed in the area for which the kit is provided or ten (10) gallons, whichever is less.

   b. One gallon of disinfectant in a sprayer capable of dispersing its charge in a mist and in a stream. The disinfectant shall be of hospital grade and of a formulation described in § 1.14(G)(3) of this Part and be effective against mycobacteria.

c. Fifty (50) red plastic infectious waste bags that meet the requirements of § 1.7(E)(3) of this Part, accompanied by sealing tape (or devices), and appropriate labels as required by § 1.11 of this Part. These bags shall be large enough to overpack any box or other container normally used for regulated medical waste handling by the facility.

d. Two (2) sets of overalls, gloves, boots, caps and protective eye covering, all of which shall be disposable and be impermeable to liquids. Overalls, boots and caps shall be oversized or fitted to medical wastes workers and be made of a moisture resistant or moisture proof material. Gloves for handling regulated medical waste where sharps are not present shall be durable and of moisture resistant or moisture proof material. Gloves for handling sharps shall be puncture resistant or puncture proof in addition to liquid resistant. Boots shall be of durable moisture resistant or moisture proof material which will not tear under the stress of walking. Minimum protective breathing devices shall be surgical masks. Tape for sealing wrists and ankles shall also be provided in the kit.

e. A first aid kit (unless emergency medical care is available on the premises), fire extinguisher, and other appropriate safety equipment.

5. The disinfectants used in cleaning up a spill shall be registered with the U.S. EPA as hospital disinfectants that are also tuberculocidal, fungicidal, virucidal and effective against HIV 1. Also approved as a disinfectant is one-to-ten (1:10) dilution of five percent (5%) sodium hypochlorite solution.

6. All regulated medical waste treatment, destruction, or destination facilities shall, at a minimum, implement the following procedures subsequent to a spill of regulated medical waste upon its discovery:

a. The cleanup crew shall utilize the protective equipment described in § 1.14(G) of this Part during the spill cleanup operation;

b. Limit access to the spill area only to authorized personnel;

c. Place broken containers and spillage inside overpack bags in the kit;

d. Disinfect the area and take other cleanup steps deemed necessary. Any absorbent materials used to disinfect the area shall be considered regulated medical waste;

e. Clean and disinfect non-disposable items;

f. Remove protective equipment and manage disposal items as regulated medical waste;

g. Take necessary steps to replenish containment and cleanup kit;

h. Call for emergency assistance if necessary;

i. Report to the Director immediately all regulated medical waste spills or accidents, unless the quantity of such spills is less than one cubic foot of waste;

j. Submit a medical waste spill report to the Director within forty-eight hours, using the spill or accident report form prescribed by the Director. Any regulated medical waste spill outside the limited access areas shall be reported to the Director. A copy of the report shall be on file at the treatment facility for a minimum of three (3) years. The report form shall include, but not be limited to:

(1) Name of facility;

(2) Name of employee(s) involved;

(3) Address of facility;

(4) Date of spill or accident;

(5) Date of report;

(6) Short detailed summary of events; and,

(7) Procedure(s) used to clean the spill or accident.

k. All spills shall be recorded in a log that is maintained for a minimum of three (3) years from the date of the last entry in the log.

7. Treatment, destruction, and destination facilities shall:

a. Store regulated medical waste in a manner and location that maintains the integrity of the packaging;

b. Maintain regulated medical wastes in a non-putrescent state, using refrigeration or freezing when necessary;

c. Lock outside storage areas containing regulated medical wastes to prevent unauthorized access;

d. Designate and label regulated medical waste storage areas not limited to authorized personnel by posting a sign stating "warning:

regulated medical waste" and/or displaying the international biohazard symbol at all points of access; and,

e. Store regulated medical waste in a manner and location that is not accessible to animals and does not provide a breeding place or a food source for insects or rodents.

8. Treatment, destruction, and destination facilities shall adhere to the following storage regulations:

a. No regulated medical waste shall be stored more than fourteen (14) days;

b. No facility shall store more than seven (7) times its total maximum daily capacity for treatment and/or destruction of regulated medical waste;

c. All facilities shall formulate a plan and submit a copy to the Director for approval. At a minimum the plan shall:

(1) Address compliance with the requirements set forth in §§ 1.15(B)(4), (6), (7), (8) of this Part, and shall provide for the removal of regulated medical waste to an alternate facility in the event that the facility is not in compliance with §§ 1.15(B)(8)(a) through (b) of this Part;

(2) Be maintained at the treatment facility; and,

(3) Designate an emergency coordinator and an alternate emergency coordinator.

d. The facility shall implement the appropriate section(s) of its plan under the following conditions:

(1) Its maximum storage capacity for regulated medical waste (as determined by § 1.15(B)(8)(b) of this Part) has been exceeded; or,

(2) The storage time for regulated medical waste has exceeded fourteen (14) days; or,

(3) The facility operator anticipates exceeding the maximum storage capacity and/or the fourteen (14) day storage time limit for regulated medical waste.

e. A generator that also treats or destroys regulated medical waste generated on premises owned or operated by the generator shall be subject to the requirements of § 1.15(B)(8) of this Part when the

untreated regulated medical waste is stored in a centralized storage area prior to treatment or destruction.

9. Training/Notification Requirement: The owner of a treatment, destruction or destination facility shall notify in writing all employees involved with the treatment and destruction of regulated medical wastes of the provisions in § 1.15 of this Part. This training/notification shall be accomplished through the use of a medical waste procedure manual and/or through appropriate training materials.

C. Use of the Tracking Form

1. Destination Facility: When a destination facility receives regulated medical waste accompanied by a tracking form, the owner or operator shall:

a. Sign and date each copy of the tracking form to certify that the regulated medical waste listed on the tracking form was received;

b. Note any discrepancies as defined in § 1.15(D) of this Part on the tracking form;

c. Immediately give the transporter at least one copy of the signed tracking form;

d. Retain a copy of each tracking form in accordance with § 1.15(E)(1) of this Part.

2. Intermediate Handlers: When an intermediate handler receives regulated medical waste accompanied by a tracking form, the owner or operator shall meet the following requirements:

a. The owner or operator shall initiate a new tracking form for each shipment of regulated medical waste that has either been treated or destroyed. The owner or operator shall also meet all the requirements for generators under §§ 1.6 through 1.13(H) of this Part including signing the tracking form, indicating the acceptance of the waste as specified in box 20, and entering the new tracking form number in box 21.

b. The owner or operator shall maintain a log matching the original generator's tracking forms to the tracking form that the owner/operator shall initiate. This log shall include:

(1) Name(s) of generator(s);

(2) Generator's address;

(3) The date the regulated medical waste was originally shipped by the generator or the generator's unique tracking form number;

(4) The new tracking form number to which the waste is assigned.

c. Within fifteen (15) days of receipt of the tracking form that was initiated by the owner/operator and that was signed by the destination facility, the intermediate handler shall:

(1) Attach a copy of the tracking form, signed by the destination facility, to the original tracking form initiated by the generator according to § 1.13(C) of this Part;

(2) Send a copy of each tracking form to the generator that initiated the tracking form; and,

(3) Retain a copy of each tracking form in accordance with the requirements of § 1.14(L) of this Part.

3. Rail Shipments: If a destination facility or intermediate handler receives regulated medical waste from a rail transporter that is accompanied by shipping papers containing the information required on the medical waste tracking form, with the exception of the generator's certification and chain of custody signatures, the owner or operator or his agent, shall:

a. Sign and date each copy of the tracking form or the shipping papers (if the tracking form has not been received);

b. Note any discrepancies, as defined in § 1.15(D) of this Part, on each copy of the tracking form or shipping papers (if the tracking form has not been received);

c. Immediately give the rail transporter at least one copy of the tracking form or shipping papers (if the tracking form has not been received);

d. If the facility is a destination facility, send a copy of the signed and dated tracking form to the generator within fifteen (15) days after the delivery. If the owner or operator has not received the tracking form within fifteen (15) days of delivery, a copy of the signed and dated shipping papers shall be sent to the party initiating the tracking form;

e. If the facility is an intermediate handler, retain a copy of the tracking form (or the shipping papers if the tracking form has not been received), until a copy of the tracking form signed by the owner or

operator of the destination facility. The destination facility or intermediate handler shall then:

(1) Attach a copy of the tracking form (signed by the destination facility) to the original tracking form (or the shipping papers if the tracking form has not been received) initiated by another party;

(2) The intermediate handler and destination facility shall send a copy of each tracking form (or each set of shipping papers) to the party who initiated the tracking form; and,

(3) The intermediate handler and destination facility shall retain a copy of each tracking form in accordance with the requirements of § 1.15(E) of this Part.

f. The intermediate handler and destination facility shall retain a copy of the tracking form (or shipping papers if signed in lieu of the tracking form) for at least three hundred and seventy-five (375) days from the date of acceptance of the regulated medical waste.

D. Tracking Form Discrepancies

1. Tracking form discrepancies required for:

a. Any variation in piece count such as a discrepancy of one box, pail, or drum in a truckload; or,

b. Any variation in the actual weight of any single container of regulated medical waste that differs from its listed weight by more than ten percent (10%); or,

c. Any variation in the actual weight of all containers in a shipment of regulated medical waste that differs from the total weight listed on the medical waste tracking form by more than five percent (5%).

d. Discrepancies in number of containers for each category of regulated medical waste as described on the label imprinted or affixed to the outer surface of the package;

e. For packaging that is broken, torn, or leaking; and,

f. Regulated medical waste that arrives at an intermediate handler or a destination facility unaccompanied by a tracking form, where the owner or operator knows such form is required, or for which the tracking form is incomplete or not signed.

2. Upon discovering a discrepancy, the owner or operator of the treatment, destruction, or destination facility shall attempt to resolve the discrepancy with the waste generator, the transporter and/or the intermediate handler. If the discrepancy is not resolved, the owner or operator shall submit a letter, within fifteen (15) days of receiving the waste, to the Director. The letter shall describe the nature of the discrepancy and the attempts the owner or operator has undertaken to reconcile it. The owner or operator shall include a legible copy of the tracking form or shipping papers in question with the letter. If the discrepancy is the type specified in § 1.15(D)(1)(d) of this Part, the report shall specify the quantity of waste received, the transporter, and the generator(s).

E. Recordkeeping

1. The owner or operator of a destination facility or an intermediate handler receiving regulated medical waste shall maintain records for a minimum of three (3) years from the date the waste was accepted. These records shall contain the following information:

   a. Copies of all tracking forms and logs required by these regulations; and,

   b. The name and address of each generator that delivered waste to the destination facility or intermediate handler under § 1.13(B)(2) of this Part, and the generator's address; and,

   c. Copies of all discrepancy reports required by § 1.15(D) of this Part.

2. The owner or operator of a destination facility or an intermediate handler that accepts regulated medical waste from generator(s) subject to § 1.13(B)(2) of this Part shall maintain the following information for each shipment of regulated medical waste accepted:

   a. The date the waste was accepted;

   b. The name and address of the generator who originated shipment;

   c. The total weight of the regulated medical waste accepted from the originating generator; and,

   d. The signature of the individual accepting the waste.

F. Treatment, Destruction, and Disposal of Regulated Medical Wastes

1. Regulated medical waste remains subject to the handling and management requirements of these regulations and to any relevant federal regulations until the regulated medical waste is both treated and destroyed.

2. Once regulated medical waste has been both treated and destroyed, its residue may be disposed of as non-regulated medical waste unless that residue meets the definition of hazardous waste as defined by DEM Rules and Regulations for Hazardous Waste Management (Subchapter 10 Part 1 of this Chapter). Untreated regulated medical waste may be transported off-site for treatment and destruction, treated on-site and transported off-site for destruction, or treated and destroyed on-site. Regulated medical waste shall not undergo mechanical destruction before it has been treated, unless the mechanical destruction and treatment are part of a single, self-contained process that does not place employees or the public at risk of exposure to untreated regulated medical waste.

3. Treatment and destruction combinations that fulfill the requirements for proper treatment and destruction of regulated medical wastes include, but are not limited to, the following:

   a. For Liquid Regulated Medical Wastes, Including Body Fluids, Human Blood and Blood Products: Acceptable disposal methods include:

      (1) Incineration;

      (2) With approval from the local sewer authority, discharge into a sanitary sewer system that has a secondary wastewater treatment facility. Methods of discharge shall be limited to: direct discharge into the sanitary sewer system; discharge after steam sterilization; or discharge after chemical disinfection with a one-to-ten (1:10) dilution of five percent (5%) sodium hypochlorite solution or equivalent chemical disinfection.

      (3) Discharge into an Individual Sewage Disposal System (ISDS), provided that chemical disinfectants and/or preservatives are not added to the body fluids, human blood and/or blood products prior to discharge and that no more than ten (10) gallons of body fluids, human blood and/or blood products are discharged in an ISDS during a twenty-four (24) hour period;

   b. For Human Pathological Wastes (Not Including Body Fluids) and Isolation Wastes: Acceptable technologies include:

      (1) Incineration;

      (2) In response to the threat posed by certain isolation waste (human or animal) the Director may prescribe alternate treatment standards as described in § 1.2(B) of this Part.

c. For Sharps and Unused Sharps: Acceptable technologies include:

(1) Incineration;

(2) Chemical disinfection, utilizing chemicals specifically approved by EPA/FIFRA for disinfection of medical waste, with or followed by grinding or shredding; and,

(3) Steam sterilization followed by grinding or shredding.

d. For Other Regulated Medical Wastes (including, but not limited to, cultures and stocks, items saturated and/or dripping and/or caked with human blood): Acceptable technologies include:

(1) Incineration;

(2) Chemical disinfection, utilizing chemicals specifically approved by EPA/FIFRA for disinfection of medical waste, with or followed by grinding or shredding;

(3) Steam sterilization followed by grinding or shredding.

4. Alternative Technologies: Any other treatment, destruction and/or disposal technology shall only be utilized if such treatment, destruction and/or disposal technology has been approved in writing by the Director.

5. Approval of Alternative Technologies:

a. The Director shall not grant approval for the use of any other combination of treatment, destruction and/or disposal technologies, unless and until such technologies are proven, on the basis of thorough tests to:

(1) Completely and reliably inactivate *Geobacillus stearothermophilus* spores or *Bacillus atrophaeus* spores at a 4 Log_{10} reduction or greater; and,

(2) Completely and reliably inactivate vegetative bacteria, fungi, viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater [this requirement is applicable to technologies not based on thermal and chemical treatment]; and,

(3) Be protective with respect to total impact on the environment; and,

(4) Ensure the health, safety and welfare of both facility employees and the general public; and,

(5) Ensure that the total weight and/or volume of the end product of the alternative technology does not exceed the total weight and/or volume of the regulated medical waste prior to treatment and/or destruction. Testing must also demonstrate that inactivation is uniformly and within containers reasonably likely to be treated in the system.

b. Notwithstanding the provisions of § 1.15(F)(5)(a) of this Part, the Director may deny any application for just cause within the scope and intent of these regulations.

1.16 Registration for Generators of Regulated Medical Waste

A. General Requirements

1. As of January 1, 2012, no person whose primary business activity of purpose is the diagnosis (including testing and laboratory analysis), treatment, or immunization of human beings or animals, in research pertaining thereto, or in the preparation of human remains for burial or cremation, or in the production or testing of biologicals, or in the development of pharmaceuticals shall engage in the generation of regulated medical waste unless that person shall have registered with the Director in accordance with the requirements contained in § 1.16(A)(2) of this Part and have been issued a regulated medical waste generator registration number. For the purpose of these regulations, a person is considered to be a single generator, even if it utilizes more than one (1) site in the course of its operation.

2. Contents of Application: A generator shall submit an application for a regulated medical waste generator registration number in a manner prescribed by the Director. The Department may require this form to be filled out on paper or in an online format. Such application shall include, as a minimum, the following:

a. Name under which the application is being made;

b. Business location(s) used to generate regulated medical waste, and mailing address if different from generation location(s);

c. The type of generator facility at each business location;

d. Applicant's business phone number;

e. The name and phone number of the primary contact person for the facility;

f. The approximate amount of regulated medical waste that will be generated per year at each location;

g. If regulated medical waste is to be treated and/or destroyed on-site, provide a description of the treatment/destruction methods;

h. If regulated medical waste is to be transported off-site for treatment and/or destruction, provide the approximate quantity of treated and untreated waste, as well as the name(s) and RI regulated medical waste transporter permit number(s) of the transporter(s);

i. The signature of the applicant or a person duly authorized to act on behalf of the applicant; and,

j. Any other information reasonably required by the Director to demonstrate that the applicant can safely generate and manage regulated medical waste in accordance with all applicable provisions of these regulations.

3. Notification of Changes: A registered generator of regulated medical waste shall notify the Director, in writing, of any change(s) in the information required by the permit application. Such notification shall be provided in advance whenever possible. However, in no case shall the notification be postmarked later than five (5) business after the effective date of the change(s). Notwithstanding the foregoing, the Director shall be notified, in writing, of any additional location(s) to be included on the registration before any regulated medical waste is generated at that location.

4. Expiration of Regulated Medical Waste Generator Registrations: Upon approval by the Director, a regulated medical waste generator registration shall expire on December 31 of the year of issuance, unless sooner suspended or revoked.

5. Renewal of Regulated Medical Waste Generator Registrations

a. Requests for renewal of a regulated medical waste generator registration shall be submitted not later than thirty (30) days prior to the expiration date of the current registration, and shall contain all the information required by § 1.16(A)(2) of this Part without reference to any previously submitted material.

b. In any case in which a holder of a regulated medical waste generator registration has filed an application in proper form for renewal not less than thirty (30) days prior to the expiration date of his/her existing registration, the existing registration number shall not expire until final action on the application has been taken by the Director.

B. Registration of More Than One Generator at the Same Site

1. Any person who generates regulated medical waste at a location operated by a legal entity of which such person has no legal relationship must register as a generator of regulated medical waste as required by R.I. Gen. Laws § 23-19.12-12, in the manner provided by § 1.16(A) of this Part. Such person shall be independently responsible for violations of the law and regulations that are committed by that person.

2. If two or more individual generators register in accordance with § 1.16(A) of this Part as a single legal entity, they shall submit to the Director verification that they are a legal entity, which is responsible for the actions of its agents regarding the generation and management of regulated medical waste.

3. Two or more individual generators at the same location who share examination rooms, jointly combine all regulated medical waste, and are each small quantity generators, but are not a single legal entity, shall each be required to obtain separate registrations pursuant to § 1.16(A) of this Part. Each person shall be independently responsible for violations of the law and regulations that are committed. For the purpose of determining registration categories, each such individual generator shall assume, unless proven otherwise, an equal proportion of all regulated medical waste generated at that location.

C. Annual Registration Fee

1. The Director has established the following annual registration fees for generators of regulated medical waste:

Generator Category	Waste Generated Per Generator Per Year	Annual Fee for Registration
1	Less than 25 lbs.	$30/generator
2	25 lbs. to 100 lbs.	$40/generator
3	101 lbs. to 500 lbs.	$60/generator
4	501 lbs. to 2,000 lbs.	$160/generator
5	More than 2,000 lbs.	$200/generator

2. Prorating of Fees. Any person submitting an application for a new regulated medical waste generator registration between July 1 and December 31 shall pay one-half of the appropriate fee specified in § 1.16(C)(1) of this Part. The fee for a new regulated medical waste

generator registration submitted between January 1 and June 30 shall not be prorated.

3. Adjustments to Fees. A facility that generates more regulated medical waste than permitted under their current generator category during the issuance period shall, upon renewal, be responsible for payment of the renewal registration fee for the higher generator category. No permit fee adjustments shall be made during the issuance period for facilities that generate less regulated medical waste than permitted under their current generator category.

1.17 Licenses for Storage, Treatment and/or Destruction of Regulated Medical Waste

A. General Requirements

1. No person or legal entity shall engage in the storage, treatment and/or destruction of regulated medical waste unless that person or entity shall have been issued a license by the Director for that purpose.

2. Notwithstanding the requirements of § 1.17(A)(1) of this Part:

a. The owner and/or operator of a treatment, destruction, and/or disposal facility that is operating under a solid waste management facility license, issued pursuant to R.I. Gen. Laws § 23-18.9-8 and the Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter), for the current license year during which these regulations take effect shall comply with this Section by the next license renewal date.

b. The owner and/or operator of a solid waste management facility which has a solid waste management facility license, issued pursuant to R.I. Gen. Laws § 23-18.9-8 and the Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter) shall have an additional ninety (90) days beyond said expiration date to comply with the requirements of this Section if there is less than six (6) months' time between the effective date of these regulations and the expiration of said license.

c. The owner and/or operator of a solid waste management facility which has applied for a solid waste management facility license pursuant to R.I. Gen. Laws § 23-18.9-8 and the Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter) but has not yet received a license for the current license

year during which these regulations take effect shall have six (6) months from the effective date of these regulations to comply.

3. Notwithstanding the requirements of § 1.17(A)(1) of this Part, the following activities do not constitute practices requiring licensure under this section:

   a. Storage by a generator before regulated medical waste is treated and/or destroyed on-site, or offered for transport off-site; and,

   b. Treatment and/or destruction of regulated medical waste by the generator of that waste if the treatment and/or destruction:

      (1) Is carried out at a generating facility owned and operated by the generator of the regulated medical waste; and,

      (2) Does not include regulated medical waste generated by any other person or legal entity.

4. Upon approval by the Director, a license for the storage, treatment and/or destruction of regulated medical waste shall expire three (3) years from the date of issuance, unless sooner modified, suspended or revoked.

5. The holder of a license for the storage, treatment and/or destruction of regulated medical waste shall notify the Director, in writing, of any changes in the information provided with the license application. Said notification shall be provided in advance whenever possible. In no case shall the notification be postmarked later than five (5) business days after the effective date of the change(s).

6. The requirements established by this section shall be in addition to, and not in lieu of any requirements established by the Director pursuant to R.I. Gen. Laws Chapters 23-18.9 and 23-63, the Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter), or other Rules and Regulations promulgated pursuant to the authority conferred by these statutes.

B. Regulated Medical Waste Storage, Treatment and/or Destruction License Fees

1. Each application for a license to construct a facility for the storage, treatment and/or destruction of regulated medical waste, or application to renew a license to operate a facility for the storage, treatment and/or destruction of regulated medical waste, shall include a fee in accordance with the following schedule:

Type of Facility	**Application Fee**	**Renewal Fee**

Medical Waste Incinerator	$20,000	$10,000
Treatment, Disinfection and/or Destruction Facility	$15,000	$7,500
Storage/Transfer Station	$10,000	$3,000
Mobile Operation(s)	$15,000	$7,500

2. Multiple Operations at One Facility: Facilities that perform multiple operations as part of a single facility operation shall only be required to possess the license with the highest fee category applicable to the activities performed at that site. However, two or more independently staffed facilities operating on the same site shall require a license for each independent facility, as well as the appropriate fee for each independent facility.

3. The fees established by this section shall be in addition to any fees assessed by the Director pursuant to R.I. Gen. Laws Chapters 23-18.9 and 23-63, the Rules and Regulations for Solid Waste Management Facilities and Organic Waste Management Facilities (Subchapter 05 Part 1 of this Chapter), or other Rules and Regulations promulgated pursuant to the authority conferred by these statutes.

1.18 Variances

A. Application

An application for a variance from the segregation, handling, transportation, storage, or treatment requirements of the medical waste Rules and Regulations shall be made in writing to the Department.

B. Review

The Director shall evaluate each request for a variance. Such variance may be granted provided the Director finds that such request will not be contrary to the purposes and policy expressed in § 1.2 of this Part and that the alternative methods proposed by the applicant fulfill the purposes of the rule from which the variance is requested.

1.19 Severability

If any provision of these Rules and Regulations, or the application thereof to any person or circumstance, is held invalid by a court of competent jurisdiction, the validity of the remainder of the Rules and Regulations shall not be affected thereby.

1.20 Superseded Rules and Regulations

On the effective date of these Rules and Regulations, all previous Rules and Regulations, and any policies regarding the administration and enforcement of the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste shall be superseded. However, any enforcement action taken by, or application submitted to, the Department prior to the effective date of these Rules and Regulations shall be governed by the Rules and Regulations in effect at the time the enforcement action was taken or the application filed.

1.21 List of Animal Diseases Associated with Isolation Waste

A. Isolated animals believed to be infected with highly communicable zoonotic diseases or foreign animal diseases.

1. Any species

    a. Borna disease

    b. *Burkholderia mallei*

    c. *Burkholderia pseudomallei*

    d. Nipah virus

    e. Rift Valley Fever

    f. Vesicular Exanthema of Swine (infection with VESV)

2. Avian

    a. Avian Influenza (high pathogenicity and foreign strains)

    b. Duck Virus Hepatitis

    c. Exotic Newcastle disease

3. Bovine

    a. Akabane Disease

b. Bovine ephemeral fever

c. Bovine Spongeform Encephalopathy (BSE)

d. Contagious Bovine Pleuropneumonia

e. Foot-and-Mouth Disease (Aphthovirus)

f. Hemorrhagic septicemia

g. Jembrana disease

h. Rinderpest

4. Caprine/Ovine

a. Capripoxviruses

b. Contagious Caprine Pleuropneumonia

c. Malignant Catarrhal Fever

d. Peste des Petits Ruminants

e. Goat and sheep pox

5. Equine

a. African Horse Sickness

b. Epizootic Lymphangitis

c. Hendra

d. Venezuelan Equine Encephalomyelitis (VEE)

6. Porcine

a. African Swine Fever

b. Classical Swine Fever

c. Swine Vesicular Disease

7. Other

a. Rabbit Hemorrhagic Disease

b. Infectious Salmon Anemia

c. Spring Viremia of Carp

1.22 Highly Communicable Endemic Animal Diseases

Disease	Zoonosis	Carcass Infectious	Special Consideration
Any Species			
Anthrax	Yes	Yes	Spores difficult to mitigate/small animals should be dealt with as infectious waste/large animals buried with DEM approval
Brucellosis	Yes	Yes	Routine bagging and burial or incineration of small animals/large animals buried with DEM approval
Leptospirosis	Yes	Yes, if contaminated	Routine bagging and burial or incineration of small animals/large animals buried with DEM approval
Lymphocytic	Yes	Yes, if contaminated	Routine bagging and burial or incineration of small animals
Choriomeningitis Plague	Yes	No	Flea vectors are required for transmission/routine disposal bagging and burial or incineration

Q-Fever	Yes	Yes, if contaminated	Routine bagging and burial or incineration of small animals/large animals buried with DEM approval
Rabies	Yes	Yes, if contaminated	Routine bagging and burial or incineration of small animals/large animals buried with DEM approval
Tuberculosis	Yes	Yes	Routine bagging and burial or incineration of small animals/large animals buried with DEM approval
Tularemia	Yes	Yes	Routine bagging and burial or incineration of small animals
Avian			
Avian Influenza	Possible	Yes	Carcasses must be disposed of in a manner consistent with RI's AI response plan
(Low Path) Salmonellosis	Yes	Yes, if contaminated	Routine bagging and burial or incineration
Bovine			
Malignant Catarrhal fever	No	No	Disposal by burial is acceptable

Pseudorabies	No	Yes to animals	Disposal by burial is acceptable
Canine			
Canine Influenza	No	Possibly	Routine bagging and burial or incineration
Parvovirus	No	Possibly	Routine bagging and burial or incineration
Caprine/Ovine			
Bluetongue	No	No	Disposal by burial is acceptable
Caseous Lymphadenitis	Rare		Disposal by burial is acceptable
Scrapie	No	Yes to animals	Prion Disease, high temp or chemical digestion only
Equine			
Equine Rhinopneumonitis	No	Yes to horses	Disposal by burial is acceptable
Equine Viral Arteritis	No	Unlikely	Disposal by burial is acceptable
Strangles	No	Yes, if contaminated	Disposal by burial is acceptable
Porcine			
Hog Cholera	No	Yes	Disposal by burial is acceptable

Pseudorabies	No	Yes to animals	Disposal by burial is acceptable

250-RICR-140-15-1

TITLE 250 - DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

CHAPTER 140 - WASTE AND MATERIALS MANAGEMENT

SUBCHAPTER 15 - MEDICAL WASTE

PART 1 - MEDICAL WASTE REGULATIONS (250-RICR-140-15-1)

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