STATE OF DELAWARE

DEPARTMENT OF NATURAL RESOURCES
AND ENVIRONMENTAL CONTROL

REGULATIONS GOVERNING SOLID WASTE

ADOPTED DECEMBER 1988

UPDATED THROUGH MARCH 1999

SECTION 11: SPECIAL WASTES MANAGEMENT

PART 1 - Infectious Waste

A. GENERAL PROVISIONS

1. All generators of infectious waste shall obtain an Infectious Waste Identification Number by registering with the Department on a form provided by the Department.

2. No person shall engage in the construction, operation, material alteration, or closure of a facility to be used in the treatment, storage, or disposal of infectious wastes, unless specifically exempted from the regulations within Section 2.C., without first having obtained the proper permits from the Department.

3. All infectious waste must be packaged in accordance with these regulations.

B. SITING

1. Infectious waste treatment facilities shall be located only in areas where the potential for degradation of the quality of air, land, and water is minimal.

2. Infectious waste treatment facilities shall be located adjacent to access roads capable of withstanding anticipated load limits.

3. No new infectious waste treatment facility shall be located in an area such that solid waste would at any time be handled:

   a. Within the 100 year flood plain.

   b. Within any state or federal wetland.

   c. So as to be in conflict with any locally adopted land use plan or zoning requirement.

C. DEFINITIONS

The following definitions are specific to the management of infectious waste as used in this part. For general definitions relating to other types of solid waste and the management of solid waste, refer to Section 3 of these regulations.

"6-LOG REDUCTION" means a 6 decade reduction or a millionth (.000001) survival probability in a microbial population, i.e., a 99.9999% reduction.

"ATCC" means American Type Culture Collection.

"AUTOCLAVE TAPE" means tape that demonstrates an evidentiary visible physical change when subjected to temperatures that will provide evidence of sterilization of materials during treatment in an autoclave or similar device.

"CFU" means colony-forming unit.

"CHALLENGE LOADS" means an infectious waste load that has been constructed by composition (i.e., organic content, moisture content, or other physical or chemical composition).

"CLASS 4 ETIOLOGIC AGENT" means a pathogenic agent that is extremely hazardous to laboratory personnel or that may cause serious epidemic disease. Class 4 etiologic agents include the following viral agents:

- Alastrim, Smallpox, Monkey pox, and Whitepox (when used for transmission or animal inoculation experiments).
- Hemorrhagic fever agents (including Crimean hemorrhagic fever (Congo), Junin, and Machupo viruses, and others not yet defined).
- Herpesvirus simiae (Monkey B virus)
- Lassa virus
- Marburg virus
- Tick-borne encephalitis virus complex (including Absettarov, Hanzalova, HYPR, Kumlinge, Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever and Central European encephalitis viruses)
- Venezuelan equine encephalitis virus (epidemic strains, when used for transmission or animal inoculation experiments)
- Yellow fever virus (wild, when used for transmission or animal inoculation experiments)

"CONTAINER" means any portable enclosure in which a material is stored, managed or transported.

"CONTAMINATION" means the degradation of naturally occurring water, air or soil quality either directly or indirectly as a result of the transfer of diseased organisms, blood or other matter that may contain disease organisms from one material or object to another.

"ETIOLOGIC AGENTS": see "INFECTIOUS SUBSTANCE"

"GENERATOR" means hospital, in or out patient clinics, laboratories, medical offices, dental offices, nursing homes, and in-patient residential facilities serving persons with diseases which may be transmitted through contact with infectious waste as well as veterinary facilities and research laboratories operating within the State of Delaware.

"INCINERATOR" means any enclosed device used to destroy waste material by using controlled flame combustion.

"INDICATOR MICROORGANISM SPORES" means those microorganism spores listed in Appendix A, Table B of Section 11, Part 1.

"INFECTIOUS SUBSTANCE" (formerly called "ETIOLOGIC AGENTS") means a viable microorganism, or its toxin, which causes or may cause disease in humans or animals, and includes any agent that causes or may cause severe, disabling, or fatal disease. The terms *infectious substance* and *etiologic agent* are synonymous.

"INFECTIOUS WASTE" means those solid wastes which may cause human disease and may reasonably be suspected of harboring human pathogenic organisms, or may pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of or otherwise managed. Types of solid wastes designated as infectious include but are not necessarily limited to the following:

1. **Biological wastes:**

   a. **Biological liquid wastes** means blood and blood products, excretions, exudates, secretions, suctionings and other body fluids including liquid wastes from renal dialysis.

   b. **Pathological wastes** means all human tissues and anatomical remains, including human fetal remains, which emanate from surgery, obstetrical procedures, autopsy, and laboratory procedures.

   c. **Cultures and stocks of etiologic agents and associated biological wastes** means, but is not limited to, specimen cultures, cultures and stocks of infectious substances, and wastes from production of biologicals and serums.

   d. **Laboratory wastes** means those wastes which have come in contact with pathogenic organisms or blood or body fluids. Such wastes include, but are not limited to, disposable materials, culture dishes, devices used to transfer, inoculate and mix cultures, paper and cloth which has come in contact with specimens or cultures which have not been sterilized or rendered noninfectious; or laboratory wastes, including cultures of infectious substances, which pose a substantial threat to health due to their volume and virulence.

   e. **Animal tissue, bedding and other waste** from animals known or suspected to be infected with a pathogen which also causes human disease, provided that prevailing evidence indicates that such tissue, bedding or other waste may act as a vehicle of transmission to humans.

   f. **Human dialysis waste materials** including blood lines and dialysate membranes.

2. **Sharps** means any discarded article that may cause puncture or cuts. Such wastes include, but are not limited to, needles, intravenous (IV) tubing with needles attached, scalpel blades, glassware and syringes that have been removed from their original sterile containers. For the purpose of these regulations, only sharps from human or animal health care facilities, human or animal research facilities or human or animal pharmaceutical manufacturing facilities shall be regulated as sharps.

3. **Discarded Biologicals** means serums and vaccines produced by pharmaceutical companies for human or veterinary use. These products may be discarded because of a bad manufacturing lot (i.e., off-specification material that does not pass quality control or that is recalled), out-dating or removal of the product from the market or other reasons. Because of the possible presence of infectious substances in these products, the discarded material constitutes infectious waste.

4. **Isolation Wastes** means discarded materials contaminated with blood, excretions, exudates and/or secretions from humans who are isolated to protect others from highly communicable diseases (those diseases identified as caused by Class 4 etiologic agents).

5. **Other infectious wastes** means any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any infectious waste.

"LARGE INCINERATOR" means an incinerator which has a capacity of greater than 1000 pounds per hour.

"LOG KILL" (L) means the difference between the logarithms of viable test microorganisms or indicator microorganism spores before and after treatment.

"MANIFEST" means a tracking document designed to record the movement of solid waste from the generator through its trip with a transporter to an approved off-site treatment or disposal facility.

"NONINFECTIOUS" means a state in which potentially harmful microorganisms are absent, free of pathogens.

"RED BAG" means an impermeable, 3-mil polyethylene bag or equivalent, red in color, for the collection, storage, and transport of infectious or regulated medical waste, which meets the following minimum performance requirements:

1. Appearance: opaque, red. Each bag must carry the words "INFECTIOUS WASTE" or "REGULATED MEDICAL WASTE" or "BIOHAZARD" in one-inch (minimum) letters and carry the Biological Hazard Symbol.

2. Dart Impact, F_{50}: 100 grams minimum.

3. Elmendorf Tear: 380 grams minimum (any direction).

4. Heavy metals: 100 ppm maximum combined total.

"REGULATED MEDICAL WASTE" means "INFECTIOUS WASTE".

"SHIPMENT" means that waste which is conveyed by a transporter between a generator and a designated facility or a subsequent transporter.

"SMALL INCINERATOR" means an incinerator which has a capacity equal to or less than 1000 pounds per hour.

"SMALL QUANTITY GENERATOR" means a private practice physician, dentist, veterinarian and any other generator of infectious waste in which three or fewer professionals are in the practice and generates less than 50 pounds per month; or a generator who can demonstrate that their facility generates less than 50 pounds per month of infectious waste.

"STORAGE AREA" means an area designated for the holding of waste for a temporary period, at the end of which time the waste is treated, disposed of, or stored elsewhere.

"TEST MICROORGANISMS" means those microorganisms listed in Appendix A, Table B of Section 11, Part 1.

D. EXEMPTIONS

The following solid wastes are not to be managed as infectious wastes:

1. Soiled diapers and feminine hygiene items produced by a person not known to have an infectious disease;

2. Wastes contaminated only with organisms which are not pathogenic to humans, and which are managed in accordance with all applicable regulations of the U.S. Department

of Agriculture and the Delaware Department of Agriculture and Consumer Services and all other regulations governing this type of waste stream;

3. Food wastes which are pathogenic to humans only through direct ingestion;

4. Any infectious waste contaminated by, co-incinerated with, or mixed with hazardous, radioactive or toxic waste becomes a hazardous, radioactive or toxic waste and shall then be managed under the appropriate regulations governing those waste types (7 Del. C. Chapter 63, 7 Del. C. Chapter 80 and any applicable federal regulations);

5. Waste consisting of human anatomical remains, including human fetal remains, managed by a licensed funeral director;

6. Bed linen, instruments, equipment and other reusable items are not wastes until they are discarded. This part and these regulations apply only to wastes. The regulations do not include the sterilization for disinfection of items that are reused for their original purpose. Therefore, the method of sterilization or disinfection of items prior to reuse is not limited. When reusable items are no longer serviceable and are discarded, they become wastes and subject to these regulations at that time and must be sterilized by steam, incinerated, or otherwise rendered non-infectious;

7. Waste generated by Delaware households;

8. Ash from incineration of infectious waste once the incineration process has been completed;

9. Residues from treatment and destruction processes of infectious waste once the waste has been both treated and destroyed;

10. Samples of infectious waste transported off-site by EPA or State-designated enforcement personnel for enforcement purposes are excepted from the requirements of this part during the enforcement proceeding; and

11. Biological liquid wastes which are directly discharged into a permitted wastewater treatment system.

E. SMALL QUANTITY GENERATOR REQUIREMENTS

1. Generators of infectious waste who produce less than 50 pounds per month are considered to be Small Quantity Generators.

2. It is the responsibility of the Small Quantity Generator to arrange for proper waste disposal. A Small Quantity Generator shall contract the services of a permitted transporter of infectious waste, or render the waste non-infectious and non-recognizable using a process or equipment approved by the Department, prior to disposal.

3. Requirements to submit manifest tracking documents shall apply to either the Small Quantity Generator or the transporter contracted by the generator for disposal of the infectious waste. The transporter who consolidates and transports infectious waste may elect to complete a consolidated manifest for the Small Quantity Generators that he or she services. In this event, the transporter assumes responsibility for the MANIFEST REQUIREMENTS, Section 11, Part 1, P, of these Regulations, which would otherwise apply to the generators of the wastes.

4. Small Quantity Generators are exempt from the storage time requirements in Section H.5.c of this part as long as not more than 50 pounds of infectious waste are stored and so long as storage is protective of human health and the environment.

5. Small Quantity Generators are exempt from the requirement to file an annual report to the Department. However, they are responsible for maintaining records of infectious waste disposal for a period of at least three years. Documentation shall include:

   a. A description of how the waste was rendered non-infectious and non-recognizable, and

   b. Copies of receipts or manifests for wastes managed by a permitted transporter of infectious waste.

F. PERMIT REQUIREMENTS

1. All application requirements found in Section 4.A.2 through 4.A.11 shall be performed unless specifically exempted within this part of the regulations.

2. Any person required to have a permit for activities that will occur in the management of infectious waste shall apply for a permit in accordance with Section 4.F. of these regulations and the appropriate sections of the Delaware Regulations Governing the Control of Air Pollution. No activity shall occur prior to receipt of all permits required by the Department.

3. A new or revised operation plan for treatment, storage and/or disposal of infectious waste shall be submitted to the Department whenever there is an increase of more than 15 percent over a three calendar month average in the maximum quantity of infectious waste receiving treatment, storage or disposal per month by the facility or when changes are otherwise made in an existing operation plan.

G. PROHIBITIONS

1. Infectious waste may not be disposed at a sanitary landfill unless the waste has been rendered noninfectious and non-recognizable. (In the case of extracted teeth, sterilization followed by landfilling would be acceptable).

2. Compactors, grinders or similar devices may not be used by a generator to reduce the volume of infectious waste until after the waste has been rendered noninfectious, or unless the device is part of an approved treatment process which renders the waste non-infectious.

3. Infectious wastes shall not be sent to a recycling facility.

4. Waste consisting of human anatomical remains, including human fetal remains, may not be disposed of at sanitary landfills. The remains must be incinerated, cremated or interred in accordance with 24 Del. C. Chapter 31.

5. Trans-chutes shall not be used to transfer infectious waste between locations where it is contained.

H. PACKAGING, LABELING, AND STORAGE REQUIREMENTS

1. Responsibility for packaging and labeling.

The generator of infectious waste shall not submit for transport, storage, treatment or disposal any waste which is not packaged in accord with this part. As a bag or other container becomes full, it must be immediately sealed, packaged, labeled and managed as described in this part. Contractors or other agents may provide services to the generator, including packaging and labeling of infectious waste; however, no contract or other relationship shall relieve the generator of the responsibility for packaging and labeling the infectious waste as required by these regulations.

2. Packaging Requirements

All infectious waste shall be packaged as follows:

a. Infectious wastes, other than sharps:

(1) Waste shall be contained in two (one bag inside the other) RED BAGS. The bags shall be individually tied or sealed. As a bag or other container becomes full, it must be immediately sealed, packaged, labeled and managed as described in this part.

(2) All bags containing infectious waste shall be red in color. Waste contained in red bags shall be considered infectious waste and managed as infectious waste.

(3) Bags shall be sealed by lapping the gathered open end and binding with tape or closing device such that no liquid can leak.

(4) In addition to the plastic bag containers described in this section, all infectious wastes must be enclosed in a double-walled corrugated fiberboard box or equivalent rigid container before it is transported beyond the site of generation.

b. Sharps

Sharps shall be contained in leakproof, rigid, puncture-resistant containers that are tightly lidded. As soon as the first sharp is placed in an empty container, the container shall be labeled with the word "SHARPS", and the Biological Hazard Symbol.

3. Labeling requirements.

All infectious waste shall be labeled immediately after packaging. A label shall be securely attached to the outer layer of packaging and be clearly legible. The label may be a tag securely affixed to the package. Indelible ink shall be used to complete the information on the labels, and the labels shall be at least three inches by five inches in size.

a. The following information shall be included on label one:

(1) The name, address and business telephone number of the generator,
(2) "Infectious" or "Regulated Medical Waste" in large print,
(3) "Pathological Waste," if pathological waste is included in the contents, and
(4) The name, address and business telephone number of the hauler or other persons to whose control the infectious waste will be transferred.