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.

b. The following shall be included on label two: the Biological Hazard Symbol. The label shall be not less than three by five inches.

4. Infectious substances

All infectious substances that are transported must be packaged as described in 49 CFR 173.196, October 1, 1996, Edition, even when that transport is wholly within the boundaries of the State.

5. Storage of infectious waste

a. Infectious waste shall be contained in a manner that:

(1) Affords protection from vectors, rain and wind,
(2) Prevents the spread of infectious agents,
(3) Does not provide a breeding place or food source for insects or rodents, and
(4) Prevents the leakage of waste from the storage bag or container.

b. Infectious waste shall be placed in separate containers from other waste at the point of origin in the producing facility.

c. Infectious waste may not be stored at the waste producing facility for more than the following periods of time:

(1) Up to fourteen days at room temperature (18 to 28 degrees Celsius, 65 to 82 degrees Fahrenheit) or up to 45 days in a refrigerator (2 to 7 degrees Celsius, 36 to 44 degrees Fahrenheit) for all types of infectious waste, so long as it does not produce conditions that are offensive or harmful to facility personnel or the public welfare.

(2) Ninety days in a freezer (-20 to -18 degrees Celsius, -4 to -1 degrees Fahrenheit) not used for food or patient related items.

(3) Exemption. Sharps which are disposed in a container specifically designed for sharps and which is sealed so as to prevent leaks when it is full, are exempt from the time limit on storage.

d. A container used for the storage of infectious waste may not be reused unless one of the following applies:

(1) It has been decontaminated utilizing a Department-approved decontam-ination procedure; or

(2) The surface of the container has been protected from direct contact with infectious waste.

e. Reusable containers for infectious waste shall be thoroughly washed and decontaminated by a method approved by the Department of Health and Social Services or the Department each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners, bags or other devices removed with the waste. Approved methods of decontamination include, but are not limited to, agitation to remove visible soil combined with one of the following procedures:

(1) All parts of the container shall come in contact with hot water of at least 82 degrees C (180 degrees F) for a minimum of 15 seconds.

(2) All parts of the container shall come in contact with chemical sanitizer by rinsing with or immersion in one of the following for a minimum of 3 minutes:

(a) Hypochlorite solution (500 ppm available chlorine),
(b) Phenolic solution (500 ppm active agent),
(c) Iodophor solution (100 ppm available iodine), or
(d) Quaternary ammonium solution (400 ppm active agent).

(3) Reusable pails, drums, dumpsters or bins used for containment of infectious waste shall not be used for containment of waste to be disposed of as noninfectious waste or for other purposes except after being decontaminated by procedures as described in this paragraph.

f. Containment of infectious waste shall be in an area separate from other wastes. Areas used for the containment of infectious waste shall be secured so as to deny access to unauthorized persons and shall be marked with prominent warning signs and the biohazard symbol on, or adjacent to, the exterior of entry doors, gates or lids. Wording of warning signs shall be in English, "CAUTION -- INFECTIOUS WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT". Warning signs shall be readily legible during daylight from a distance of at least 25 feet.

I. MANAGEMENT OF SPILLS

Spill containment and cleanup kit. All infectious waste management facilities are required to keep a small containment and cleanup kit within one hundred feet of any area where infectious wastes are managed. The facility shall maintain and implement a plan that provides the means of decontamination of any person having had bodily contact with infectious waste while transporting the waste to the treatment or disposal site or while handling or disposing of the waste at the site.

J. CLOSURE REQUIREMENT

When a facility that has been used for infectious waste management is to cease operations involving infectious wastes, it shall be thoroughly cleaned and disinfected. All waste shall be disposed of in accord with these regulations, and items of equipment shall be disinfected. (Note: Due to the variability in the type of infectious waste facilities, the Department will specify individual closure requirements in the permit issued to the facility.)

K. METHODS OF TREATMENT AND DISPOSAL

1. All treatment of infectious waste must utilize a method that will render the waste non-infectious.

2. All pathological waste must be incinerated, cremated or interred in accordance with 24 Del. C. Chapter 31. Other disposal methods are not acceptable for this type of waste. This requirement does not prohibit the disposal of certain specified wastes in a permitted wastewater treatment system (see Section D.11 of this part).

L. RECORDKEEPING AND REPORTING REQUIREMENTS

All waste management or treatment facilities that manage infectious waste shall maintain, for a period of three years, the following records and assure that they are accurate and current:

1. A list containing the names of all individuals responsible for the management of infection control for the facility, their address, their phone numbers and the periods covering their assignment of this duty.

2. The date, persons involved and short description of events in each spill of infectious wastes.

3. A notebook or file containing the policies and procedures of the facilities for dealing with infectious wastes.

4. A log of all special training received by persons involved in the management of infectious waste.

5. A log of infectious waste generated at the site or received from off-site, including the amount, the date of generation, receipt dates, and the date of shipment.

6. Anyone that sterilizes or incinerates infectious waste shall maintain a log indicating the method of monitoring the waste as well as a verification that it has been rendered noninfectious.

7. The operator of a facility that incinerates infectious waste shall submit to the Department, at least annually during the life of the facility, a chemical analysis of composite samples of the ash residue. Parameters that are to be monitored will be specified in the permit.

M. EVIDENCE OF EFFECTIVENESS OF TREATMENT

1. Treatment of infectious waste must be conducted in a manner which:

   a. Eliminates the infectious potential of the waste. A treatment process eliminates the infectious potential of infectious waste if the owner or operator of a treatment unit demonstrates that an Initial Efficacy Test and Periodic Verification Test(s) have been completed successfully.

      (1) Successful completion of an Initial Efficacy Test is demonstrated by a 6-log reduction/kill of test microorganisms. For a thermal unit that maintains the integrity of container, a 6-log kill of indicator microorganism spores may be used as an alternative test.

      (2) Successful completion of a Periodic Verification Test is demonstrated by:

         (a) a 6-log kill of test microorganisms or indicator microorganism spores as provided in Subsection 11, Part 1, L.1.a; or

         (b) a minimum 3-log kill of indicator microorganism spores that have been correlated with a 6-log kill of test microorganism; or

         (c) an alternate method submitted to and approved by the Department.

b. Disposes treatment residues in accordance with these regulations.

c. Provides for quality assurance programs that must include, at a minimum, a written plan that:

(1) Designates responsibility to personnel.
(2) Describes parameters that must be monitored to insure effectiveness of the treatment process.
(3) Identifies monitoring devices.
(4) Ensures that monitoring devices are operating properly.
(5) Establishes appropriate ranges for operating parameters.
(6) Identifies Person(s) who shall collect and organize data for inclusion in operating records.
(7) Identifies Person(s) who shall evaluate any discrepancies or problems.
(8) Identifies Person(s) who shall propose actions to correct problems identified, and
(9) Identifies Person(s) who shall assess actions taken and document improvement.

d. Provides for periodic biological testing, where appropriate, that demonstrates proper treatment of the waste.

e. Provides for assurances that clearly demonstrate that infectious waste has been properly treated; and

f. Is in compliance with all federal, state and local laws and regulations pertaining to environmental protection.

2. Initial Efficacy Test.

a. The manufacturer, owner, or operator of a treatment unit shall conduct an Initial Efficacy Test, pursuant to Appendix A of this Section, for each model prior to its operation. If significant mechanical changes are made to a treatment unit, the Initial Efficacy Test must be repeated. The treatment units are considered to be the same model if they:

(1) Are manufactured by same company,
(2) Have the same company name, and
(3) Have no significant mechanical changes.

b. The Initial Efficacy Test shall be conducted using option 1, 2 or 3 as described in Appendix A of this Section, using the challenge loads listed in Table C of Appendix A, or by an equivalent procedure that meets the requirements of the Initial Efficacy Test and has been approved by the Department. If any of the challenge loads fails the Initial Efficacy Test, the operating conditions must be revised and the Initial Efficacy Test must be repeated for all challenge loads. The Initial Efficacy Test must also meet the requirements of this Section.

c. Composition of challenge loads

(1) For treatment units designed to treat all types of infectious wastes, all three types of challenge loads must be used in conducting the Initial Efficacy Test. The three (3) types of challenge loads represent infectious waste with a high moisture content, low moisture content and high organic content. The quantity of each challenge load must equal 100% of the maximum capacity of the treatment unit.

Each challenge load must consist of a minimum 5% (by weight) of each of the following categories: blood/broth cultures, fibers, metals, sharps, plastics, pathological waste, glass, non-woven fibers, and bottles of liquids. Table C of Appendix A contains the moisture and organic content requirements that must be met in each type of challenge load.

(2) For treatment units designed to treat select categories of infectious waste (e. g., sharps treatment unit), modification in the composition of the challenge load(s) may be used if approved by the Department in writing.

d. The Initial Efficacy Test must be conducted under the same operating conditions under which the treatment unit operates on a day-to-day basis. The feed rate for the treatment unit must remain constant throughout the Initial Efficacy Test. This feed rate must never be exceeded during the operation of the treatment unit.

e. The Initial Efficacy Test must be performed so that:

(1) Each container of the test microorganisms and/or indicator microorganism spores is placed in the load to simulate the worst case scenario (i. e., that part of load that is the most difficult to treat). For example, the worst case scenario for an autoclave would be to place the container(s) of test microorganisms and/or indicator microorganism spores within a sharps container that must in turn be deposited in a plastic biohazard bag that is then located centrally within the challenge loads.

(2) Test microorganisms and/or indicator microorganisms must be cultured and enumerated in accordance with instructions provided by the supplier of microorganisms and Standard Methods for the Examination of Water and Wastewater.

f. A Document of Initial Efficacy Test must be retained in the treatment facility, and made available during normal business hours for inspection and photocopying by an authorized representative of the Department. The Document of Initial Efficacy Test must include at the minimum:

(1) A detailed description of the test procedures used, including all test data generated, with descriptions of data handling, and interpretation of final test results.

(2) A detailed description and verification of the operating parameters (e. g., temperature, pressure, retention times, chemical concentrations, irradiation dose, and feed rates).

(3) A description of quality assurance/quality control procedures and practices for the culture, storage and preparation of test and/or indicator microorganisms (including, but not limited to, organism history, source, stock culture maintenance, and enumeration procedures). The purity of the test microorganisms and/or indicator microorganism spores must be certified by a commercial or clinical laboratory.

3. Periodic Verification Test(s)

a. The effectiveness of the treatment unit shall be verified by conducting Periodic Verification Test(s) which must be carried out in accordance with this Subsection.

b. Periodic Verification Test(s) must be conducted quarterly or more frequently if required by the permit or recommended by the manufacturer.

c. The manufacturer, owner, or operator of a treatment unit must perform Periodic Verification Test(s) that satisfy at least one (1) of the following:

(1) Passing the Initial Efficacy Test by using option 1, 2 or 3 of appendix A of this part (whichever is applicable). The three challenge loads described in Appendix A, Table C, do not need to be used. The test microorganism or indicator microorganisms must be placed in a representative load in accordance with Subsection 11, Part 1, L.2.e.(1). For example, an autoclave may use option 3 (e. g., demonstrate at a minimum the destruction of one million *Bacillus stearothermophilus* spores) to meet the Periodic Verification Test requirement. In the case of an incinerator a stainless steel pipe with threaded ends and removable caps lined with ceramic insulation may be used to contain a glass culture vial with a *Bacillus subtilis* spores strip. The pipe with the spore strips may be placed in the load of infectious waste for the Periodic Verification Test. After the treatment, the pipe with the spore strips may be recovered and the spores may be cultured to assess whether, at a minimum, one million spores have been destroyed to meet the Periodic Verification Test(s) requirement.

(2) Correlating the log kill (L) of the test microorganisms in the Initial Efficacy Test to an equivalent log kill (T) of indicator microorganism spores in accordance with Appendix B. The equivalent log kill (T) of indicator microorganism spores must be used for all subsequent Periodic Verification Tests. The correlation must be done with three challenge loads identified in Table C of Appendix A (See Subsection 11, Part 1, L.3.d below for further requirements).

(3) Submitting to and obtaining written approval by the Department for a procedure that is equivalent to Subsection 11, Part 1, L.3.c.(1) and (2). Examples of alternatives include, but are not limited to, use of another indicator microorganism, or measurement of disinfectant concentrations in the treated residue. For incinerators only, an example of an alternative is visually inspecting the ash from each load of treated infectious waste to ensure that all infectious waste within the load is completely combusted. The approval of an alternative by the Department may require more frequent testing and/or monitoring of the treatment unit.

d. If correlation is being used for the Periodic Verification Test, (i. e., the correlation of log kill (L) of the test microorganisms with equivalent log kill (T) of the indicator microorganism spores) the following procedures apply:

(1) At a minimum, an initial population of one million indicator microorganism spores per gram of waste solids in each challenge load must be used.

(2) The fraction of surviving indicator microorganism spores that correlates to a log kill (L) of six (6) for each test microorganism must be used for future Periodic Verification Test(s). [For example, if a log kill (L) of four (4) for the indicator microorganism spores per gram of waste solids is achieved during this demonstration, then a population of 10,000 of indicator microorganism spores must be used in future Periodic Verification Test(s).] Challenge loads described in Appendix A, Table C, do not need to be used. The test microorganism or

indicator microorganism spores must be placed in a representative load in accordance with Subsection 11, Part 1, L.2.e.(1).

(3) An equivalent log kill (T) of at least three (3) for the indicator microorganism spores must be achieved to ensure that all test microorganisms are destroyed.

(4) Test microorganisms and/or indicator microorganism spores must be cultured and enumerated in accordance with instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater.

(5) The Periodic Verification Test and Initial Efficacy Test may be run concurrently to verify the correlation.

e. If a load of infectious waste fails a Periodic Verification Test, the Periodic Verification Test(s) must be repeated. The operator shall implement the quality assurance program and contact the manufacturer. If applicable, identify and correct the exact problem(s) until the unit can eliminate the infectious potential of the infectious waste. If the operating parameters are altered another Initial Efficacy Test must be performed to demonstrate the effectiveness of the unit and, if applicable, another Periodic Verification Test correlation, pursuant to Subsection 11, Part 1, L.3.c must be repeated. Loads of infectious waste that were processed prior to receiving the results showing a failure of Periodic Verification Test are considered treated. A second Periodic Verification Test must be run immediately after the first Periodic Verification Test indicates failure. The second Periodic Verification Test is to determine whether or not the treatment unit is eliminating the infectious potential of the waste. After the second Periodic Verification Test shows a failure of the treatment unit, any waste processed after the first detection of failure is considered infectious waste and must be managed accordingly.

f. Results of the Periodic Verification Test(s) must be received, verified and made available for inspection by the Department within 2 weeks of when the test was conducted. When a Periodic Verification Test is used to confirm the failure of a treatment unit, the results of the Periodic Verification Test(s) must be made available in accordance with the requirements of subsection h below.

g. A Document of Correlating Periodic Verification Demonstration must be prepared by and retained for at least three (3) years at the treatment facility during normal business hours for inspection by the Department. The Document of Periodic Verification Demonstration must include, at a minimum:

(1) A detailed description of the test procedures used and the correlation between the log kill (L) of the test microorganisms and the equivalent log kill (T) of the indicator microorganism spores. An evaluation of the test results must include all test data generated, a description of data handling, and a presentation and interpretation of test results.

(2) A detailed description and verification of the operating parameters (e. g., temperature, pressure, retention times, chemical concentrations, irradiation dose, and feed rates).

(3) A description of quality assurance/quality control procedures and practices for the culture, storage and preparation of test and/or indicator microorganisms

(including, but not limited to, organism history, source, stock culture maintenance, and enumeration procedures). The purity of the test microorganisms and/or indicator microorganism spores must be certified by a commercial or clinical laboratory.

h. Records of Periodic Verification Test(s) must be prepared and retained for at least three (3) years at the treatment facility, and made available at the treatment facility during normal business hours for inspection by the Department. These records will include, at the minimum:

(1) The date(s) on which the Periodic Verification Test(s) were performed.
(2) Operating parameters (e. g., temperature, pressure, retention times, chemical concentrations, irradiation dose and feed rates).
(3) Test protocols.
(4) Evaluation of test results.
(5) The name(s), date, signature(s) and title(s) of Person(s) conducting the Periodic Verification Test(s).

i. Periodic Verification Test(s) must be conducted under the same operating conditions under which the treatment unit operates on day-to-day basis. The feed rate for the treatment unit is the maximum feed rate at which the unit operates on day-to-day basis. The feed rate must remain constant throughout the Periodic Verification Test(s). This feed rate must never be exceeded during the operation of the treatment unit.

N. TRANSPORTATION

All transporters of infectious waste must be in compliance with all applicable federal and state regulations and codes.

1. Temperature Control and Storage Period

The transporter must deliver infectious waste to a disposal facility within 15 days from collection from the generation facility.

a. Infectious waste shall be transported in a manner that:

(1) Affords protection from vectors, rain and wind,
(2) Prevents the spread of infectious agents,
(3) Does not provide a breeding place or food source for vectors, and
(4) Prevents leakage of waste from the storage bags or other containers.

b. Infectious waste shall be transported to off-site processing or disposal facilities in a manner consistent with these regulations.

c. Motor Vehicles for transporting infectious waste shall be noncompaction type vehicles.

Surfaces of vehicles that have been in direct physical contact with infectious waste, because of a leak in a container or because of some other reason, shall be decontaminated as soon as possible after unloading. Surfaces of vehicles that have not been in direct physical contact with infectious waste shall be decontaminated weekly.

2. Packaging, Labeling and Placards

   a. No person shall transport or receive for transport any infectious waste that is not packaged and labeled in accord with these regulations.

   b. Any vehicle holding infectious waste in transport shall have a warning sign in bold letters, a minimum of 4 inches in height and in a color that contrasts the color of the vehicle, that indicates the cargo is infectious waste.

   c. Vehicle access door labeling:

      (1) Transporters in interstate commerce must comply with one of the following labeling options:

         (a) The access doors to the cargo area of the vehicle must meet the requirement for intrastate transporters of infectious waste, as described in Section N.2.c.(2) of this part; or

         (b) The access doors to the cargo area of the vehicle must comply with the labeling requirements of the state of origin of the infectious waste or the labeling requirements of the state of destination of the infectious waste. Examples of the labeling must be submitted to and approved by the Department prior to transport of the infectious waste through Delaware.

      (2) Transporters in intrastate commerce: The access doors to the cargo area of the vehicle must bear a sign with the words INFECTIOUS WASTE in bold, four inch letters. Such sign must be easily readable from a distance of 25 feet. The access doors to the cargo area of the vehicle must additionally bear a sign with the universal biological hazard symbol with minimum symbol dimension of six inches, and with the word BIOHAZARD in bold letters at least one inch in height. The symbol must be easily recognizable from a distance of 25 feet.

3. Management of Spills of Infectious Waste

   a. Spill containment and cleanup kit.

      All infectious waste transportation vehicles are required to keep within the vehicle the containment and cleanup kit specified in the permit. The vehicle shall be equipped with a written plan, approved by the Department, that provides the means of decontamination of a release of infectious waste while transporting the waste to the treatment or disposal site or while handling the waste at the site. The driver shall be trained by the employer to implement this plan.

   b. As required in 7 Del. C. Chapter 60, the Department is to be notified immediately of all spills.

4. Loading and Unloading

   Persons manually loading or unloading containers of infectious waste on or from transport vehicles shall wear protective gloves or clothing, as appropriate.

O. STERILIZATION

1. Application

The requirements of this part apply to all persons that steam sterilize infectious waste.

2. Performance Standards

All persons that steam sterilize infectious waste shall maintain the following level of operational performance at all times:

a. Operational temperature and detention.

Whenever infectious wastes are treated in a steam sterilizer, all the waste shall be subjected to a temperature of not less than 250 degrees Fahrenheit for 90 minutes at 15 pounds per square inch of gauge pressure or not less than 272 degrees Fahrenheit for 45 minutes at 27 pounds per square inch of gauge pressure. Other combinations of operational temperatures, pressure and time may be used if the installed equipment has been proved to achieve a reliable and complete kill of all microorganisms in waste at capacity. Complete and thorough testing shall be fully documented, including tests of the capacity of kill B. stearothermophilus.

b. Operational controls and records.

(1) Each package of waste to be steam sterilized shall have autoclave tape attached that will indicate if the sterilization temperature has been reached and waste will not be considered satisfactorily sterilized if the indicator fails to indicate that the temperature was reached during the process.

(2) Steam sterilization units shall be evaluated for effectiveness with spores of B. stearothermophilus no less than once every 40 hours of operation or once per month, whichever is more often.

(3) A log shall be kept at each sterilization unit that is complete for the proceeding three year period. The log shall record the date, time, temperature, pressure, type of waste, type of container(s), closure on container(s), pattern of loading, water content, operator of each usage; the type and approximate amount of waste treated; the post-sterilization reading of the temperature sensitive tape; the dates and results of calibration; and the results of effectiveness testing with B. stearothermophilus.

(4) Infectious waste shall not be compacted or subjected to violent mechanical stress before sterilization; however, after it is fully sterilized it may be compacted in a closed container.

3. Compliance with Other Parts of these Regulations

In general, sterilizer facilities shall comply with all other parts of these regulations. The site of the sterilizer facility is a storage facility and must comply with those regulations. Spills or the opening in an emergency of any infectious waste package, shall comply with the regulations pertaining to spills.

4. Off-Site Operations

   Any person who operates off-site facilities for the sterilization of infectious waste shall operate those facilities in compliance with a plan approved by the Department. The plan shall address in detail practices, procedures and precautions in the unloading, preparation and sterilizer loading of the waste.

P. MANIFEST REQUIREMENTS

1. A generator of infectious waste shall complete a manifest before shipping, or causing the shipment of, infectious waste off site. The manifest shall consist of a multicopy form provided by the Department or equivalent approved in writing by the Department.

2. No person shall accept custody of infectious waste unless the waste is packaged in accordance with the requirements of Section H of this part and is accompanied by a properly completed manifest which complies with the requirements of Section P of this part.. Upon accepting custody of infectious waste, the transporter shall sign and date the manifest. After the manifest has been signed and dated by both the generator and the transporter, the generator shall retain one copy of the form. The transporter shall keep the remaining four copies until the waste is delivered to the infectious waste facility.

3. The operator of an infectious waste management facility may accept custody of infectious waste only if the waste is accompanied by a manifest which complies with the requirements of Section P of this part. Upon accepting the waste, the operator of the infectious waste management facility shall sign and date the manifest, give one copy to the transporter, and keep the remaining three copies. The operator shall:

   a. Sign and date the remaining three copies of the manifest certifying that the waste will be treated and/or handled in accordance with all applicable regulations and facility permits.

      When multiple consignments are received and disposed as a batch, a cover letter with a list of manifest numbers, date received, date rendered non-infectious, certification of disposal, signature and date may be substituted for individual certification on each manifest. The cover letter must be mailed to the State with manifests attached. The generator copy of these manifests may use a date and signature stamp in lieu of original signature.

   b. Send one copy of the manifest to the generator no later than fifteen calendar days from the date on which the waste was treated or disposed of;

   c. Send one copy of the manifest to the Department; and

   d. Keep the remaining copy.

4. Any generator of infectious waste who does not receive a copy of the manifest signed by the operator of the infectious waste management facility within fifteen calendar days of the date of shipment shall immediately contact the transporter and the facility to determine the status of the shipment. If, within twenty days of the date of shipment, the generator still has not received a signed copy of the manifest from the infectious waste management facility, the generator shall notify the Department in writing. The notification shall include a legible copy of the manifest as signed by the generator and transporter, a

description of the efforts made by the generator to locate the shipment, and the results of those efforts.

5. Copies of the manifest shall be retained by all parties for at least three years.

6. Each generator of infectious waste shall submit an annual report on a form provided by the Department, summarizing the information from all manifests completed during the preceding calendar year. This report shall be submitted to the Department within ninety days after the end of the calendar year. The information contained in the report shall include, but not be limited to, the following:

   a. A description of infectious waste generated and transported off site for treatment and disposal;

   b. The total weight of infectious waste generated and transported off site for treatment and disposal;

   c. The names and addresses of persons engaged by the generator to transport infectious waste off site;

   d. The names and locations of the infectious waste management facilities with which the generator contracted for the treatment and/or disposal of infectious waste.

7. Each transporter of infectious waste shall submit an annual report on a form provided by the Department, summarizing the information from all manifests completed during the preceding calendar year. This report shall be submitted to the Department within ninety days after the end of the calendar year. The information contained in the report shall include, but not be limited to the following:

   a. A description of infectious waste transported off site for treatment and disposal;

   b. The total weight of infectious waste transported off site for treatment and disposal;

   c. The names and addresses of generators contracting with the transporter to transport infectious waste off site.

   d. The names and locations of the infectious waste management facilities where the transporter deposited the infectious waste for treatment and /or disposal.

SECTION 11, PART 1

APPENDIX A

Initial Efficacy Test Procedures

The manufacturer, owner, or operator of an infectious waste treatment unit must carry out an Initial Efficacy Test by using Option 1, 2, or, 3 below, as appropriate for the type of unit, or other procedures, if approved in advance by the Department.

1. Option 1

This option consists of two (2) Phases:

a. Phase 1: Determining the dilution of each test microorganism from the treatment unit for each challenge load (Types A through C) identified in Table C of this Appendix.

(1) Prepare and sterilize by autoclaving two (2) challenge loads of Type A as identified in Table C. Reserve one challenge load for Phase 2.

(2) Process each test microorganism in separate runs through the treatment unit. Prior to each run, determine the number of viable test microorganisms in each container, in accordance with applicable manufacturer's recommendations and Standard Methods for the Examination of Water and Wastewater.

(3) Process each challenge load within thirty (30) minutes after introducing the container of test microorganism into the treatment unit. The container of test microorganisms and the challenge loads must be processed together without the physical and/or chemical agents designed to kill the test microorganisms. For example, in treatment units that use chemical disinfectant(s), an equal volume of liquid (e. g., sterile saline solution (0.9%, volume/volume), phosphate buffer solution, or tap water) must be substituted in place of the chemical disinfectant(s).

(4) Obtain at least five (5) representative grab samples from the processed residue of each challenge load in accordance with Test Methods for Evaluating Solid Waste Physical/Chemical Methods (SW-846). The number of viable test microorganisms in each grab sample must be determined in accordance with applicable manufacturer's recommendations and Standard Methods for the Examination of Water and Wastewater.

(5) Calculate the effect of dilution for the treatment unit as follows:

$SA = \text{Log } N_0A - \text{Log}N1A$: where $\text{Log } N1A \geq 6$

where: SA is the log of the number of viable test microorganisms (CFU/gram of waste solids) that were not recovered after processing challenge load Type A.

N_0A is the number of viable test microorganisms (CFU/gram of waste solids) introduced into the treatment unit for challenge load Type A.

N1A is the number of viable test microorganisms (CFU/gram of waste solids) remaining in the processed residue for challenge load Type A.

If Log N1A is less than 6, then the number of viable test microorganisms introduced into the treatment unit must be increased and steps (1) through (6) in Phase 1 must be repeated until LogN1A is ³ 6. N_0A is the inoculum size for challenge load Type A in Phase 2 below.

(6) Repeat steps (1) through (5) in Phase 1 for challenge loads of infectious waste for Type B and C identified in Table C of this Appendix to determine the effect of dilution (SB and SC respectively).

b. Phase 2: Determining the log kill of each test microorganism in each challenge load (Type A through C) identified in Table C of this Appendix.

(1) Using the inoculum size (N_0A) determined in Phase 1 above, repeat Phase 1 steps (1) through (5) under the same operating parameters, except that the physical and/or chemical agents designed to kill the test microorganisms must be used.

(2) Calculate the effectiveness of the treatment unit by subtracting the log of viable cells after the treatment from the log of the viable cells introduced into the treatment unit as inoculum, as follows:

LA = Log N_0A - SA - Log N2A ³ 6

where: LA is the log kill of the test microorganisms (CFU/gram of waste solids) after treatment in the challenge load Type A.

N_0A is the number of viable test microorganisms (CFU/gram of waste solids) introduced into the treatment unit as the inoculum for challenge load Type A as determined in Phase 1 above.

SA is the log of the number of viable test microorganisms (CFU/gram of waste solids) that were not recovered after processing challenge load Type A in Phase 1 above.

N2A is the log of the number of viable test microorganisms (CFU/gram of waste solids) remaining in the treated residue for challenge load Type A.

(3) Repeat steps (1) and (2) in Phase 2 for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC respectively).

2. Option 2:

a. Place one microbiological indicator assay containing one of the test microorganisms at numbers greater than one million in a sealed container that remains intact during the treatment. The inside diameter of the container must be no larger than required to contain the assay vial(s). The vial(s) must contain the test microorganisms.

b. Place the container of test microorganisms within a Type A challenge load as identified in Table C of this Appendix.

c. Process the load.

d. Calculate the effectiveness of the treatment unit by subtracting the log of viable cells after treatment from log of viable cells introduced into the treatment unit as inoculum, as follows:

$LA = \text{Log } N_0 - \text{Log } N2A^{3\,6}$

where: LA is the log kill of the test microorganisms (CFU/gram of waste solids) after treatment in the challenge load Type A.

N_0 is the number of viable test microorganisms (CFU/gram of waste solids) introduced into the treatment unit as the inoculum.

N2A is the log of the number of viable test microorganisms (CFU/gram of waste solids) remaining in the treated residue for challenge load Type A.

e. Repeat steps a through d in this option for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC respectively).

3. Option 3:

a. Place one microbiological indicator assay containing at least one million spores of one of the indicator microorganisms listed in Table B of this Appendix, in a sealed container that remains intact during treatment. The inside diameter of the container must be no larger than required to contain the assay vial(s).

b. Place the container of the indicator microorganisms within a Type A challenge load as identified in Table C of this Appendix.

c. Process the load.

d. Calculate the effectiveness of the treatment unit by subtracting the log of viable cells after treatment from log of viable cells introduced into the treatment unit as inoculum, as follows:

$LA = \text{Log } N_0 - \text{Log } N2A^{36}$

where: LA is the log kill of the test microorganisms (CFU/gram of waste solids) after treatment in challenge load Type A.

N_0 is the number of viable indicator microorganisms (CFU/gram of waste solids) introduced into the treatment unit as the inoculum.

N2A is the log of the number of viable test microorganisms (CFU/gram of waste solids) remaining in the treated residue for challenge load Type A.

e. Repeat steps a through d in this option for challenge loads Types B and C identified in Table C of this Appendix to determine the effectiveness of the treatment unit (LB and LC, respectively).

APPENDIX A: TABLES

TABLE A: Test Microorganisms

a. Staphylococcus aureus (ATCC 6538)

b. Pseudomonas aeruginosa (ATCC 15442)

c. Candida albicans (ATCC 18804)

d. Trichophyton mentagrophytes (ATCC 9533)

e. MS-2 Bacteriophage (ATCC 15597-B1)

f. Mycobacterium smegmatis (ATCC 14468)

TABLE B: Indicator Microorganisms

a. Bacillus subtilis (ATCC 19659)

b. Bacillus stearothermophilus (ATCC 7953)

c. Bacillus pumilus (ATCC 27142)

TABLE C: Challenge Loads

This Table identifies the three types of challenge loads of infectious waste that must be used as a part of Initial Efficacy Test and Periodic Verification Test(s).

COMPOSITION OF CHALLENGE LOADS % (w/w)

Type	A	B	C
Moisture	£5	³50	-----
Organic	---	----	³70

APPENDIX B

Correlating Periodic Verification Procedures

1. Use a certified microbiological indicator assay containing the test microorganisms and indicator microorganism spores.

2. Place the test microorganisms and indicator microorganism spores into sealed containers that remain intact during treatment.

3. Place a container of the test microorganisms and indicator microorganism spores in each challenge load (as described in Appendix A, Table C) to simulate the worst case scenario (i. e., that part of load that is the most difficult to treat). For example, the worst case scenario for an autoclave would be to place the container of test microorganisms and indicator microorganism spores within a sharp container that must in turn be deposited in a plastic biohazard bag that is then located centrally within the treatment unit.

4. Determine the effectiveness of the treatment unit by calculating the log kill (L) of the test microorganisms in accordance with Option 2 of Appendix A. The equivalent kill (T) of the indicator microorganism spores is calculated by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as inoculum as follows:

   $TA = \text{Log } N_0 - \text{Log } N2A^3 3$

   where: TA is the equivalent log kill of the viable indicator microorganisms (CFU/gram of waste solids) after treatment in the challenge load Type A.

   N_0 is the number of viable indicator microorganism spores (CFU/gram of waste solids) introduced into the treatment unit as the inoculum (^{3}6).

   N2A is the number of viable indicator microorganisms (CFU/gram of waste solids) remaining after treatment in challenge load Type A.

5. Repeat steps 1 through 4 for challenge loads Types B and C identified in Table C of Appendix A to determine the correlation between the log kill of the test microorganisms and equivalent kill of the indicator microorganism spores (LB and LC, respectively).