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.