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).