TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE M: BIOLOGICAL MATERIALS
CHAPTER I: POLLUTION CONTROL BOARD
SUBCHAPTER b: POTENTIALLY INFECTIOUS MEDICAL WASTES

PART 1422
DESIGN AND OPERATION OF FACILITIES

SUBPART A: GENERAL PROVISIONS

Section

SUBPART B: STORAGE OR TRANSFER OPERATIONS

Section

SUBPART C: TREATMENT FACILITIES

Section

Section

AUTHORITY: Implementing and authorized by Sections 56.2 and 27 of the Environmental Protection Act (Ill. Rev. Stat. 1991, ch. 111 1/2, pars. 1056.2 and 1027) [415 ILCS 5/56.2 and 27].

SOURCE: Adopted in R91-20, at 17 Ill. Reg. 9911, effective June 21, 1993.

SUBPART A: GENERAL PROVISIONS

Section 1422.101 Compliance Date

Persons subject to this Part shall comply with its requirements by June 21, 1993.

Section 1422.105 PIMW Permit Application Contents

An application for a permit for a PIMW treatment, storage or transfer operation must contain the information specified in this Section. If the applicant believes that the documentation or information required pursuant to any subsection of this Section is not applicable for reasons such as irrelevancy, the application must include the reasons in support of such belief.

a) Legal description of the site at which the facility is to be located.

b) Maps and floor plans showing the location of the facility, the facility boundary and the location of all units included in the facility.

c) Process flow diagrams or schematic drawings showing the flow of waste through the facility. The diagrams or drawings must show, but not be limited to, the locations of residuals, recycled streams, sample points, equipment and process monitoring devices. Equipment must be labeled on the process flow diagram to correspond to an equipment number.

d) Written description of the facility or facility operations with supporting documentation describing the procedures and plans that will be used at the facility to comply with the requirements of Parts 1420 through 1422 of this Subtitle and any other applicable Parts of 35 Ill. Adm. Code: Chapter 1. Such description must include, but not be limited to, the following information:

    1) The type of waste management units and the types and volumes of waste;

    2) The overall process to be used for treating or storing PIMW and the anticipated performance of the process;

3) In detail, the major activities at the facility, such as transfer, storing, screening, weighing, processing and treatment (including the number of units) of PIMW;

4) The operations for initial facility startup, daily startup and scheduled and unscheduled shutdowns;

5) The days and hours of operation;

6) The operating parameters for the treatment units;

7) The safety and monitoring equipment for the treatment units;

8) A cleaning and disinfection plan describing the daily cleanup procedures, including the methods to disinfect emptied reusable PIMW containers, transport vehicles, and facility surfaces and equipment contaminated with PIMW;

9) The methods to control: emissions of odors and aerosols generated, including all supporting design and engineering data; dust, noise, litter and vectors; and handling and storing;

10) The methods to treat, transfer, or dispose of residual wastes generated from the operation of the facility;

11) Adequacy of the utilities to operate the facility and to respond to emergency situations;

12) Numbers and duties of employees directly responsible for the operation of the site or facility; and

13) Location and type of security devices to prevent unauthorized access.

e) A waste screening plan that describes procedures to be used to identify and prevent the acceptance of unauthorized wastes.

f) Description of procedures to be used for inspection, contingency, recordkeeping and closure plans as required by this Part.

g) For a facility at which the owner or operator is required to conduct either Initial Efficacy Tests or Periodic Verification Tests, a written description of procedures to be used for recordkeeping, classifying residuals and collecting data for the Document of Initial Efficacy Demonstration and Correlating Periodic Verification Demonstration.

Section 1422.106 IMW Permit Application Certifications

An application for a permit for PIMW treatment, storage or transfer operation must contain the certifications specified in this Section.

a) The permit application must contain a certificate of ownership of the permit area or a copy of the lease and its duration. The lease must clearly specify that the owner authorizes the construction of a PIMW waste management facility on the leased premises. The owner or operator shall certify that the Agency will be notified 30 days prior to any changes in ownership or conditions in the lease affecting the permit area.

b) All permit applications must be signed by a duly authorized agent of the operator and the property owner, must be accompanied by an oath or affidavit attesting to the agent's authority to sign the application and must be notarized. The following persons are considered duly authorized agents of the operator and the property owner:

1) For corporations, a principal executive officer of at least the level of vice president;

2) For a sole proprietorship or partnership, a proprietor or general partner, respectively; and

3) For a municipality, state, federal or other public agency, by the head of the agency or ranking elected official.

c) All permit applications must contain the name, address and telephone number of the duly authorized agent of the operator and the property owner to whom all inquiries and correspondence must be addressed.

d) All designs presented in the application must be prepared by, or under the supervision of, a professional engineer. The professional engineer shall affix the name of the engineer, date of preparation, registration number, a statement attesting to the accuracy of the information and design and a professional seal to all designs.

e) The applicant must state whether the facility is a new regional pollution control facility, as defined in Section 3.32 of the Act, which is subject to the site location suitability approval requirements of Sections 39(c) and 39.2 of the Act. If such approval by a unit of local government is required, the application must identify the unit of local government with jurisdiction. The application must contain any approval issued by that unit of local government. If no approval has been granted, the application must describe the status of the approval request.

Section 1422.107 PIMW Permit Application Filing Requirements

a) All permit applications must be filed with the Agency, on forms as prescribed by the Agency. Hand delivered applications must be delivered during the Agency's normal business hours to the offices of the Permit Section. The Agency shall provide a dated, signed receipt of filing only if the applicant requests. The date of filing must be that recorded by the Agency, unless proven otherwise by a dated, signed receipt.

b) The permit application must be accompanied by all filing fees required pursuant to Section 5(f) of the Act.

SUBPART B: STORAGE OR TRANSFER OPERATIONS

Section 1422.110 Scope and Applicability

This Subpart applies to the owner or operator of a PIMW storage site or transfer station, collectively referred to as a "storage operation" in this Subpart.

Section 1422.111 Design and Operating Standards and Criteria

a) ANY PERSON WHO STORES PIMW PRIOR TO TREATMENT OR DISPOSAL ON-SITE OR TRANSPORT OFF-SITE MUST COMPLY WITH ALL OF THE FOLLOWING STORAGE REQUIREMENTS:

1) STORE THE PIMW IN A MANNER AND LOCATION THAT MAINTAINS THE INTEGRITY OF THE PACKAGING AND PROVIDES PROTECTION FROM WATER, RAIN, AND WIND.

2) MAINTAIN THE PIMW IN A NONPUTRESCENT STATE, USING REFRIGERATION WHEN NECESSARY.

3) LOCK THE OUTDOOR STORAGE AREAS CONTAINING PIMW TO PREVENT UNAUTHORIZED ACCESS.

4) LIMIT ACCESS TO ON-SITE STORAGE AREAS TO AUTHORIZED EMPLOYEES.

5) STORE THE PIMW IN A MANNER THAT AFFORDS PROTECTION FROM ANIMALS AND DOES NOT PROVIDE A BREEDING PLACE OR FOOD SOURCE FOR VECTORS. (Section 56.1(e)(2)(D)(i)-(v) of the Act)

6) PIMW packages must not be compacted or subjected to stress that compromises the integrity of the container.

7) Multiple generators in the same building may store their PIMW packages in a common storage area.

8) Reusable PIMW containers or facility equipment (e.g., carts, squeegees or shovels) which are visually contaminated with PIMW must be cleaned in a designated area in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.

9) Residues from cleaning a PIMW contaminated container, equipment or work surface are regulated under this Subtitle, except when directly discharged into a sanitary or combined sewer in accordance with 35 Ill. Adm. Code: Subtitle C.

BOARD NOTE: Interested persons should note that discharges to sewer systems can also be regulated by units of local government.

10) Copies of all PIMW manifests required by 35 Ill. Adm. Code 1420.105 of this Subtitle must be retained by and kept at the storage operation for three (3) years and must be made available at the storage operation during normal business hours for inspection and photocopying by the Agency. The retention period for PIMW manifests is extended automatically during the course of any unresolved enforcement action regarding the storage operation or as requested in writing by the Agency.

11) Upon closure of a storage operation, the owner or operator shall clean the area, equipment and structures in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.

b) In addition to the requirements listed in subsection (a) of this Section, storage operations required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle must also comply with the following requirements that the Agency shall review during the permitting process:

1) Storage operations shall weigh in pounds the amount of PIMW received, unless previously weighed by the transporter. PIMW must be weighed with a device for which certification has been obtained under the Weights and Measures Act (Ill. Rev. Stat. 1991, ch. 147, pars. 101 et seq.) [225 ILCS 470].

2) PIMW packages must be stored in designated areas so as not to contaminate other waste or materials.

3) Cardboard packages must be stored in an enclosed area at an elevation above that of the floor.

4) PIMW must be stored on a surface that allows drainage and collection of liquids and that minimizes exposure to workers and the public.

5) Adequate aisle space, as specified in the permit, must be maintained between packages to allow inspection of at least one side of each package. Packages must be stacked so that labels are readable. A vehicle containing PIMW is exempt from the above aisle space requirement:

   A) When loading or unloading a vehicle; or

   B) When a fully-loaded vehicle is on a site. Either exemption, or both exemptions, must not exceed five (5) calendar days.

6) Material handling equipment must be designed so as to maintain the integrity of the package.

7) Signs identifying the storage operation must be prominently displayed at the points of access to the secured storage area. Signs must be marked in lettering that is readable at a minimum distance of five (5) feet. At a minimum, the signs must display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421.Illustration A and the word "biohazard".

8) Personnel training must be provided to all staff prior to the handling of PIMW. Annual personnel training must include, at a minimum, a thorough explanation of the operating procedures to be taken during normal and emergency situations. The owner or operator shall keep records verifying training of personnel.

9) Storage operations must have a written contingency plan and the applicable sections must be implemented in the event of a discharge or personal injury. The contingency plan must describe the actions that personnel shall take in response to emergency situations such as, but not limited to, personal injury, discharges of PIMW, rupture of plastic bags and equipment failure. This contingency plan must, at a minimum, include a list of all emergency equipment at the storage operation, an up-to-date list of names, addresses and phone numbers (office and home) of all persons qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue, repackaging of PIMW and alternate arrangements for PIMW storage and transfer. A copy of the contingency plan must be maintained at the storage operation. Emergency phone numbers

and a brief description of the emergency procedures must be posted at the storage operation.

10) The owner or operator shall keep a written operating record at the storage operation. At a minimum, the following information must be recorded and maintained in the operating record:

A) Quantities and disposition of PIMW stored or transferred;

B) Date and time the PIMW arrived at the permitted storage operation site;

C) Date and time the PIMW left the storage operation;

D) Waste stream permit number (authorization number), if applicable, issued by the Agency;

E) Generator name(s), location(s) and if applicable, the generator identification number(s) issued by the Agency for each PIMW load received at the storage operation;

F) Temperature(s) the PIMW load was maintained at the storage operation;

G) Destination of packages, which must include at a minimum the name of the receiving facility, the location of the receiving facility, the identification number of the receiving facility issued by the Agency (if applicable) and the disposition (i.e., storage, transfer, treatment or disposal); and

H) In a separate log, the date, time, nature and extent of all discharges and personal injuries and the date, time, nature and result of any response(s) taken.

11) The records required by subsections (b)(8) and (10) of this Section must be retained by and kept at the storage operation and must be made available at the storage operation during normal business hours for inspection and photocopying by the Agency. These records must be kept until closure of the storage operation. The retention period is extended automatically during the course of any unresolved enforcement action regarding the storage operation or as requested in writing by the Agency.

12) Unless otherwise authorized by the Agency in the permit, PIMW must not be stored for more than:

A) Seventy-two (72) hours at the storage operation unless the surface temperature of the package is maintained at or below 45 degrees Fahrenheit, and

B) Thirty (30) days at the storage operation regardless of temperature.

13) At least sixty (60) days prior to closing a storage operation, the owner or operator shall notify the Agency of the planned closure. Within ninety (90) days after the date the final load of PIMW is received at the storage operation, the owner or operator shall certify to the Agency that final closure has been completed in accordance with the permit, the Act and all applicable regulations promulgated thereunder.

SUBPART C: TREATMENT FACILITIES

Section 1422.120 Scope and Applicability

This Subpart applies to the owner or operator of a facility in Illinois that is designed to treat PIMW to eliminate its infectious potential. This Subpart also applies to owners or operators of treatment facilities where the treated PIMW residual is disposed of in Illinois. For purposes of this Part, a facility or operation that is designed to treat PIMW to eliminate its infectious potential is referred to as a "treatment facility".

Section 1422.121 Treatment Facility Certification

No person shall cause or allow the disposal of any PIMW where the infectious potential has been eliminated by treatment unless the treatment facility certifies to the transporter, if other than the generator, and certifies to the landfill operator or receiving facility operator that the PIMW has been treated in accordance with this Part, and, if applicable, with all terms and conditions specified in its operating permit. Data to verify the efficacy of the treatment unit must be made available to the receiving facility upon request of the receiving facility. No person shall falsely certify that PIMW has been treated in accordance with this Part.

Section 1422.122 Design and Operating Standards

a) Treatment of PIMW must be conducted in a manner that:

1) ELIMINATES THE INFECTIOUS POTENTIAL OF THE WASTE. A treatment process eliminates the infectious potential of PIMW if the owner or operator of a treatment unit demonstrates that an Initial Efficacy Test and Periodic Verification Test have been completed successfully.

A) Successful completion of an Initial Efficacy Test must be demonstrated by a 6-log kill of test microorganisms. For a thermal unit that maintains the integrity of the container, a 6-log kill of indicator microorganism spores may be used as an alternative test. These demonstrations must be conducted in accordance with Section 1422.124.

B) Successful completion of a Periodic Verification Test must be demonstrated, in accordance with Section 1422.125, by:

i) a 6-log kill of test microorganisms or indicator microorganism spores as provided in subsection (a)(1)(A) above; or

ii) a minimum 3-log kill of indicator microorganism spores that has been correlated with a 6-log kill of test microorganisms; or

iii) an alternate method submitted to and approved in writing by the Agency.

2) PREVENTS THE COMPACTION AND RUPTURE OF CONTAINERS DURING HANDLING OPERATIONS, except when compaction or rupture is an integral part of the treatment process and the treatment process is conducted without discharge of PIMW to the environment;

3) DISPOSES OF TREATMENT RESIDUALS IN ACCORDANCE WITH THIS ACT AND REGULATIONS ADOPTED THEREUNDER;

4) PROVIDES FOR QUALITY ASSURANCE PROGRAMS that must include, at a minimum, a written plan that:

A) Designates responsibility to personnel;

B) Describes operating parameters that must be monitored to insure effectiveness of the treatment process;

C) Identifies monitoring devices;

D) Insures monitoring devices are operating properly;

E) Establishes appropriate ranges for all operating parameters;

F) Identifies the person(s) who shall collect and organize data for inclusion in the operating record;

G) Identifies the person(s) who shall evaluate any discrepancies or problems;

H) Identifies the person(s) who shall propose actions to correct any problems identified; and

I) Identifies the person(s) who shall assess actions taken and document improvement;

5) PROVIDES FOR PERIODIC TESTING USING BIOLOGICAL TESTING, WHERE APPROPRIATE, THAT DEMONSTRATE PROPER TREATMENT OF THE WASTE;

6) PROVIDES FOR ASSURANCES THAT CLEARLY DEMONSTRATE THAT POTENTIALLY INFECTIOUS MEDICAL WASTE HAS BEEN PROPERLY TREATED; and

7) IS IN COMPLIANCE WITH ALL FEDERAL AND STATE LAWS AND REGULATIONS PERTAINING TO ENVIRONMENTAL PROTECTION. (Section 56.2(a)(1)-(7) of the Act)

b) In addition to the requirements in subsection (a) of this Section:

1) Residues from cleaning a PIMW contaminated container, equipment or work surface are regulated under this Subtitle, except when directly discharged into a sanitary or combined sewer in accordance with 35 Ill. Adm. Code: Subtitle C.

BOARD NOTE: Interested persons should note that discharges to sewer systems can also be regulated by units of local government.

2) Ash resulting from the incineration of PIMW is an industrial process waste, as defined in Section 3.17 of the Act, and must be managed as a special waste in accordance with 35 Ill. Adm. Code 807 and 809.

3) Copies of PIMW manifests required by 35 Ill. Adm. Code 1420.105 of this Subtitle must be retained by and kept at the treatment facility for three (3) years and must be made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. The retention period for PIMW manifests is extended automatically during the course of any

unresolved enforcement action regarding the treatment facility or as requested in writing by the Agency.

4) COMMENCING MARCH 31, 1993, AND ANNUALLY THEREAFTER, EACH TREATMENT FACILITY FOR WHICH A PERMIT IS REQUIRED pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle and EACH FACILITY NOT REQUIRED TO HAVE A PERMIT pursuant to Section 1420.105 of this Subtitle THAT TREATS MORE THAN 50 POUNDS PER MONTH OF POTENTIALLY INFECTIOUS MEDICAL WASTE SHALL FILE A REPORT WITH THE AGENCY SPECIFYING THE QUANTITIES AND DISPOSITION OF POTENTIALLY INFECTIOUS MEDICAL WASTE TREATED DURING THE PREVIOUS CALENDAR YEAR. SUCH REPORTS SHALL BE ON FORMS PRESCRIBED AND PROVIDED BY THE AGENCY. (Section 56.3 of the Act)

5) Upon closure of a treatment facility, the owner or operator shall clean the area, equipment and structures in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.

c) In addition to the requirements listed in subsections (a) and (b) of this Section, owners or operators of treatment facilities required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle shall also comply with the following requirements that the Agency shall review during the permitting process:

1) Amounts of PIMW received must be weighed in pounds with a device for which certification has been obtained under the Weights and Measures Act (Ill. Rev. Stat. 1991, ch. 147, pars. 101 et seq.). [225 ILCS 470]

2) Signs identifying that the facility treats PIMW must be prominently displayed at the points of access to the treatment area. Signs must be marked in lettering that is readable at a minimum distance of five (5) feet. At a minimum, the signs must display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421.Illustration A and the word "biohazard".

3) Personnel training must be provided to all staff prior to the handling of PIMW. Annual personnel training must include, at a minimum, a thorough explanation of the operating procedures to be taken during normal and emergency situations. The owner or operator shall keep records verifying training of personnel.

4) Treatment facilities must have a written contingency plan and the applicable sections must be implemented in the event of a discharge, equipment failure or personal injury. The contingency plan must describe the actions that personnel shall take in response to emergency situations such as, but not limited to, personal injury, discharges of PIMW and equipment failure. This contingency plan must, at a minimum, include a list of all emergency equipment at the treatment facility, an up-to-date list of names, addresses and phone numbers (office and home) of all persons qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue and alternative arrangements for PIMW treatment. A copy of the contingency plan must be maintained at the treatment facility. Emergency phone numbers and a brief description of the emergency procedures must be posted at the treatment facility.

5) The owner or operator shall keep a written operating record at the treatment facility. At a minimum, the following information must be recorded and maintained in the operating record:

A) Quantities and disposition of PIMW treated;

B) Date and time the PIMW arrived at the permitted PIMW site;

C) Date and time the PIMW was treated;

D) The operating parameters of the treatment unit (e.g., temperature, pressure, residence time, chemical concentration, irradiation dose);

E) Date and time the PIMW left the treatment facility;

F) Generator name(s), location(s) and, if applicable, the generator identification number(s) issued by the Agency for each PIMW load received at the treatment facility;

G) The destination of the treated waste which must include, at a minimum, the name of the receiving facility, the location of the receiving facility, the identification number of the receiving facility issued by the Agency (if applicable) and the disposition; and

H) In a separate log, the date, time, nature and extent of all discharges and personal injuries and the date, time, nature and result of any response(s) taken.

6) The records required by subsections (c)(3) and (c)(5) of this Section must be retained by and kept at the treatment facility and must be made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. These records must be kept until closure of the treatment facility. The retention period is extended automatically during the course of any unresolved enforcement action regarding the treatment facility or as requested in writing by the Agency.

7) At least sixty (60) days prior to closing a treatment facility, the owner or operator shall notify the Agency of the planned closure. Within ninety (90) days after the date the final load of PIMW is received at the treatment facility, the owner or operator shall certify to the Agency that final closure has been completed in accordance with the permit, the Act and all applicable regulations promulgated thereunder.

Section 1422.123 Treatment Units

a) A treatment unit must be:

1) Designed and operated to eliminate the infectious potential of PIMW as demonstrated by the Initial Efficacy Test and Periodic Verification Tests, pursuant to Sections 1422.124 and 1422.125 of this Part;

2) Operated according to the manufacturer's instructions, if it is a commercially available unit;

3) Operated under the same conditions that have been used to demonstrate that the infectious potential was eliminated in accordance with this Part;

4) Operated with a PIMW feed rate not to exceed that which was used to demonstrate that the infectious potential was eliminated; and

5) Designed and operated to limit the emission of microorganisms into the air.

b) A treatment unit may be used by the owner or operator of a treatment facility not required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle, if the requirements of subsection (b)(1) or (2) below are met.

1) The treatment unit meets the standards of subsections (a)(1)-(5) of this Section, and:

A) The treatment unit utilizes a thermal, chemical or irradiation treatment, as defined in 35 Ill. Adm. Code 1420.102 of this Subtitle; or

B) The owner or operator maintains a copy of the Initial Efficacy Test results for the treatment unit. In addition, the owner or operator shall conduct Periodic Verification Tests in accordance with the manufacturer's instructions and Section 1422.125. Test results shall be retained and made available for inspection in accordance with Section 1422.125(d) and (g); and

C) The owner or operator retains any notification from the manufacturer of the permitted commercially available treatment unit of a permit modification.

2) The Board has granted the owner's or operator's petition for an adjusted standard pursuant to 35 Ill. Adm. Code 106.Subpart G or a site-specific rulemaking pursuant to 35 Ill. Adm. Code 102. The petition must include a demonstration that the treatment unit meets the standards of subsection (a)(1)-(5) of this Section.

c) For an autoclave, incinerator or ethylene oxide unit installed or operated prior to the effective date of these regulations, an Initial Efficacy Test is not required. The first Periodic Verification Test must be performed within three (3) months of the effective date of these regulations to demonstrate that the infectious potential has been eliminated.

d) For treatment facilities required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle, the permit application must include, at a minimum, the following information regarding the treatment unit:

1) An operating plan that includes a description of the treatment facility's operating procedures and parameters; and

2) Test data and supporting documentation demonstrating that the infectious potential has been eliminated from either similar existing PIMW treatment units or pilot projects.

e) The treated PIMW is managed in accordance with this Subtitle and 35 Ill. Adm. Code: Subtitle G.

Section 1422.124 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 Part, for each model prior to its operation. If significant mechanical changes are made to a treatment unit, the Initial Efficacy Test must be repeated. Treatment units are considered to be the same model if they:

1) Are manufactured by the same company;

2) Have the same capacity; and

3) Have no significant mechanical changes.

b) The Initial Efficacy Test must be conducted by the use of Options 1, 2 or 3 of Appendix A of this Part, and the challenge loads as described in Table C of Appendix A of this Part. 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.

1) Option 1 must be used for a treatment unit that does not maintain the integrity of the container of test microorganisms (e.g., grinding followed by chemical disinfection). This option is a two phase test.

A) The first phase is to determine the dilution of each test microorganism from the operation of the treatment unit for each challenge load. The log of the number of viable test microorganisms in the processed residue must be greater than or equal to six (6).

B) The second phase is to determine the effectiveness of the treatment unit. The log kill (L) for each test microorganism after treatment must be greater than or equal to six (6).

2) Option 2 must be used for a treatment unit that maintains the integrity of the container of test microorganisms (e.g., autoclaving). The log kill (L) for each test microorganism after treatment must be greater than or equal to six (6).

3) Option 3 can only be used for a thermal treatment unit that maintains the integrity of the container of indicator microorganism spores (e.g., autoclaving, incinerating). The log kill (L) of indicator microorganism spores after treatment must be greater than or equal to six (6).

c) Composition of Challenge Loads

1) For treatment units designed to treat all types of PIMW, all three (3) types of challenge loads must be used in conducting the Initial Efficacy Test. The three (3) types of challenge loads represent PIMW 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 include, at a minimum, 5% 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 of this Part contains the moisture and organic content requirements that must be met in each type of challenge load.

2) For treatment units designed to treat only select categories of PIMW (e.g., a sharps treatment unit), a modification in the composition of the challenge load(s) may be used if approved by the Agency 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 test microorganisms and/or indicator microorganism spores is placed in the load to simulate the worse case scenario (i.e., that part of the 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/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 each of the challenge loads.

2) Test microorganisms and/or indicator microorganisms 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, incorporated by reference at 35 Ill. Adm. Code 1420.103.

f) A Document of Initial Efficacy Demonstration must be retained at the treatment facility, and made available at the treatment facility during

normal business hours for inspection and photocopying by the Agency. The Document of Initial Efficacy Demonstration must include, at a minimum:

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

2) A detailed description and verification of the operating parameters (e.g., temperatures, pressures, retention times, chemical concentrations, irradiation doses, 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;

4) A description of microorganism preparation and packaging, challenge load weight and composition, unit testing scheme (numbers of test rows) and sampling strategy (e.g., number and weight of solid and/or liquid samples);

5) A description and demonstration of microorganism recovery including sample processing, incubation and effective neutralization, and absence of toxic compounds due to neutralization (as applicable);

6) Appendices containing raw data and assumptions in tabular form;

7) The name(s), date, signature(s) and title(s) of person(s) conducting the Initial Efficacy Test, and their qualifications; and

8) A list of references used to evaluate the data and obtain the final conclusion.

Section 1422.125 Periodic Verification Test(s)

a) The effectiveness of the treatment unit is verified by the Periodic Verification Test(s), which must be conducted in accordance with this Section. 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 Options 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 microorganisms or indicator microorganisms must be placed in a representative load in accordance with Section 1422.124(e)(1) of this Part. For example, an autoclave may use Option 3 (e.g., demonstrate at a minimum the destruction of one million (1,000,000) Bacillus stearothermophilus spores) to meet the Periodic Verification Tests(s) requirement. In the case of an incinerator, a stainless steel pipe with threaded ends and removable caps lined with a ceramic insulation may be used to contain a glass culture vial with Bacillus subtilis spore strips. The pipe with the spore strips may be placed in a load of PIMW 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 the indicator microorganism spores in accordance with Appendix B of this Part. The equivalent log kill (T) of the indicator microorganism spores must be used for all subsequent Periodic Verification Tests. The correlation must be done with the three challenge loads identified in Table C of Appendix A of this Part. (See subsection (b) of this Section for further requirements); or

3) Submitting and obtaining written approval by the Agency for a procedure that is equivalent to subsection (a)(2) of this Section. 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 PIMW to insure that all PIMW within the load is completely combusted. The approval of an alternative by the Agency may require more frequent testing and/or monitoring of the treatment unit.

b) For the Correlating Periodic Verification Test, which provides the correlation of log kill (L) of the test microorganisms with the equivalent log kill (T) of the indicator microorganisms, the following procedures apply:

1) At a minimum, an initial population of one million (1,000,000) indicator microorganism spores per gram of waste solids in each challenge load must be used;

2) The fraction of surviving indicator microorganisms that correlates to a log kill (L) of six (6) for each test microorganism must be used in 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 ten thousand (10,000) of the indicator microorganism must be used in all future Periodic Verification Test(s)). For future Periodic Verification Tests, the three challenge loads described in Appendix A, Table C, do not need to be used. The test microorganisms or indicator microorganism spores must be placed in a representative load in accordance with Section 1422.124(e)(1) of this Part;

3) An equivalent log kill (T) of three (3) for the indicator microorganism spores must be the minimum threshold death rate to insure that all test microorganisms are destroyed;

4) Test microorganisms and/or indicator microorganisms 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, incorporated by reference at 35 Ill. Adm. Code 1420.103; and

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

c) If a load of PIMW fails a Periodic Verification Test(s), the Periodic Verification Test(s) must be repeated. The operator shall implement the quality assurance program (in Section 1422.122 (a)(4) of this Part) and contact the manufacturer, if applicable, to identify and correct the problem(s) until the unit can eliminate the infectious potential of the PIMW. 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 (a) of this Section, must also be repeated. Loads of PIMW that were first processed prior to receiving results showing a failure of the Periodic Verification Tests are considered treated. A second Periodic Verification Test must be run immediately after the first Periodic Verification Test indicates a 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, the processed waste is considered PIMW and must be managed in accordance with this Subtitle.

d) Results of the Period Verification Test(s) must be received, verified and made available for inspection by the Agency within two 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 received, verified and made available for inspection by the Agency within one week of when the test was conducted. Results of Periodic Verification Tests must be made available in accordance with the requirements of subsection (g), below.

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

f) A Document of Correlating Periodic Verification Demonstration must be prepared by and retained at the treatment facility, and must be available at the treatment facility during normal business hours for inspection and photocopying by the Agency. The Document of Periodic Verification Demonstration must include, at a minimum:

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

2) A detailed description of the operating parameters (e.g., temperatures, pressures, 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;

4) A description of microorganism preparation and packaging, challenge load weight and composition, unit testing scheme (numbers of test rows) and sampling strategy (e.g., number and weight of solid and/or liquid samples);

5) A description and demonstration of microorganism recovery including sample processing, incubation and effective neutralization, and absence of toxic compounds due to neutralization;

6) Appendices containing raw data and assumptions in tabular form;

7) The names(s), date, signature(s) and title(s) of person(s) conducting the Initial Efficacy Test, and their qualifications; and

8) A list of references used to evaluate the data and obtain the final conclusion.

g) Records of Periodic Verification Test(s) must be prepared by and retained at the treatment facility, and made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. These records must include, at a minimum:

1) The dates the Periodic Verification Test(s) were performed;

2) Operating parameters (e.g., temperatures, pressures, retention times, chemical concentrations, irradiation dose and feed rates);

3) Test protocols;

4) Evaluation of test results; and

5) The name(s), dates, signatures(s) and title(s) of person(s) conducting the Periodic Verification Test(s).

h) Periodic Verification Test(s) 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 is the maximum feed rate at which the unit operates on a 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.

Section 1422.126 Sharps

Sharps may be disposed of in a landfill only if they have been treated to eliminate the infectious potential and:

a) Have been rendered unrecognizable and therefore are no longer PIMW; or

b) Have been:

1) Packaged, marked and labeled in accordance with Part 1421, Subparts C and D;

2) Delivered by a transporter with a PIMW hauling permit as required by 35 Ill. Adm. Code 1420.105 of this Subtitle, unless specifically exempted; and

3) Accompanied by a PIMW manifest as required by 35 Ill. Adm. Code 1420.105 of this Subtitle, unless specifically exempted.

Section 1422.127 Experimental Permits

a) The Agency may issue Experimental Permits for processes or techniques that do not satisfy the standards set forth in this Subpart if the applicant can provide proof that the process or technique has a reasonable chance for success and that the environmental hazards are minimal. A description of the type of residuals anticipated and how they will be managed and disposed of must be included.

b) A valid Experimental Permit constitutes a prima facie defense to any action brought against the permit holder for a violation of the Act or regulations promulgated thereunder, but only to the extent that such action is based upon the failure of the process or technique.

c) All Experimental Permits have a duration not to exceed two (2) years. These permits can only be renewed once. Original experimental permits and renewals granted to any person cannot exceed a total of four (4) years.

d) Application for renewal of an experimental permit must be submitted to the Agency at least ninety (90) days prior to the expiration of the existing permit. To the extent the information to be supplied for renewal is identical with that contained in the prior permit application, the applicant shall so note on the renewal application, and the Agency shall not require the resubmittal of data and information previously supplied to it.

e) A report must be submitted at the end of the experimental permit period, or as required by the Agency, which includes, at a minimum, the following:

1) A summary of operating data, including results of the Initial Efficacy Test(s) or Periodic Verification Test(s);

2) A discussion of how the equipment performed;

3) A discussion of how residuals were managed; and

4) A demonstration that the infectious potential has been eliminated.

Section 1422.APPENDIX A INITIAL EFFICACY TEST PROCEDURES

All PIMW treatment units must demonstrate that the infectious potential has been eliminated by using an Initial Efficacy Test in accordance with this Appendix.

This Option 1 is for a treatment unit that compromises the integrity of the container of test microorganisms (e.g., grinding followed by chemical disinfection).

The purpose of this Phase 1 is to determine 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.

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

b) Each test microorganism must be processed in separate runs through the treatment unit. Prior to each run, the number of viable test microorganisms in each container must be determined in accordance with applicable manufacturer's recommendations, and Standard Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.

c) Processing of the PIMW must occur within thirty (30) minutes after introducing the container of test microorganisms into the treatment unit.

d) The container of test microorganisms and 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, tap water) must be substituted in place of the chemical disinfectant(s).

e) A minimum of five (5) representative grab samples must be taken from the processed residue of each challenge load in accordance with Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846), incorporated by reference at 35 Ill. Adm. Code 1420.103. 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, incorporated by reference at 35 Ill. Adm. Code 1420.103.

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

SA = Log NoA - Log N1A; where Log N1A $\geq$ 6

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

NoA is the number of viable test microorganisms (CFU/gram of waste solids and PFU/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 and PFU/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 (a) through (f) in Phase 1 must be repeated until Log N1A is $\geq$6. NoA is the inoculum size for challenge load Type A in Phase 2 below.

g) Repeat steps (a) through (f) in Phase 1 for challenge loads of PIMW for Types B and C identified in Table C of this Appendix to determine the effect of dilution (SB and SC, respectively).

The purpose of this Phase 2 is to determine the log kill of each test microorganism in each challenge load (Types A through C) identified in Table C of this Appendix.

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

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

LA = Log NoA - SA - Log N2A $\geq$6

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

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

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

c) Repeat steps (a) through (b) 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).

This Option 2 is for a treatment unit that maintains the integrity of the container of test microorganisms (e.g., autoclaves).

a) One microbiological indicator assay containing one of the test microorganisms at numbers greater than one million (1,000,000) must be placed 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). The vial(s) must only contain the test microorganisms.

b) The container of test microorganisms must be placed within a Type A challenge load as identified in Table C of this Appendix.

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

$LA = \text{Log No} - \text{Log N2A} \geq 6$

where: LA is the log kill of the test microorganisms (CFU and PFU) after treatment in challenge load Type A.
No is the number of viable test microorganisms (CFU and PFU) introduced into the treatment unit as the inoculum.
N2A is the number of viable test microorganisms (CFU and PFU) remaining after treatment in challenge load Type A.

d) Repeat steps (a) through (c) 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).

This Option 3 is for a treatment unit that uses thermal treatment and maintains the integrity of the container of indicator microorganism spores (e.g., autoclaves and incinerators).

a) One microbiological indicator assay containing at least one million (1,000,000) spores of one of the indicator microorganisms listed in Table B of this Appendix must be placed 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). The vial must contain only the indicator microorganism vial.

b) The container of indicator microorganisms must be placed within a Type A challenge load as identified in Table C of this Appendix.

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

$LA = Log\ No - Log\ N2A \geq 6$

where: LA is the log kill of the viable indicator microorganisms (CFU) after treatment in challenge load Type A.

No is the number of viable indicator microorganisms (CFU) introduced into the treatment unit as the inoculum.

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

d) Repeat steps (a) through (c) 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).

Section 1422.TABLE A Test Microorganisms

1. Staphylococcus aureus (ATCC 6538)
2. Pseudomonas aeruginosa (ATCC 15442)
3. Candida albicans (ATCC 18804)
4. Trichophyton mentagrophytes (ATCC 9533)
5. MS-2 Bacteriophage (ATCC 15597-B1)
6. Mycobacterium smegmatis (ATCC 14468)

Section 1422.TABLE B Indicator Microorganisms

1. Bacillus subtilis (ATCC 19659)
2. Bacillus stearothermophilus (ATCC 7953)
3. Bacillus pumilus (ATCC 27142)

Section 1422.TABLE C Challenge Loads

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

COMPOSITION OF CHALLENGE LOADS
% (w/w)

	A	B	C
Moisture	≤5	≥50	-----
Organic	-----	-----	≥70

Section 1422.APPENDIX B Correlating Periodic Verification Test Procedures

a) A certified microbiological indicator assay containing the test microorganisms and indicator microorganism spores is introduced into each challenge load as identified in Table C of Appendix A.

b) The test microorganisms and indicator microorganism spores must be placed in a sealed container that remains intact during treatment.

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

d) The effectiveness of the treatment unit is demonstrated by calculating the log kill (L) of the test microorganisms in accordance with Option 2 of Appendix A of this Part. The equivalent log 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 the inoculum as follows:

$TA = \text{Log No} - \text{Log N2A} \geq 3$

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

No is the number of viable indicator microorganism spores (CFU) introduced into the treatment unit as the inoculum (≥6)

N2A is the number of viable indicator microorganism (CFU) remaining after treatment in challenge load Type A.

e) Repeat steps (a) through (d) 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 the equivalent kill of the indicator microorganism spores (LB and LC, respectively).