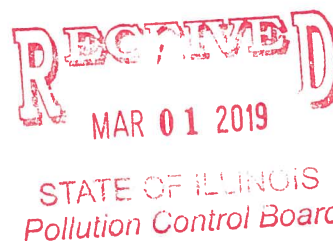


## POLLUTION CONTROL BOARD

## NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: Design and Operation of Facilities
- 2) Code Citation: 35 Ill. Adm. Code 1422
- 3) 

<u>Section Numbers</u> :	<u>Proposed Actions</u> :
1422.101	Repealed
1422.105	Amendment
1422.106	Amendment
1422.107	Amendment
1422.111	Amendment
1422.121	Amendment
1422.122	Amendment
1422.123	Amendment
1422.124	Amendment
1422.125	Amendment
1422.126	Amendment
1422.127	Amendment
1422.APPENDIX A	Amendment
1422.TABLE C	Amendment
1422.APPENDIX B	Amendment
- 4) Statutory Authority: Implementing Section 56.2 and authorized by Section 27 of the Environmental Protection Act [415 ILCS 5/56.2 and 5/27].
- 5) A Complete Description of the Subjects and Issues Involved: Part 1422 contains the design and operation standards for the storage, transfer, and treatment operations and facilities of potentially infectious medical waste. In Part 1422, the Board is removing legalese, redundant and superfluous language, and is reorganizing some provisions for clarity. The Board repeals Section 1422.101 because the compliance dates are no longer relevant. The Board also recodifies appendices and tables.
- 6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None
- 7) Will this rulemaking replace an emergency rule currently in effect? No
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? No



## POLLUTION CONTROL BOARD

## NOTICE OF PROPOSED AMENDMENTS

- 10) Are there any other rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objective: The amendments seek to improve accessibility and ease compliance with the Board's rules. The proposed changes involve updating definitions and references, and removing legalese and reorganizing some provisions to simplify language and improve clarity.
- 12) Time, Place, and Manner in which interested persons may comment on this proposed rulemaking: The Board will accept written public comments on this proposal for a period of at least 45 days after the date of publication in the *Illinois Register*. Public comments must be filed with the Clerk of the Board. Public comments should reference Docket R18-29 and be addressed to:
- Clerk's Office  
Illinois Pollution Control Board  
JRTC 100 W. Randolph St., Suite 11-500  
Chicago IL 60601
- Public comments may also be filed electronically through the Clerk's Office On-Line (COOL) on the Board's website at [pcb.illinois.gov](http://pcb.illinois.gov).
- Interested persons may request copies of the Board's opinion and order in R18-29 by calling the Clerk's office at 312/814-3620, or may download copies from the Board's website at [pcb.illinois.gov](http://pcb.illinois.gov).
- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not-for-profit corporations affected: None, the amendments are non-substantive.
- B) Reporting, bookkeeping or other procedures required for compliance: None
- C) Types of professional skills necessary for compliance: None
- 14) Small Business Impact Analysis: None
- 15) Regulatory Agenda on which this rulemaking was summarized: July 2018

The full text of the Proposed Amendments begins on the next page:

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

- 1422.101 Compliance Date (Repealed)
- 1422.105 PIMW Permit Application Contents
- 1422.106 PIMW Permit Application Certifications
- 1422.107 PIMW Permit Application Filing Requirements

SUBPART B: STORAGE OR TRANSFER OPERATIONS

Section

- 1422.110 Scope and Applicability
- 1422.111 Design and Operating Standards and Criteria

SUBPART C: TREATMENT FACILITIES

Section

- 1422.120 Scope and Applicability
- 1422.121 Treatment Facility Certification
- 1422.122 Design and Operating Standards
- 1422.123 Treatment Units
- 1422.124 Initial Efficacy Test
- 1422.125 Periodic Verification ~~Test(s)~~ Tests
- 1422.126 Sharps
- 1422.127 Experimental Permits

~~Section~~

- 1422.APPENDIX A Initial Efficacy Test Procedures
- 1422.TABLE A Test Microorganisms
- 1422.TABLE B Indicator Microorganisms
- 1422.TABLE C Challenge Loads
- 1422.APPENDIX B Correlating Periodic Verification Test Procedures

AUTHORITY: Implementing Section 56.2 and authorized by Section 27 of the Environmental Protection Act [415 ILCS 5/~~56.2~~ and ~~5/27~~].

SOURCE: Adopted in R91-20, at 17 Ill. Reg. 9911, effective June 21, 1993; ~~adopted~~ amended in R18-29 at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_.

SUBPART A: GENERAL PROVISIONS

Section 1422.101 Compliance Date (Repealed)

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

(Source: Repealed at 43 Ill. Reg. ~~---~~         , effective         )

#### Section 1422.105 PIMW Permit Application Contents

- a) ~~AAn application for a~~ permit application 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.~~
- 1a) Legal description of the facility's ~~location~~located site at which the facility is to be.location.
- 2b) Maps and floor plans showing the location of the facility, the facility boundary, and the location of all units included in the facility.
- 3e) 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.
- 4a) 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 35 Ill. Adm. Code ~~Parts 1420 through 1422 of this Code~~ Subtitle M and any other applicable Board ~~rules~~Parts of 35 Ill. Adm. Code: Chapter 1. ~~The~~Such rules. The description must include, ~~but not be limited to, the following information:~~
- A1) The type of waste management units, and the types and volumes of waste;
- B2) The overall process to be used for treating or storing PIMW and the anticipated performance of the process;
- C3) In detail, the major activities at the facility, such as transfer, storing, screening, weighing, processing, and treatment (including the number of units) of PIMW;
- D4) The operations for initial facility startup, daily startup, and scheduled and unscheduled shutdowns;
- E5) The days and hours of operation;

- F6) The operating parameters for the treatment units;
  - G7) The safety and monitoring equipment for the treatment units;
  - H8) 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;
  - I9) 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;
  - J10) The methods to treat, transfer, or dispose of residual wastes generated from the operation of the facility;
  - K11) Adequacy of the utilities to operate the facility and to respond to emergency situations;
  - L12) Numbers and duties of employees directly responsible for the operation of the site or facility; and
  - M13) Location and type of security devices to prevent unauthorized access.
- 5e) A waste screening plan that describes procedures to be used to identify and prevent the acceptance of unauthorized wastes.
- 6f) Description of procedures to be used for inspection, contingency, recordkeeping, and closure plans as required by this Part.
- 7g) ~~WhereFor~~ 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.
- b) If the applicant believes that any of the documentation or information listed in subsection (a) is not applicable for reasons such as irrelevancy, the application must include the reasons in support of ~~such that~~ belief.

(Source: Amended at 43 Ill. Reg. ~~—~~ \_\_\_\_\_, effective \_\_\_\_\_)

#### Section 1422.106 PIMW Permit Application Certifications

~~AA~~ application for a permit application 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 ~~must~~shall~~must~~ 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 ~~must~~shall~~must~~ 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 ~~3.3303-323.330~~ of the Act, ~~which~~that 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.

(Source: Amended at 43 Ill. Reg. ~~---~~ \_\_\_\_\_, effective \_\_\_\_\_)

#### Section 1422.107 PIMW Permit Application Filing Requirements

a) All permit applications must be filed with the Agency, on forms ~~provided as prescribed~~provided 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 ~~must~~shall~~must~~ 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 ~~by~~pursuant to~~by~~ Section 5(f) of the Act.

(Source: Amended at 43 Ill. Reg. ~~---~~ \_\_\_\_\_, effective \_\_\_\_\_)

#### SUBPART B: STORAGE OR TRANSFER OPERATIONS

##### 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 the following: ~~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 PIMW in a manner and location that maintains the integrity of the packaging and provides protection from water, rain, and wind. ~~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 PIMW in a nonputrescent state, using refrigeration when necessary. ~~MAINTAIN THE PIMW IN A NONPUTRESCENT STATE, USING REFRIGERATION WHEN NECESSARY.~~

3) Lock the outdoor storage areas containing PIMW to prevent unauthorized access. ~~LOCK THE OUTDOOR STORAGE AREAS CONTAINING PIMW TO PREVENT UNAUTHORIZED ACCESS.~~

4) Limit access to on-site storage areas to authorized employees. ~~LIMIT ACCESS TO ON-SITE STORAGE AREAS TO AUTHORIZED EMPLOYEES.~~

5) Store PIMW in a manner that affords protection from animals and does not provide a breeding place or food source for vectors. ~~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) Clean ~~reusable~~Reusablereusable PIMW containers or facility equipment (e.g., carts, squeegees, or shovels), ~~which~~that are visually

contaminated with PIMW, ~~must be cleaned~~ in a designated area in ~~compliance accordance compliance~~ with 35 Ill. Adm. Code ~~1420.107 of this Subtitle. 1420.107.~~

9) Manage ~~residues Residues 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 ~~compliance accordance compliance~~ with 35 Ill. Adm. Code ~~Subtitle C.~~

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

10) Retain ~~copies Copies 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 make ~~them must be made them~~ 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 ~~involving regarding involving~~ the storage operation or as requested in writing by the Agency ~~in writing.~~

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

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

1) Unless previously weighed by the transporter, ~~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) Store PIMW packages ~~must be stored~~ in designated areas ~~so as not to~~ not contaminate other waste or materials.

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

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

5) Maintain ~~adequate Adequate adequate~~ aisle space, ~~as specified in the permit, must be maintained~~ between packages, as specified in the permit, to allow inspection of at least one side of each package and stack



packages. ~~Packages must be stacked~~ so that labels are readable. A vehicle containing PIMW is exempt from the ~~above~~ aisle space requirement ~~for a period that does not exceed five calendar days when:~~

A) ~~When loading~~ 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.~~

C) ~~Either exemption, or both exemptions, must not exceed five (5) calendar days.~~

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

7) Prominently display ~~signs~~ Signs ~~signs~~ identifying the storage operation ~~must be prominently displayed at~~ the points of access to the secured storage area. The signs must: ~~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".~~

A) Display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421. Illustration A and the word "Biohazard"; and

B) Be marked in lettering that is readable at a minimum distance of five ~~(5)~~ feet.

8) Provide ~~personnel~~ Personnel ~~personnel~~ training ~~must be provided to~~ all staff annually and prior to the handling of PIMW that includes ~~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 ~~must~~ shall ~~must~~ keep records verifying training of personnel.

9) ~~Have~~ Storage operations ~~must have~~ Have a written contingency plan ~~and the~~. ~~The applicable sections of that plan must be implemented if there is in the event of is an injury or~~ a discharge of PIMW ~~or personal injury.~~

A) The contingency plan must:

i) ~~Describe~~ describe Describe the actions to be taken ~~by that~~ by 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; and.~~

ii) ~~Include~~ This contingency plan must, at a minimum, ~~include a~~ 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; and.

B) The storage operation must keep ~~a~~<sup>a</sup> copy of the contingency plan, and ~~must post emergency~~ ~~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) ~~Keep~~<sup>Keep</sup> The owner or operator shall ~~keep~~<sup>Keep</sup> a written operating record that ~~includes~~<sup>at the storage operation.</sup> ~~At a minimum,~~<sup>includes</sup> 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)~~<sup>names</sup>, location or ~~location(s)~~<sup>locations</sup>, and, if applicable, the generator identification ~~number(s)~~<sup>numbers</sup> issued by the Agency for each PIMW load received at the storage operation;

F) ~~Temperature(s)~~<sup>Temperatures</sup> the PIMW load was maintained at the storage operation;

G) Destination of packages, ~~including~~<sup>which must include at a minimum</sup> including 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) ~~A~~<sup>In a</sup> separate log with,

~~i)~~ the date, time, nature, and extent of all discharges and ~~personal~~ injuries; and

~~ii)~~ the date, time, nature, and result of any ~~response(s)~~<sup>responses</sup> taken.

11) Retain records as follows:

~~A)~~ The records ~~under~~<sup>required by</sup> ~~required by~~ subsections (b)(8) and (10) ~~of this Section~~ must be:

~~A)~~ ~~Kept~~<sup>Retained by and kept i)</sup> ~~Kept~~ at the storage operation until closure of the storage operation; and

B) ~~Must be made~~ ii) 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.~~

EB) The retention period in subsection (b) (11) (A) is extended :

i) automatically during ~~the course of~~ any unresolved enforcement action ~~involving regarding involving~~ the storage operation, or ~~if as requested in writing by~~

ii) at the written request of the Agency ~~in writing~~.

12) Unless otherwise authorized by the Agency in the permit, do not store 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; ~~7~~ and

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

13) For a planned closure:

A) Notify the agency of the planned closure ~~atAtat~~ at least ~~sixty (60)~~ days prior to closing a storage operation; and, ~~the owner or operator shall notify the Agency of the planned closure.~~

B) ~~CertifyWithin ninety (90) days after the date the final load of PIMW is received at the storage operation, the owner or operator shall certify~~ Certify to the Agency that final closure has been completed in ~~compliance accordance~~ compliance with the permit, the Act, and all applicable regulations promulgated ~~thereunder~~ under the Act within ~~ninety (90)~~ days after the date the final load of PIMW is received at the storage operation.

(Source: Amended at 43 Ill. Reg.        , effective    

## SUBPART C: TREATMENT FACILITIES

### Section 1422.121 Treatment Facility Certification

~~ANe~~ A person must ~~notshallnot~~ cause or allow the disposal of any PIMW ~~wherewhen~~ 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 ~~compliance accordance~~ compliance 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. ANo. A~~ person must ~~not~~shall not falsely certify that PIMW has been treated in ~~compliance~~accordance~~compliance~~ with this Part.

(Source: Amended at 43 Ill. Reg. ~~---~~       , effective       )

#### 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. ~~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) Demonstrate ~~successful~~successful~~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 ~~comply~~be conducted in accordance~~comply~~ with Section 1422.124.

B) Successful completion of a Periodic Verification Test must ~~comply be demonstrated, in accordance~~comply with Section 1422.125, and may be demonstrated 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 compaction and rupture of containers during handling ~~operations~~PREVENTS THE COMPACTION AND RUPTURE OF CONTAINERS DURING HANDLING OPERATIONS~~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 the Act and Board regulations; ~~DISPOSES OF TREATMENT RESIDUALS IN ACCORDANCE WITH THIS ACT AND REGULATIONS ADOPTED THEREUNDER;~~

4) Provides for quality assurance ~~programs~~PROVIDES FOR QUALITY ASSURANCE PROGRAMS~~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 ~~ensure~~~~insure~~ensure effectiveness of the treatment process;
- C) Identifies monitoring devices;
- D) ~~Ensures~~~~Insures~~Ensures monitoring devices are operating properly;
- E) Establishes appropriate ranges for all operating parameters;
- F) Identifies the person or ~~person(s)~~persons who ~~must~~~~shall~~must collect and organize data for inclusion in the operating record;
- G) Identifies the person or ~~person(s)~~persons who ~~must~~~~shall~~must evaluate any discrepancies or problems;
- H) Identifies the person or ~~person(s)~~persons who ~~must~~~~shall~~must propose actions to correct any problems identified; and
- I) Identifies the person or ~~person(s)~~persons who ~~must~~~~shall~~must assess actions taken and document improvement;

5) Provides for periodic testing using biological testing, where appropriate, that demonstrate proper treatment of the waste; ~~PROVIDES FOR PERIODIC TESTING USING BIOLOGICAL TESTING, WHERE APPROPRIATE, THAT DEMONSTRATE PROPER TREATMENT OF THE WASTE;~~

6) Provides for assurances that clearly demonstrate that PIMW has been properly treated; ~~PROVIDES FOR ASSURANCES THAT CLEARLY DEMONSTRATE THAT POTENTIALLY INFECTIOUS MEDICAL WASTE HAS BEEN PROPERLY TREATED;~~ and

7) Is in compliance with all ~~Federal~~federal and State laws and regulations pertaining to environmental protection. ~~IS IN COMPLIANCE WITH ALL FEDERAL AND STATE LAWS AND REGULATIONS PERTAINING TO ENVIRONMENTAL PROTECTION.~~ (Section 56.2(a) (1) ~~through~~ (7) of the Act)

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

1) Manage ~~residues~~Residuesresidues 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 ~~compliance~~~~accordance~~compliance with 35 Ill. Adm. Code ~~Subtitle C.~~

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

2) Manage ~~ash~~Ashash 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~~ ~~compliance~~~~accordance~~compliance



with 35 Ill. Adm. Code 807 and 809 because it is an industrial process waste, as defined in Section 3.235 of the Act.

3) Retain ~~copies~~Copiescopies 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 make ~~them~~themmust be made them 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 ~~if as~~as requested in writing by the Agency ~~in writing~~.

4) Commencing March 31, 1993, and annually thereafter, each treatment facility for which a permit is required by ~~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 shall file the report required by this subsection (b) (4).~~ Additionally, each facility not required to have a permit by ~~EACH FACILITY NOT REQUIRED TO HAVE A PERMIT pursuant to Section under~~ 35 Ill. Adm. Code 1420.105 ~~of this Subtitle~~ that treats more than 50 pounds per month of PIMW shall file ~~at the~~ the report. The report shall be filed with the Agency specifying and shall specify the quantities and disposition of PIMW treated during the previous calendar year. ~~Such~~These reports shall be on forms prescribed and provided by the Agency. ~~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 ~~compliance~~accordancecompliance with 35 Ill. Adm. Code ~~1420.107 of this Subtitle.~~1420.107.

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

1) Weigh ~~amounts~~Amountsamounts 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) Prominently display ~~signs~~Signssigns identifying that the facility treats PIMW ~~must be prominently displayed~~ at the points of access to the treatment area. The signs ~~must~~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".

A) Display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421. Illustration A and the word "Biohazard"; and

B) Be marked in lettering that is readable at a minimum distance of five ~~(5)~~ feet.

3) Provide ~~personnel~~~~Personnel~~~~personnel~~ training ~~must be provided~~ to all staff annually, and prior to the handling of PIMW, that includes. ~~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 ~~must~~~~shall~~~~must~~ keep records verifying training of personnel.

4) ~~Have~~~~Treatment facilities must have~~~~Have~~ a written contingency plan and implement the applicable sections ~~of that plan~~ if there ~~is~~~~must be implemented in the event of a discharge of PIMW,~~ ~~is~~ equipment failure, ~~or personal injury, or a discharge of PIMW.~~

A) The contingency plan must:

i) ~~Describe~~~~describe~~~~Describe~~ the actions to be taken ~~by that by~~ personnel ~~shall take in~~ response to emergency situations such as, ~~but not limited to,~~ personal injury, discharges of PIMW, and equipment failure; and. ~~---~~

ii) ~~Include~~~~This contingency plan must, at a minimum, include a~~~~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; and. ~~---~~

B) The treatment facility must keep ~~a~~~~A~~ copy of the contingency plan, and ~~must~~ post emergency ~~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) ~~Keep~~~~The owner or operator shall keep~~~~Keep~~ a written operating record that ~~includes at the treatment facility.~~ ~~At a minimum,~~ ~~includes~~ 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)~~names, location or ~~location(s)~~locations, and, if applicable, the generator identification ~~number(s)~~numbers 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) ~~A~~In a separate log, with the date, time, nature, and extent of all discharges and ~~personal injuries,~~ and ~~with~~ the date, time, nature, and result of any ~~response(s)~~responses taken.

6) Retain the following records:

~~A)~~ The records ~~underrequired~~required by subsections (c) (3) and (c) (5) ~~of this Section~~ must be:

~~A)~~ ~~Keptretained by and kept i)~~ Kept at the treatment facility until closure of the treatment facility; and

~~B)~~ ~~Mademust be made ii)~~ 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.~~

~~EB)~~ The retention period in subsection (c) (6) (A) is extended automatically during ~~the course of~~ any unresolved enforcement action ~~involvingregarding~~involving the treatment facility or ~~if as requested in writing by~~ at the written request of the Agency ~~in writing~~.

7) For a planned closure:

A) Notify the Agency of the planned closure ~~atAtat~~ at least ~~sixty (60)~~ days prior to closing a treatment facility; and, ~~the owner or operator shall notify the Agency of the planned closure.~~

B) ~~CertifyWithin ninety (90) days after the date the final load of PIMW is received at the treatment facility, the owner or operator shall certify~~Certify to the Agency that final closure has been completed in ~~complianceeaceordance~~compliance with the permit, the Act, and all applicable regulations promulgated ~~thereunder~~under the Act within ~~ninety (90)~~ days after the date the final load of PIMW is received at the storage operation.

(Source: Amended at 43 Ill. Reg.     , effective     )



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, ~~underpursuant to~~ under 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 ~~compliance~~ accordance ~~compliance~~ 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 ~~by~~ pursuant to 35 Ill. Adm. Code 1420.105 ~~of this Subtitle, if: the requirements of subsection (b) (1) or (2) below are met. if:~~

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

A) The treatment unit ~~uses~~ utilizes uses 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, and conducts ~~— In addition, the owner or operator shall conduct~~ Periodic Verification Tests ~~compliant in accordance~~ compliant with the manufacturer's instructions and ~~Section 1422.125's~~ the requirements of Section 1422.125. Test results ~~must~~ shall must be ~~kept~~ retained kept and made available for inspection as required by ~~in accordance with~~ Section 1422.125(d) and (g); and

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

2) The Board has granted the owner's or operator's petition for an adjusted standard as authorized ~~by~~ pursuant to 35 Ill. Adm. Code 106.Subpart G or a site-specific rulemaking ~~underpursuant to~~ under 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. ~~ed~~ For treatment facilities required to have a permit ~~by~~ pursuant to 35 Ill. Adm. Code ~~1420.105 of this Subtitle, 1420.105,~~ 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.

~~ed~~) The treated PIMW is managed in ~~compliance~~ accordance ~~compliance~~ with this Subtitle and 35 Ill. Adm. Code, Subtitle G.

(Source: Amended at 43 Ill. Reg. ~~—~~ \_\_\_\_\_, effective \_\_\_\_\_)

#### Section 1422.124 Initial Efficacy Test

a) The manufacturer, owner, or operator of a treatment unit ~~must~~ shall ~~must~~ conduct an Initial Efficacy Test, ~~under~~ pursuant to ~~under~~ Section 1422. 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 ~~using~~ by the use of ~~Options~~ using Option 1, 2, or 3 of Section 1422. (see Appendix A of this Part), and the challenge loads as described in Section 1422. ~~Table C of Appendix A, Table C 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) must use Option 1. 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) must use Option 2. 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: ~~—~~

A) Conduct the Initial Efficacy Test using all three ~~(3)~~ types of challenge in ~~Section 1422~~. Appendix A, Table ~~Loads must be used in conducting the Initial Efficacy Test. C.~~ The three ~~(3)~~ types of challenge loads represent PIMW with a high moisture content, low moisture content, and high organic content. ~~Section 1422~~. Appendix A, Table C contains the moisture and organic content requirements that must be met in each type of challenge load.

B) The quantity of each challenge load must equal 100% of the maximum capacity of the treatment unit.

C) 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)~~ loads 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 ~~worst~~~~worse~~~~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 container of test microorganisms ~~and/or~~ indicator microorganism spores within a sharps container that ~~is 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 ~~following in accordance with~~ following instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater, ~~see incorporated by reference at~~ (see 35 Ill. Adm. Code ~~1420.103.1420.103~~).

f) A Document of Initial Efficacy Demonstration must be ~~kept retained~~ kept 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/ and 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)~~, and qualifications of the person or ~~person(s)~~ persons conducting the Initial Efficacy Test, ~~and their qualifications~~; and

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

(Source: Amended at 43 Ill. Reg. ~~\_\_\_~~ \_\_\_\_\_, effective \_\_\_\_\_)

Section 1422.125 Periodic Verification ~~Test(s)~~ Tests

a) The effectiveness of the treatment unit is verified by the Periodic Verification ~~Test(s)~~, ~~which must be conducted in accordance with this Section~~ Tests. The manufacturer, owner, or operator of a treatment unit must perform Periodic Verification ~~Test(s)~~ Tests that satisfy at least one ~~(1)~~ of the following:

1) Passing the Initial Efficacy Test by using ~~Options~~ Option 1, 2, or 3 ~~of Section 1422. (see Appendix A of this Part)~~, (whichever is applicable). The three challenge loads described in ~~Section 1422. Appendix A, Table C,~~ do not need to be used. The test microorganisms or indicator microorganisms must be placed in a representative load in ~~compliance~~ ~~accordance~~ compliance 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 ~~Test(s)~~ Test 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~~ 1,000,000 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 ~~compliance~~ ~~accordance~~ compliance with ~~Section 1422. 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 ~~Section 1422. Table C of Appendix~~ Appendix A, Table C of this Part. (~~see~~ 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~~.

A) Examples of alternatives include, ~~but are not limited to,~~ use of another indicator microorganism or measurement of disinfectant concentrations in the treated residue.

B) For incinerators only, an example of an alternative is visually inspecting the ash from each load of treated PIMW to ~~ensure~~~~insure~~ensure that all PIMW within the load is completely combusted.

C) 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) ~~Use~~~~At a minimum,~~Use 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) Use ~~the~~~~The~~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)~~Tests.

A) ~~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)~~Tests.

B) For future Periodic Verification Tests, the three challenge loads described in ~~Section 1422~~. Appendix A, Table C<sub>7</sub> do not need to be used.

C) The test microorganisms or indicator microorganism spores must be placed in a representative load in ~~compliance~~~~accordance~~compliance with Section 1422.124 (e) (1) ~~of this Part~~;

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

4) Test microorganisms ~~and/or~~ indicator microorganisms must be cultured and enumerated ~~compliant in accordance~~compliant with instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater, ~~see incorporated by reference at~~ (see 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.

1) The operator ~~must~~~~shall~~must implement the quality assurance program (see ~~in Section~~Section 1422.122 (a)(4) ~~of this Part~~) and contact the manufacturer, if applicable, to identify and correct the problem or ~~problem(s)~~problems until the unit can eliminate the infectious potential of the PIMW.

2) 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, ~~underpursuant to~~under subsection (a) ~~of this Section~~, must also be repeated.

3) Loads of PIMW that were first processed prior to receiving results showing a failure of the Periodic Verification Tests are considered treated.

4) 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.

5) After the second Periodic Verification Test shows a failure of the treatment unit, the processed waste is considered PIMW and must be managed in ~~compliance~~~~accordance~~compliance with this Subtitle.

d) Results of the Period Verification ~~Test(s)~~Tests 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 ~~compliance~~~~accordance~~compliance with the requirements of subsection (g) ~~below~~.

e) Periodic Verification ~~Test(s)~~Tests must be conducted monthly~~7~~ 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 ~~kept~~~~retained~~kept 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/ and 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) name,~~ date, signature(s), ~~and title(s),~~ and qualifications of the person or ~~person(s) persons~~ conducting the Periodic ~~Verification Initial Efficacy Test, and their qualifications~~ Verification Test; and

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

g) Records of Periodic Verification ~~Test(s) Tests~~ must be prepared by and ~~kept retained~~ kept 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) Tests~~ 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,~~ date, signature, title(s), and qualifications of the person or ~~person(s) persons~~ conducting the Periodic Verification ~~Test(s) Tests.~~

h) Periodic Verification ~~Test(s)~~ Tests 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.

(Source: Amended at 43 Ill. Reg. ~~==~~ \_\_\_\_\_, effective \_\_\_\_\_)

#### Section 1422.126 Sharps

Sharps may not be disposed of in a landfill ~~unless only if~~ unless 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 ~~compliance accordance~~ compliance with 35 Ill. Adm. Code 1421.Subparts C and ~~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, 1420.105~~, unless specifically exempted; and
  - 3) Accompanied by a PIMW manifest as required by 35 Ill. Adm. Code ~~1420.105 of this Subtitle, 1420.105~~, unless specifically exempted.

(Source: Amended at 43 Ill. Reg. ~~==~~ \_\_\_\_\_, effective \_\_\_\_\_)

#### 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. ~~The~~ The description must ~~include~~ include the type of residuals anticipated and how they will be managed and disposed of ~~must be included~~.
- b) A valid Experimental Permit ~~is~~ is a prima facie defense to any action brought against the permit holder for a violation of the Act or regulations promulgated ~~thereunder~~ under the Act, but only to the extent that ~~the~~ the 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. The applicant must note in its renewal application ~~if to the extent whether~~ 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~~ The Agency ~~may shall may~~ 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 must ~~include includes, at a minimum, include~~ the following:

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

(Source: Amended at 43 Ill. Reg. ~~—~~ \_\_\_\_\_, effective \_\_\_\_\_)

#### 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 ~~Section 1422. Table C of this Appendix- A, Table C.~~

- a) Prepare and sterilize by autoclaving, two ~~(2)~~ challenge loads of Type A as identified in ~~Section 1422. Table C of this Appendix A, Table C.~~ Reserve one ~~(1)~~ challenge load for Phase 2.
- b) Process ~~each Each 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 ~~using in accordance with using~~ applicable manufacturer's recommendations,

and Standard Methods for the Examination of Water and Wastewater, ~~see incorporated by reference at (see 35 Ill. Adm. Code 1420.103, 1420.103).~~

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

d) Process ~~theThe~~ 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 a 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) Take ~~aA~~ minimum of five ~~(5)~~ representative grab samples ~~must be taken~~ from the processed residue of each challenge load in ~~compliance~~ ~~accordance~~ compliance with Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846), ~~see incorporated by reference at (see 35 Ill. Adm. Code 1420.103, 1420.103).~~ Determine ~~theThe~~ the number of viable test microorganisms in each grab sample ~~using~~ ~~must be determined in accordance with~~ using applicable manufacturer's recommendations, and Standard Methods for the Examination of Water and Wastewater, ~~see incorporated by reference at (see 35 Ill. Adm. Code 1420.103, 1420.103).~~

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

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

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 ~~Section 1422, Table C of this~~



Appendix A, Table C 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 ~~Section 1422, Table C of this~~ Appendix A, Table C.

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:

$$LA = \text{Log NoA} - SA - \text{Log N2A} \geq 6$$

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 ~~Section 1422, Table C of this~~ Appendix A, Table C 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) Place ~~one~~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)~~vials. The ~~vial(s)~~vials must only contain the test microorganisms.



b) Place ~~the~~The~~the~~ container of test microorganisms ~~must be placed~~ within a Type A challenge load as identified in ~~Section 1422. Table C of this Appendix.~~ A, Table C.

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:

$$LA = \text{Log } N_0 - \text{Log } N_{2A} \geq 6$$

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

$N_0$  is the number of viable test microorganisms (CFU and PFU) introduced into the treatment unit as the inoculum.

~~$N_{2A}$  is the number of viable test microorganisms (CFU and PFU) remaining after treatment in challenge load Type A.~~

~~$N_0$  is the number of viable test microorganisms (CFU and PFU) introduced into the treatment unit as the inoculum.~~

$N_{2A}$  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 ~~Section 1422. Table C of this Appendix.~~ A, Table C 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) Place ~~one~~One~~one~~ microbiological indicator assay containing at least ~~one million (1,000,000)~~ spores of one of the indicator microorganisms listed in ~~Section 1422. Table B of this Appendix.~~ must be placed A, Table B 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)~~vials. The vial must contain only the indicator microorganism vial.

b) Place ~~the~~The~~the~~ container of indicator microorganisms ~~must be placed~~ within a Type A challenge load as identified in ~~Section 1422. Table C of this Appendix.~~ A, Table C.

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:

$$LA = \text{Log } N_0 - \text{Log } N_{2A} \geq 6$$



d) ~~Calculate the effectiveness of the treatment unit is demonstrated by calculating the~~ Calculate the log kill (L) of the test microorganisms ~~compliant in accordance~~ compliant with Option 2 of ~~Section 1422~~ Appendix A to determine the effectiveness of the treatment unit ~~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:

$$TA = \text{Log } N_0 - \text{Log } N_{2A} \geq 3$$

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

$N_0$  is the number of viable indicator microorganism spores (CFU) introduced into the treatment unit as the inoculum ( $\geq 6$ )

$N_{2A}$  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 ~~Section 1422, Table C of Appendix~~ Appendix A, Table C, 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).

(Source: Amended at 43 Ill. Reg. ~~—~~ \_\_\_\_\_, effective \_\_\_\_\_)

~~ILLINOIS REGISTER~~

~~POLLUTION CONTROL BOARD~~

~~NOTICE OF PROPOSED AMENDMENTS~~

~~JCAR351422-1902994r01~~

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1 TITLE 35: ENVIRONMENTAL PROTECTION  
2 SUBTITLE M: BIOLOGICAL MATERIALS  
3 CHAPTER I: POLLUTION CONTROL BOARD  
4 SUBCHAPTER b: POTENTIALLY INFECTIOUS MEDICAL WASTES  
5

6 PART 1422  
7 DESIGN AND OPERATION OF FACILITIES  
8

9 SUBPART A: GENERAL PROVISIONS  
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- 11 Section  
12 1422.101 Compliance Date (Repealed)  
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22

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24

- 25 Section  
26 1422.120 Scope and Applicability  
27 1422.121 Treatment Facility Certification  
28 1422.122 Design and Operating Standards  
29 1422.123 Treatment Units  
30 1422.124 Initial Efficacy Test  
31 1422.125 Periodic Verification Tests~~Test(s)~~  
32 1422.126 Sharps  
33 1422.127 Experimental Permits  
34

- 35 Section  
36 1422.APPENDIX A Initial Efficacy Test Procedures  
37 1422.TABLE A Test Microorganisms  
38 1422.TABLE B Indicator Microorganisms  
39 1422.TABLE C Challenge Loads  
40 1422.APPENDIX B Correlating Periodic Verification Test Procedures  
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42 AUTHORITY: Implementing Section 56.2 and authorized by Section 27 of the Environmental  
43 Protection Act [415 ILCS 5].

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SOURCE: Adopted in R91-20, at 17 Ill. Reg. 9911, effective June 21, 1993; amended in R18-29 at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_.

SUBPART A: GENERAL PROVISIONS

**Section 1422.101 Compliance Date (Repealed)**

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

(Source: Repealed at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 1422.105 PIMW Permit Application Contents**

- ~~a)~~ ~~An application for a permit application 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.~~
  - ~~1a)~~ Legal description of the facility's locationsite at which the facility is to be located.
  - ~~2b)~~ Maps and floor plans showing the location of the facility, the facility boundary, and the location of all units included in the facility.
  - ~~3e)~~ 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.
  - ~~4d)~~ 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 35 Ill. Adm. Code Parts 1420 through 1422 of this Subtitle M and any other applicable Board rules ~~Parts of 35 Ill. Adm. Code: Chapter 1. The~~ Such description must include, ~~but not be limited to,~~ the following information:
    - ~~A1)~~ The type of waste management units, and the types and volumes of waste;
    - ~~B2)~~ The overall process to be used for treating or storing PIMW and

- 87 the anticipated performance of the process;  
 88  
 89 C3) In detail, the major activities at the facility, such as transfer,  
 90 storing, screening, weighing, processing, and treatment (including  
 91 the number of units) of PIMW;  
 92  
 93 D4) The operations for initial facility startup, daily startup, and  
 94 scheduled and unscheduled shutdowns;  
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 96 E5) The days and hours of operation;  
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 98 F6) The operating parameters for the treatment units;  
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 100 G7) The safety and monitoring equipment for the treatment units;  
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 102 H8) A cleaning and disinfection plan describing the daily cleanup  
 103 procedures, including the methods to disinfect emptied reusable  
 104 PIMW containers, transport vehicles, and facility surfaces and  
 105 equipment contaminated with PIMW;  
 106  
 107 I9) The methods to control: emissions of odors and aerosols  
 108 generated, including all supporting design and engineering data;  
 109 dust, noise, litter, and vectors; and handling and storing;  
 110  
 111 J10) The methods to treat, transfer, or dispose of residual wastes  
 112 generated from the operation of the facility;  
 113  
 114 K11) Adequacy of the utilities to operate the facility and to respond to  
 115 emergency situations;  
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 117 L12) Numbers and duties of employees directly responsible for the  
 118 operation of the site or facility; and  
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 120 M13) Location and type of security devices to prevent unauthorized  
 121 access.  
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 123 5e) A waste screening plan that describes procedures to be used to identify  
 124 and prevent the acceptance of unauthorized wastes.  
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 126 6f) Description of procedures to be used for inspection, contingency,  
 127 recordkeeping, and closure plans as required by this Part.  
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 129 7g) For a facility at which the owner or operator is required to conduct either

130 Initial Efficacy Tests or Periodic Verification Tests, a written description  
131 of procedures to be used for recordkeeping, classifying residuals, and  
132 collecting data for the Document of Initial Efficacy Demonstration and  
133 Correlating Periodic Verification Demonstration.  
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- 135 b) If the applicant believes that any of the documentation or information listed in  
136 subsection (a) is not applicable for reasons such as irrelevancy, the application  
137 must include the reasons in support of that belief.  
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139 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)  
140

141 **Section 1422.106 PIMW Permit Application Certifications**  
142

143 ~~An application for a permit~~ application for PIMW treatment, storage, or transfer operation must  
144 contain the certifications specified in this Section.  
145

- 146 a) The permit application must contain a certificate of ownership of the permit area  
147 or a copy of the lease and its duration. The lease must clearly specify that the  
148 owner authorizes the construction of a PIMW waste management facility on the  
149 leased premises. The owner or operator ~~must~~ shall certify that the Agency will be  
150 notified 30 days prior to any changes in ownership or conditions in the lease  
151 affecting the permit area.  
152
- 153 b) All permit applications must be signed by a duly authorized agent of the operator  
154 and the property owner, must be accompanied by an oath or affidavit attesting to  
155 the agent's authority to sign the application, and must be notarized. The following  
156 persons are considered duly authorized agents of the operator and the property  
157 owner:  
158
- 159 1) For corporations, a principal executive officer of at least the level of vice  
160 president;
  - 161 2) For a sole proprietorship or partnership, a proprietor or general partner,  
162 respectively; and  
163
  - 164 3) For a municipality, state, federal, or other public agency, by the head of  
165 the agency or ranking elected official.  
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- 168 c) All permit applications must contain the name, address, and telephone number of  
169 the duly authorized agent of the operator and the property owner to whom all  
170 inquiries and correspondence must be addressed.  
171
- 172 d) All designs presented in the application must be prepared by, or under the



173 supervision of, a professional engineer. The professional engineer ~~must~~ shall affix  
174 the name of the engineer, date of preparation, registration number, a statement  
175 attesting to the accuracy of the information, and design and a professional seal to  
176 all designs.

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178 e) The applicant must state whether the facility is a new regional pollution control  
179 facility, as defined in Section ~~3.3303-32~~ of the Act, ~~that~~ which is subject to the site  
180 location suitability approval requirements of Sections 39(c) and 39.2 of the Act.  
181 If ~~such~~ approval by a unit of local government is required, the application must  
182 identify the unit of local government with jurisdiction. The application must  
183 contain any approval issued by that unit of local government. If no approval has  
184 been granted, the application must describe the status of the approval request.

185  
186 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)  
187

188 **Section 1422.107 PIMW Permit Application Filing Requirements**  
189

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

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197 b) The permit application must be accompanied by all filing fees required  
198 by ~~pursuant to~~ Section 5(f) of the Act.  
199

200 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)  
201

202 SUBPART B: STORAGE OR TRANSFER OPERATIONS  
203

204 **Section 1422.111 Design and Operating Standards and Criteria**  
205

206 a) Any person who stores PIMW prior to treatment or disposal on-site or transport  
207 off-site must comply with ~~all of the following storage requirements~~:

208  
209 1) Store ~~the~~ PIMW in a manner and location that maintains the integrity of  
210 the packaging and provides protection from water, rain, and wind.

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212 2) Maintain ~~the~~ PIMW in a nonputrescent state, using refrigeration when  
213 necessary.

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215 3) Lock the outdoor storage areas containing PIMW to prevent unauthorized

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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) ~~Clean reusable~~ Reusable PIMW containers or facility equipment (e.g., carts, squeegees, or shovels) ~~that~~ which are visually contaminated with PIMW ~~must be cleaned in a designated area in compliance~~ compliance ~~accordance~~ with 35 Ill. Adm. Code 1420.107 ~~of this Subtitle.~~
- 9) ~~Manage residues~~ 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 compliance~~ compliance ~~accordance~~ with 35 Ill. Adm. Code: Subtitle C.  
  
BOARD NOTE: Interested persons should note that local government units can regulate discharges to sewer systems ~~can also be regulated by units of local government.~~
- 10) ~~Retain copies~~ 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 make them~~ 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 involving~~ 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 compliance~~ compliance ~~accordance~~ with 35 Ill. Adm. Code 1420.107 ~~of this Subtitle.~~
- b) In addition to the requirements listed in subsection (a) ~~of this Section, the owner or operator of PIMW storage operations required to have a permit~~ by ~~pursuant to~~

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35 Ill. Adm. Code 1420.105 of this Subtitle must also comply with the following requirements that the Agency ~~will~~ shall review during the permitting process:

- 1) ~~Unless previously weighed by the transporter, 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) ~~Store PIMW packages must be stored in designated areas so as not to not~~ contaminate other waste or materials.
- 3) ~~Store cardboard~~ Cardboard packages must be stored in an enclosed area at an elevation above that of the floor.
- 4) ~~Store PIMW must be stored on a surface that allows drainage and collection of liquids and that minimizes exposure to workers and the public.~~
- 5) ~~Maintain adequate~~ Adequate aisle space, as specified in the permit, must be maintained between packages, as specified in the permit, to allow inspection of at least one (1) side of each package and stack packages. Packages must be stacked so that labels are readable. A vehicle containing PIMW is exempt from the above aisle space requirement for a period that does not exceed five calendar days when:
  - A) ~~Loading~~ When loading or unloading a vehicle; or
  - B) ~~A~~ When a fully-loaded vehicle is on a site. Either exemption, or both exemptions, must not exceed five (5) calendar days.
- 6) ~~Use material~~ Material handling equipment must be designed so as to maintain the integrity of the package.
- 7) ~~Prominently display signs~~ Signs identifying the storage operation must be prominently displayed at the points of access to the secured storage area. The signs must; 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".
  - A) ~~Display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421.Illustration A and the word "Biohazard"; and~~

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- B) Be marked in lettering that is readable at a minimum distance of five feet.
  
- 8) Provide personnel~~Personnel training must be provided~~ to all staff annually and prior to the handling of PIMW that includes.~~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 must~~shall~~ keep records verifying training of personnel.
  
- 9) Have~~Storage operations must have~~ a written contingency plan. The and the applicable sections of that plan must be implemented if there is an injury or in the event of a discharge of PIMW or personal injury.
  - A) The contingency plan must:
    - i) Describe~~describe~~ the actions to be taken by~~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; and-~~
    - ii) Include~~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; and-
  - B) The storage operation must keep a~~A copy of the contingency plan and must post emergency 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) Keep~~The owner or operator shall keep~~ a written operating record that includes~~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



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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 ~~names~~name(s), ~~location or locations,~~location(s) and, if applicable, the generator identification ~~numbers~~number(s) issued by the Agency for each PIMW load received at the storage operation;
- F) ~~Temperatures~~Temperature(s) the PIMW load was maintained at the storage operation;
- G) Destination of packages, ~~including 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) ~~A~~In a separate log with:
  - i) the date, time, nature, and extent of all discharges and ~~personal injuries~~; and
  - ii) the date, time, nature, and result of any ~~responses~~response(s) taken.

11) Retain records as follows:

- A) The records ~~underrequired by subsections (b)(8) and (10) of this Section~~ must be:
  - i) ~~Kept retained by and kept~~ at the storage operation until closure of the storage operation; and
  - ii) ~~Made 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.~~
- B) The retention period in subsection (b)(11)(A) is extended;

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- i) automatically during the course of any unresolved enforcement action involving regarding the storage operation; or
- ii) at the written request of as requested in writing by the Agency.

12) Unless otherwise authorized by the Agency in the permit, do not store 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) For a planned closure:

- A) Notify the agency of the planned closure at ~~At least sixty (60)~~ days prior to closing a storage operation; ~~and, the owner or operator shall notify the Agency of the planned closure.~~
- B) Certify ~~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~~ compliance ~~accordance~~ with the permit, the Act, and all applicable regulations promulgated under the Act ~~thereunder~~ within 90 days after the date the final load of PIMW is received at the storage operation.

(Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

### SUBPART C: TREATMENT FACILITIES

#### Section 1422.121 Treatment Facility Certification

~~A~~ No person must not ~~shall~~ cause or allow the disposal of any PIMW when ~~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 compliance ~~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~~

431 receiving facility. ~~ANo person must not~~ shall falsely certify that PIMW has been treated in  
 432 compliance~~accordance~~ with this Part.

433  
 434 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)  
 435

436 **Section 1422.122 Design and Operating Standards**  
 437

438 a) Treatment of PIMW must be conducted in a manner that:  
 439

440 1) *Eliminates the infectious potential of the waste.* A treatment process  
 441 eliminates the infectious potential of PIMW if the owner or operator of a  
 442 treatment unit demonstrates that an Initial Efficacy Test and Periodic  
 443 Verification Test have been completed successfully.  
 444

445 A) ~~Demonstrate successful~~Successful completion of an Initial  
 446 Efficacy Test ~~must be demonstrated~~by a 6-log kill of test  
 447 microorganisms. For a thermal unit that maintains the integrity of  
 448 the container, a 6-log kill of indicator microorganism spores may  
 449 be used as an alternative test. These demonstrations must  
 450 comply~~be conducted in accordance~~ with Section 1422.124.  
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452 B) Successful completion of a Periodic Verification Test must  
 453 comply~~be demonstrated, in accordance~~ with Section 1422.125, and  
 454 may be demonstrated by:  
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456 i) a 6-log kill of test microorganisms or indicator  
 457 microorganism spores as provided in subsection (a)(1)(A)  
 458 above; or  
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460 ii) a minimum 3-log kill of indicator microorganism spores  
 461 that has been correlated with a 6-log kill of test  
 462 microorganisms; or  
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464 iii) an alternate method ~~submitted to and~~ approved in writing  
 465 by the Agency.  
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467 2) *Prevents the compaction and rupture of containers during handling*  
 468 *operations*, except when compaction or rupture is an integral part of the  
 469 treatment process and the treatment process is conducted without  
 470 discharge of PIMW to the environment;  
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472 3) *Disposes of treatment residuals in accordance with the~~this~~ Act and Board*  
 473 *regulations*~~adopted thereunder~~;

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- 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 ~~ensure~~insure effectiveness of the treatment process;
    - C) Identifies monitoring devices;
    - D) ~~Ensures~~Insures monitoring devices are operating properly;
    - E) Establishes appropriate ranges for all operating parameters;
    - F) Identifies the person or persons~~person~~(s) who ~~must~~shall collect and organize data for inclusion in the operating record;
    - G) Identifies the person or persons~~person~~(s) who ~~must~~shall evaluate any discrepancies or problems;
    - H) Identifies the person or persons~~person~~(s) who ~~must~~shall propose actions to correct any problems identified; and
    - I) Identifies the person or persons~~person~~(s) who ~~must~~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 PIMW~~potentially infectious medical waste~~ has been properly treated; and*
  - 7) *Is in compliance with all ~~federal~~Federal and State laws and regulations pertaining to environmental protection. (Section 56.2(a)(1) ~~through~~ –(7) of the Act)*
- b) In addition to the requirements in subsection (a) ~~of this Section:~~
- 1) Manage residues~~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 compliance~~accordance~~ with 35 Ill. Adm. Code ~~–~~ Subtitle C.



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

- 2) Manage ash ~~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 compliance ~~accordance~~ with 35 Ill. Adm. Code 807 and 809 because it is an industrial process waste, as defined in Section 3.235 of the Act.
- 3) Retain copies ~~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 make them ~~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 by* ~~pursuant to~~ 35 Ill. Adm. Code 1420.105 shall file the report required by this subsection (b)(4). Additionally, of this Subtitle and each facility not required to have a permit under ~~pursuant to~~ 35 Ill. Adm. Code ~~Section 1420.105 of this Subtitle that treats more than 50 pounds per month of PIMW potentially infectious medical waste shall file thea report.~~ The report shall be filed with the Agency and shall specify ~~agency specifying~~ the quantities and disposition of PIMW ~~potentially infectious medical waste treated during the previous calendar year. These~~ ~~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~~ compliance ~~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,~~ the owners or operators of PIMW treatment facilities required to have a permit by ~~pursuant to~~ 35 Ill. Adm. Code 1420.105 ~~must of this Subtitle shall~~ also comply with the following requirements that the Agency will ~~shall~~ review during the permitting process:

- 1) Weigh amounts ~~Amounts~~ of PIMW received ~~must be weighed~~ in pounds

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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) Prominently display signs Signs identifying that the facility treats PIMW ~~must be prominently displayed at the points of access to the treatment area. The signs must;~~ 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".~~

A) Display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421. Illustration A and the word "Biohazard"; and

B) Be marked in lettering that is readable at a minimum distance of five feet.

3) Provide personnel Personnel training ~~must be provided to all staff annually, and prior to the handling of PIMW, that includes. 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 ~~must~~ shall keep records verifying training of personnel.

4) Have Treatment facilities ~~must have~~ a written contingency plan and implement the applicable sections of that plan if there is ~~must be implemented in the event of a discharge, equipment failure, or personal injury, or a discharge of PIMW.~~

A) The contingency plan must:

i) Describe describe the actions to be taken by that personnel ~~shall take in response to emergency situations such as, but not limited to, personal injury, discharges of PIMW, and equipment failure; and.~~

ii) Include 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; and.

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- B) ~~The treatment facility must keep a~~ copy of the contingency plan and ~~must post emergency 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) ~~Keep~~The owner or operator shall keep a written operating record that includesat 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 names, location or locations,~~name(s), location(s)~~ and, if applicable, the generator identification numbers~~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) ~~A~~In a separate log, ~~with,~~ the date, time, nature, and extent of all discharges and ~~personal injuries,~~ and with the date, time, nature, and result of any ~~responses~~response(s) taken.
  
- 6) Retain the following records:
  - A) The records required by subsections (c)(3) and (c)(5) ~~of this Section~~ must be:
    - i) ~~Kept~~retained by and kept at the treatment facility until closure of the treatment facility; and

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~~ii) Mademust 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.~~

~~B) The retention period in subsection (c)(6)(A) is extended automatically during the course of any unresolved enforcement action involvingregarding the treatment facility or at the written request ofas requested in writing by the Agency.~~

7) For a planned closure:

~~A) Notify the Agency of the planned closure atAt least sixty (60) days prior to closing a treatment facility; and, the owner or operator shall notify the Agency of the planned closure.~~

~~B) CertifyWithin 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 complianceeaccordance with the permit, the Act, and all applicable regulations promulgated under the Actthereunder within 90 days after the date the final load of PIMW is received at the storage operation.~~

(Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**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, ~~underpursuant 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 ~~complianceeaccordance~~ with this Part;
- 4) Operated with a PIMW feed rate not to exceed that which was used to



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- 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 ~~by~~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 ~~subsection (a)~~subsections (a)(1)-(5) of this Section, and:
- A) The treatment unit ~~uses~~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 and conducts. ~~In addition, the owner or operator shall conduct~~ Periodic Verification Tests compliant in accordance with the manufacturer's instructions and the requirements of Section 1422.125. Test results must~~shall~~ be kept~~retained~~ and made available for inspection as required by ~~in accordance with~~ Section 1422.125(d) and (g); and
- C) The owner or operator keeps~~retains~~ any notification from the manufacturer of the permitted commercially available treatment unit of a permit modification; or.
- 2) The Board has granted the owner's or operator's petition for an adjusted standard as authorized by~~pursuant to~~ 35 Ill. Adm. Code 106.Subpart G or a site-specific rulemaking under~~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~~.
- e) ~~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.~~
- cd) For treatment facilities required to have a permit by~~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:

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- 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.
- de) The treated PIMW is managed in ~~compliance~~ accordance with this Subtitle and 35 Ill. Adm. Code- Subtitle G.

(Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**Section 1422.124 Initial Efficacy Test**

- a) The manufacturer, owner, or operator of a treatment unit ~~must~~ shall conduct an Initial Efficacy Test, ~~underpursuant to Section 1422. 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 ~~using Option~~ by the use of Options 1, 2, or 3 ~~(see of Appendix A) of this Part,~~ and the challenge loads as described in ~~Section 1422. Table C of Appendix A, Table C 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) ~~A 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)~~ must use Option 1. 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

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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) ~~A Option 2 must be used for a treatment unit that maintains the integrity of the container of test microorganisms (e.g., autoclaving) must use Option 2.~~ 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;

A) ~~Conduct the Initial Efficacy Test using all three-(3) types of challenge in Appendix A, Table C 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. Appendix A, Table C contains the moisture and organic content requirements that must be met in each type of challenge load.

B) The quantity of each challenge load must equal 100% of the maximum capacity of the treatment unit.

C) ~~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 ~~loads~~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

818 under which the treatment unit operates on a day-to-day basis. The feed rate for  
 819 the treatment unit must remain constant throughout the Initial Efficacy Test. This  
 820 feed rate must never be exceeded during the operation of the treatment unit.  
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822 e) The Initial Efficacy Test must be performed so that:

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 824 1) Each container of test microorganisms ~~and/or~~ indicator microorganism  
 825 spores is placed in the load to simulate the ~~worst~~worse case scenario (i.e.,  
 826 that part of the load that is the most difficult to treat). For example, the  
 827 worst case scenario for an autoclave would be to place the container of test  
 828 microorganisms ~~and/or~~ indicator microorganism spores within a sharps  
 829 container that ~~is~~must in turn be deposited in a plastic biohazard bag that is  
 830 then located centrally within each of the challenge loads.  
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832 2) Test microorganisms ~~and/or~~ indicator microorganisms must be cultured  
 833 and enumerated ~~following in accordance with~~ instructions provided by the  
 834 supplier of the microorganisms and Standard Methods for the Examination  
 835 of Water and Wastewater, ~~incorporated by reference at~~ (see 35 Ill. Adm.  
 836 Code 1420.103).  
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838 f) A Document of Initial Efficacy Demonstration must be ~~kept~~retained at the  
 839 treatment facility; and made available at the treatment facility during normal  
 840 business hours for inspection and photocopying by the Agency. The Document of  
 841 Initial Efficacy Demonstration must include, ~~at a minimum~~:

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 843 1) A detailed description of the test procedures used, including all test data  
 844 generated, with descriptions of data handling, and a presentation and  
 845 interpretation of final test results;  
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847 2) A detailed description and verification of the operating parameters (e.g.,  
 848 temperatures, pressures, retention times, chemical concentrations,  
 849 irradiation doses, and feed rates);  
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851 3) A description of quality assurance ~~and~~ /quality control procedures and  
 852 practices for the culture, storage, and preparation of test ~~and/or~~ indicator  
 853 microorganisms (including, ~~but not limited to~~, organism history, source,  
 854 stock culture maintenance, and enumeration procedures). The purity of  
 855 the test microorganisms ~~and/or~~ indicator microorganism spores must be  
 856 certified by a commercial or clinical laboratory;  
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858 4) A description of microorganism preparation and packaging, challenge load  
 859 weight and composition, unit testing scheme (numbers of test rows), and  
 860 sampling strategy (e.g., number and weight of solid ~~and/or~~ liquid



- 861 samples);
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- 863 5) A description and demonstration of microorganism recovery, including
- 864 sample processing, incubation and effective neutralization, and absence of
- 865 toxic compounds due to neutralization (as applicable);
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- 867 6) Appendices containing raw data and assumptions in tabular form;
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- 869 7) The ~~name~~name(s), date, ~~signature~~signature(s) and ~~title~~title, and
- 870 ~~qualification~~title(s) of the person or persons~~person(s)~~ conducting the
- 871 Initial Efficacy Test, ~~and their qualifications~~; and
- 872
- 873 8) A list of references used to evaluate the data and obtain the ~~final~~
- 874 conclusion.
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876 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

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878 **Section 1422.125 Periodic Verification Tests~~Test(s)~~**

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- 880 a) The effectiveness of the treatment unit is verified by the Periodic Verification
- 881 Tests~~Test(s)~~, ~~which must be conducted in accordance with this Section~~. The
- 882 manufacturer, owner, or operator of a treatment unit must perform Periodic
- 883 Verification Tests~~Test(s)~~ that satisfy at least one ~~(1)~~ of the following:
- 884
- 885 1) Passing the Initial Efficacy Test by using ~~Option~~Options 1, 2, or 3 (~~see of~~
- 886 Appendix A) ~~of this Part~~ (whichever is applicable). The three challenge
- 887 loads described in Appendix A, Table C, do not need to be used. The test
- 888 microorganisms or indicator microorganisms must be placed in a
- 889 representative load in ~~compliance~~accordance with Section 1422.124(e)(1)
- 890 ~~of this Part~~. For example, an autoclave may use Option 3 (e.g.,
- 891 demonstrate ~~at a minimum~~ the destruction of ~~one million~~ (1,000,000)
- 892 Bacillus stearotherophilus spores) to meet the Periodic Verification
- 893 Test~~Tests(s)~~ requirement. In the case of an incinerator, a stainless steel
- 894 pipe with threaded ends and removable caps lined with a ceramic
- 895 insulation may be used to contain a glass culture vial with Bacillus subtilis
- 896 spore strips. The pipe with the spore strips may be placed in a load of
- 897 PIMW for the Periodic Verification Test. After the treatment, the pipe
- 898 with the spore strips may be recovered and the spores may be cultured to
- 899 assess whether ~~1,000,000, at a minimum, one million~~ spores have been
- 900 destroyed to meet the Periodic Verification Test~~Test(s)~~ requirement.
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- 902 2) Correlating the log kill ~~(L)~~ of the test microorganisms in the Initial
- 903 Efficacy Test to an equivalent log kill ~~(T)~~ of the indicator microorganism

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spores in ~~compliance~~~~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 (~~3~~) challenge loads identified in ~~Table C of Appendix A, Table C 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~~.
  - A) Examples of alternatives include, ~~but are not limited to~~, use of another indicator microorganism or measurement of disinfectant concentrations in the treated residue.
  - B) For incinerators only, an example of an alternative is visually inspecting the ash from each load of treated PIMW to ~~ensure~~~~insure~~ that all PIMW within the load is completely combusted.
  - C) 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) ~~Use~~~~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) ~~Use the~~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 ~~Tests~~ Test(s).
    - A) (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 ~~Tests~~ Test(s)).
    - B) For future Periodic Verification Tests, the three challenge loads described in Appendix A, Table C, do not need to be used.
    - C) The test microorganisms or indicator microorganism spores must

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be placed in a representative load in ~~compliance~~ accordance with Section 1422.124(e)(1) ~~of this Part~~;

- 3) ~~The minimum threshold death rate is an~~ An equivalent log kill ~~(T)~~ of three ~~(3)~~ for the indicator microorganism spores ~~must be the minimum threshold death rate to~~ ensure insure that all test microorganisms are destroyed;
  - 4) Test microorganisms ~~and/or~~ indicator microorganisms must be cultured and enumerated ~~compliant in accordance~~ with instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater; ~~(see 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~~ Test(s), the Periodic Verification ~~Test~~ Test(s) must be repeated.
- 1) The operator ~~must~~ shall implement the quality assurance program ~~(see in Section 1422.122(a)(4) of this Part)~~ and contact the manufacturer, if applicable, to identify and correct the problem or problems ~~problem(s)~~ until the unit can eliminate the infectious potential of the PIMW.
  - 2) 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, underpursuant ~~to subsection (a) of this Section~~, must also be repeated.
  - 3) Loads of PIMW that were first processed prior to receiving results showing a failure of the Periodic Verification Tests are considered treated.
  - 4) 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.
  - 5) After the second Periodic Verification Test shows a failure of the treatment unit, the processed waste is considered PIMW and must be managed in ~~compliance~~ accordance with this Subtitle.
- d) Results of the Period Verification ~~Tests~~ Test(s) must be received, verified, and made available for inspection by the Agency within two weeks of when the test

- 990 was conducted. When a Periodic Verification Test is used to confirm the failure of  
 991 a treatment unit, the results of the Periodic Verification ~~Test~~Test(s) must be  
 992 received, verified, and made available for inspection by the Agency within one  
 993 week of when the test was conducted. Results of Periodic Verification Tests must  
 994 be made available in ~~compliance~~accordance with the requirements of subsection  
 995 (g), ~~below~~.
- 996
- 997 e) Periodic Verification ~~Tests~~Test(s) must be conducted monthly, or more frequently  
 998 if required by the permit or recommended by the manufacturer.  
 999
- 1000 f) A Document of Correlating Periodic Verification Demonstration must be  
 1001 prepared by and ~~kept~~retained at the treatment facility, and must be available at the  
 1002 treatment facility during normal business hours for inspection and photocopying  
 1003 by the Agency. The Document of Periodic Verification Demonstration must  
 1004 include, ~~at a minimum~~:
- 1005
- 1006 1) A detailed description of the test procedures used and documentation  
 1007 showing the correlation between the log kill (~~L~~) of the test  
 1008 microorganisms and the equivalent kill (~~T~~) of the indicator microorganism  
 1009 spores. An evaluation of the test results must include: All test data  
 1010 generated, with description of data handling, and a presentation and  
 1011 interpretation of final test results;  
 1012
  - 1013 2) A detailed description of the operating parameters (e.g., temperatures,  
 1014 pressures, retention times, chemical concentrations, irradiation dose, and  
 1015 feed rates);  
 1016
  - 1017 3) A description of quality assurance and /quality control procedures and  
 1018 practices for the culture, storage, and preparation of test and/or indicator  
 1019 microorganisms (including, ~~but not limited to~~, organism history, source,  
 1020 stock culture maintenance, and enumeration procedures). The purity of  
 1021 the test microorganisms and/or indicator microorganism spores must be  
 1022 certified by a commercial or clinical laboratory;  
 1023
  - 1024 4) A description of microorganism preparation and packaging, challenge load  
 1025 weight and composition, unit testing scheme (numbers of test rows), and  
 1026 sampling strategy (e.g., number and weight of solid ~~and~~ or liquid  
 1027 samples);  
 1028
  - 1029 5) A description and demonstration of microorganism recovery including  
 1030 sample processing, incubation, and effective neutralization, and absence of  
 1031 toxic compounds due to neutralization;  
 1032

- 1033 6) Appendices containing raw data and assumptions in tabular form;  
1034  
1035 7) The ~~name~~names(s), date, ~~signature~~signature(s) and ~~title~~title, and  
1036 qualificationtitle(s) of ~~the person or persons~~person(s) conducting the  
1037 Periodic Verification~~Initial Efficacy Test~~, and their qualifications; and  
1038  
1039 8) A list of references used to evaluate the data and obtain the ~~final~~  
1040 conclusion.  
1041  
1042 g) Records of Periodic Verification ~~Tests~~Test(s) must be prepared by and  
1043 ~~kept~~retained at the treatment facility, and made available at the treatment facility  
1044 during normal business hours for inspection and photocopying by the Agency.  
1045 These records must include, ~~at a minimum~~:  
1046  
1047 1) The dates the Periodic Verification ~~Tests~~Test(s) were performed;  
1048  
1049 2) Operating parameters (e.g., temperatures, pressures, retention times,  
1050 chemical concentrations, irradiation dose, and feed rates);  
1051  
1052 3) Test protocols;  
1053  
1054 4) Evaluation of test results; and  
1055  
1056 5) The ~~name~~name(s), ~~date~~dates, ~~signature~~signatures(s) and ~~title~~title, and  
1057 qualificationtitle(s) of ~~the person or persons~~person(s) conducting the  
1058 Periodic Verification ~~Tests~~Test(s).  
1059  
1060 h) Periodic Verification ~~Tests~~Test(s) must be conducted under the same operating  
1061 conditions ~~under which~~ the treatment unit operates on a day-to-day basis. The  
1062 feed rate for the treatment unit is the maximum feed rate at which the unit  
1063 operates on a day-to-day basis. The feed rate must remain constant throughout  
1064 the Periodic Verification ~~Test~~Test(s). This feed rate must never be exceeded  
1065 during the operation of the treatment unit.  
1066

1067 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)  
1068

1069 **Section 1422.126 Sharps**  
1070

1071 Sharps may not be disposed of in a landfill unless~~only~~ if they have been treated to eliminate the  
1072 infectious potential and:  
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- 1074 a) Have been rendered unrecognizable and therefore are no longer PIMW; or  
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- b) Have been:
  - 1) Packaged, marked, and labeled in ~~compliance~~ accordance with 35 Ill. Adm. Code 1421.Subparts C and D~~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.

(Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

**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. ~~The~~ A description must include ~~of~~ the type of residuals anticipated and how they will be managed and disposed of ~~must be included~~.
- b) A valid Experimental Permit ~~is~~ constitutes a prima facie defense to any action brought against the permit holder for a violation of the Act or regulations promulgated under the Act~~thereunder~~, but only to the extent that ~~the~~ 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. The applicant must note in its renewal application whether ~~To the extent the information to be supplied for renewal is identical with that contained in the prior permit application. The, the applicant shall so note on the renewal application, and the Agency may~~ 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 must include~~includes~~, at a ~~minimum~~, the following:

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- 1) A summary of operating data, including results of the Initial Efficacy Tests~~Test~~(s) or Periodic Verification Tests~~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.

(Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

1131 **Section 1422.APPENDIX A Initial Efficacy Test Procedures**

1132

1133 All PIMW treatment units must demonstrate that the infectious potential has been eliminated by  
 1134 using an Initial Efficacy Test in accordance with this Appendix.

1135

1136 This Option 1 is for a treatment unit that compromises the integrity of the container of test  
 1137 microorganisms (e.g., grinding followed by chemical disinfection).

1138

1139 The purpose of this Phase 1 is to determine the dilution of each test microorganism from the  
 1140 treatment unit for each challenge load (Types A through C) identified in Appendix A, Table C of  
 1141 ~~this Appendix.~~

1142

1143 a) Prepare and sterilize by autoclaving, two ~~(2)~~ challenge loads of Type A as  
 1144 identified in Appendix A, Table C of ~~this Appendix~~. Reserve one ~~(1)~~ challenge  
 1145 load for Phase 2.

1146

1147 b) ~~Process each~~ Each test microorganism ~~must be processed~~ in separate runs through  
 1148 the treatment unit. Prior to each run, the number of viable test microorganisms in  
 1149 each container must be determined ~~using in accordance with~~ applicable  
 1150 manufacturer's recommendations, and Standard Methods for the Examination of  
 1151 Water and Wastewater, ~~(see incorporated by reference at 35 Ill. Adm. Code~~  
 1152 1420.103).

1153

1154 c) ~~Process~~ Processing of the PIMW ~~must occur~~ within ~~thirty~~ (30) minutes after  
 1155 introducing the container of test microorganisms into the treatment unit.

1156

1157 d) ~~Process the~~ The container of test microorganisms and challenge loads ~~must be~~  
 1158 ~~processed~~ together without the physical and/or chemical agents designed to kill  
 1159 the test microorganisms. For example, in treatment units that use a chemical  
 1160 ~~disinfectant~~ disinfectant(s), an equal volume of liquid (e.g., sterile saline solution  
 1161 (0.9%, volume/volume), phosphate buffer solution, tap water) must be substituted  
 1162 in place of the chemical ~~disinfectant~~ disinfectant(s).

1163

1164 e) ~~Take a~~ A minimum of five ~~(5)~~ representative grab samples ~~must be taken~~ from the  
 1165 processed residue of each challenge load in ~~compliance~~ accordance with Test  
 1166 Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846);  
 1167 ~~(see incorporated by reference at 35 Ill. Adm. Code 1420.103)~~. Determine the The  
 1168 number of viable test microorganisms in each grab sample ~~using~~ must be  
 1169 ~~determined in accordance with~~ applicable manufacturer's recommendations, and  
 1170 Standard Methods for the Examination of Water and Wastewater;  
 1171 ~~(see incorporated by reference at 35 Ill. Adm. Code 1420.103)~~.

1172

1173 f) Calculate the effect of dilution for the treatment unit as follows:

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

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 Appendix A, 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 Appendix A, 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:

$$LA = \text{Log NoA} - SA - \text{Log N2A} \geq 6$$

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

1217 as the inoculum for challenge load Type A as determined in Phase 1  
 1218 above.

1219  
 1220 SA is the log of the number of viable test microorganisms (CFU/gram  
 1221 of waste solids and PFU/gram of waste solids) that were not recovered  
 1222 after processing the challenge load Type A in Phase 1 above.

1223  
 1224 N2A is the number of viable test microorganisms (CFU/gram of waste  
 1225 solids and PFU/gram of waste solids) remaining in the treated residue  
 1226 for challenge load Type A.

1227  
 1228 c) Repeat steps (a) through (b) in Phase 2 for challenge loads Types B and C  
 1229 identified in Appendix A, Table C of this Appendix to determine the effectiveness  
 1230 of the treatment unit (LB and LC, respectively).

1231  
 1232 This Option 2 is for a treatment unit that maintains the integrity of the container of test  
 1233 microorganisms (e.g., autoclaves).

1234  
 1235 a) Place one~~One~~ microbiological indicator assay containing one of the test  
 1236 microorganisms at numbers greater than ~~one million (1,000,000) must be placed~~  
 1237 in a sealed container that remains intact during treatment. The inside diameter of  
 1238 the container must be no larger than required to contain the assay vial(s).  
 1239 The vial(s) must only contain the test microorganisms.

1240  
 1241 b) Place the~~The~~ container of test microorganisms ~~must be placed~~ within a Type A  
 1242 challenge load as identified in Appendix A, Table C of this Appendix.

1243  
 1244 c) Calculate the effectiveness of the treatment unit by subtracting the log of viable  
 1245 cells after treatment from the log of viable cells introduced into the treatment unit  
 1246 as the inoculum, as follows:

1247  
 1248 
$$LA = \text{Log } N_o - \text{Log } N_{2A} \geq 6$$

1249  
 1250 where: LA is the log kill of the test microorganisms (CFU and PFU) after  
 1251 treatment in challenge load Type A.

1252  
 1253 No is the number of viable test microorganisms (CFU and PFU)  
 1254 introduced into the treatment unit as the inoculum.

1255  
 1256 N2A is the number of viable test microorganisms (CFU and PFU)  
 1257 remaining after treatment in challenge load Type A.

1258  
 1259 d) Repeat steps (a) through (c) in this option for challenge loads Types B and C



1260 identified in Appendix A, Table C of this Appendix to determine the effectiveness  
 1261 of the treatment unit (LB and LC, respectively).  
 1262

1263 This Option 3 is for a treatment unit that uses thermal treatment and maintains the integrity of the  
 1264 container of indicator microorganism spores (e.g., autoclaves and incinerators).  
 1265

1266 a) Place oneOne microbiological indicator assay containing at least one million  
 1267 (1,000,000) spores of one of the indicator microorganisms listed in Appendix A,  
 1268 Table B of this Appendix must be placed in a sealed container that remains intact  
 1269 during treatment. The inside diameter of the container must be no larger than  
 1270 required to contain the assay vialsvial(s). The vial must contain only the indicator  
 1271 microorganism vial.  
 1272

1273 b) Place theThe container of indicator microorganisms must be placed within a Type  
 1274 A challenge load as identified in Appendix A, Table C of this Appendix.  
 1275

1276 c) Calculate the effectiveness of the treatment unit by subtracting the log of viable  
 1277 cells after treatment from the log of viable cells introduced into the treatment unit  
 1278 as the inoculum, as follows:  
 1279

$$LA = \text{Log } N_0 - \text{Log } N_{2A} \geq 6$$

1280 where: LA is the log kill of the viable indicator microorganisms (CFU) after  
 1281 treatment in challenge load Type A.  
 1282

1283 No is the number of viable indicator microorganisms (CFU) introduced  
 1284 into the treatment unit as the inoculum.  
 1285

1286 N2A is the number of viable indicator microorganisms (CFU)  
 1287 remaining after treatment in challenge load Type A.  
 1288

1289 d) Repeat steps (a) through (c) in this option for challenge loads Types B and C  
 1290 identified in Appendix A, Table C of this Appendix to determine the effectiveness  
 1291 of the treatment unit (LB and LC, respectively).  
 1292

1293 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)  
 1294  
 1295  
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1297 **Section 1422.APPENDIX A Initial Efficacy Test Procedures**

1298

1299 **Section 1422.TABLE C Challenge Loads**

1300

1301 This table identifies the three types of challenge loads of PIMW that must be used as part of the  
 1302 Initial Efficacy Test and Periodic Verification ~~Test~~Test(s).

1303

COMPOSITION OF CHALLENGE LOADS  
 % (w/w)

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

1304

1305 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)

1306

1307 **Section 1422.APPENDIX B Correlating Periodic Verification Test Procedures**  
 1308

- 1309 a) A certified microbiological indicator assay containing the test microorganisms  
 1310 and indicator microorganism spores is introduced into each challenge load as  
 1311 identified in ~~Table C of Appendix A, Table C.~~  
 1312  
 1313 b) ~~Place the~~The test microorganisms and indicator microorganism spores ~~must be~~  
 1314 ~~placed~~ in a sealed container that remains intact during treatment.  
 1315  
 1316 c) ~~Place the~~The container ~~must be placed~~ in each challenge load to simulate the  
 1317 worst case scenario (i.e., that part of the load that is the most difficult to treat).  
 1318 For example, the worst case scenario for an autoclave would be to place the test  
 1319 microorganisms and indicator microorganism spores container within a sharps  
 1320 container that must in turn be deposited in a plastic biohazard bag that is then  
 1321 located centrally within the treatment unit.  
 1322  
 1323 d) ~~Calculate~~The effectiveness of the treatment unit is ~~demonstrated by calculating~~  
 1324 the log kill (~~L~~) of the test microorganisms ~~compliant in accordance with Option 2~~  
 1325 of Appendix A ~~to determine the effectiveness of the treatment unit of this Part.~~  
 1326 The equivalent log kill (~~T~~) of the indicator microorganism spores is calculated by  
 1327 subtracting the log of viable cells after treatment from the log of viable cells  
 1328 introduced into the treatment unit as the inoculum as follows:  
 1329

$$TA = \text{Log } N_0 - \text{Log } N_{2A} \geq 3$$

1330  
 1331  
 1332 where: TA is the equivalent log kill of the viable indicator microorganisms  
 1333 (CFU) after treatment in challenge load Type A.

1334  
 1335 No is the number of viable indicator microorganism spores (CFU)  
 1336 introduced into the treatment unit as the inoculum ( $\geq 6$ )  
 1337

1338 N2A is the number of viable indicator microorganism (CFU) remaining  
 1339 after treatment in challenge load Type A.  
 1340

- 1341 e) Repeat steps (a) through (d) for challenge loads Types B and C identified in ~~Table~~  
 1342 ~~C of Appendix A, Table C~~ to determine the correlation between the log kill of the  
 1343 test microorganisms and the equivalent kill of the indicator microorganism spores  
 1344 (LB and LC, respectively).  
 1345

1346 (Source: Amended at 43 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)