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)

Section Numbers:	Proposed Actions:
1422.101	Repealed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.

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.

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~~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.~~

1~~a~~) Legal description of the facility's ~~locationlocated site at which the facility is to be.~~location.

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

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

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

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

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

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

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

E~~5~~) The days and hours of operation;

F~~6~~) The operating parameters for the treatment units;

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

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

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

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

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

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

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

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

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

7~~g~~) ~~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

~~AAn application for a~~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 ~~mustshall~~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 ~~mustshall~~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 ~~3.3303.32~~3.330 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 ~~providedas 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 ~~mustshall~~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 ~~bypursuant 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 ~~reusableReusable~~reusable 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 ~~complianceaccordance~~compliance with 35 Ill. Adm. Code ~~1420.107 of this Subtitle.~~1420.107.

9) Manage ~~residuesResidues~~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 ~~complianceaccordance~~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 ~~copiesCopies~~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 ~~themmust 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 ~~involvingregardinginvolving~~ 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 ~~complianceaccordance~~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 ~~bypursuant to~~by 35 Ill. Adm. Code 1420.105 ~~of this Subtitle~~ must also comply with the following requirements that the Agency ~~willshall~~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. 191 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 ~~cardboardCardboard~~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 ~~adequateAdequate~~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 loadingLoading or unloading a vehicle; or

B) When aA 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 materialMaterialmaterial handling equipment must be designed so as to maintain the integrity of the package.

7) Prominently display signsSignssigns 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 personnelPersonnelpersonnel 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 mustshallmust keep records verifying training of personnel.

9) HaveStorage operations must haveHave a written contingency plan and the. The applicable sections of that plan must be implemented if there isin the event ofis an injury or a discharge of PIMW or personal injury.

A) The contingency plan must:

i) DescribedescribeDescribe the actions to be taken bythatby 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) IncludeThis contingency plan must, at a minimum, includeaInclude 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 ~~aA~~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) ~~KeepThe owner or operator shall keep~~Keep a written operating record that ~~includesat the storage operation. At a minimum,~~ includes 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)~~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 storage operation;

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

G) Destination of packages, ~~includingwhich must include at a minimum~~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) ~~AIn aA~~ 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)~~responses taken.

11) Retain records as follows:

A) The records ~~underrequired by~~under subsections (b)(8) and (10) ~~of this Section~~ must be:

~~A)~~ ~~Keptretained by and kept~~i) Kept at the storage operation until closure of the storage operation; and

~~B)~~ ~~Mademust 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.~~

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

i) automatically during ~~the course of~~ any unresolved enforcement action ~~involvingregarding~~involving the storage operation~~;~~ or ~~ifas 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~~;~~ 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 ~~atAt~~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 ~~complianceaccordance~~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

~~ANo~~A person must ~~notshall~~not cause or allow the disposal of any PIMW ~~where~~when 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 ~~complianceaccordance~~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 ~~notshall~~not falsely certify that PIMW has been treated in ~~complianceaccordance~~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 ~~successfulSuccessful~~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 ~~complybe conducted in accordance~~comply with Section 1422.124.

B) Successful completion of a Periodic Verification Test must ~~complybe 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 ~~operationsPREVENTS 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 ~~programsPROVIDES 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 ~~ensureinsure~~ensure effectiveness of the treatment process;

C) Identifies monitoring devices;

D) ~~EnsuresInsures~~Ensures monitoring devices are operating properly;

E) Establishes appropriate ranges for all operating parameters;

F) Identifies the person or ~~person(s)~~persons who ~~mustshall~~must collect and organize data for inclusion in the operating record;

G) Identifies the person or ~~person(s)~~persons who ~~mustshall~~must evaluate any discrepancies or problems;

H) Identifies the person or ~~person(s)~~persons who ~~mustshall~~must propose actions to correct any problems identified; and

I) Identifies the person or ~~person(s)~~persons who ~~mustshall~~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 ~~residuesResidues~~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 ~~complianceaccordance~~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 ~~ashAsh~~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 ~~complianceaccordance~~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 ~~copiesCopies~~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 ~~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 ~~ifas~~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 ~~a~~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 ~~complianceaccordancecompliance~~ 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 ~~bypursuant to~~by 35 Ill. Adm. Code 1420.105 ~~of this Subtitle mustshall~~must also comply with the following requirements that the Agency ~~willshall~~will review during the permitting process:

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

2) Prominently display ~~signsSigns~~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 ~~(5)~~ feet.

3) Provide ~~personnelPersonnel~~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 ~~mustshall~~must keep records verifying training of personnel.

4) ~~HaveTreatment facilities must have~~Have a written contingency plan and implement the applicable sections of that plan if there ~~ismust 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) ~~Describedescribe~~Describe the actions to be taken ~~bythat~~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) ~~IncludeThis contingency plan must, at a minimum, includea~~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 ~~aA~~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) ~~KeepThe owner or operator shall keep~~Keep a written operating record that ~~includesat 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) ~~AIn a~~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.~~

~~C~~B) 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 ~~atAt~~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 ~~complianceaccordance~~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 _____)

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~~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 ~~complianceaccordancec~~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 ~~bypursuant to~~by 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 ~~usesutilizes~~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 ~~compliantin accordance~~compliant with the manufacturer's instructions and ~~Section 1422.125's~~the requirements~~ of Section 1422.125~~. Test results ~~mustshall~~must be ~~keptretained~~kept and made available for inspection as required by ~~in accordance with~~ Section 1422.125(d) and (g); and

C) The owner or operator ~~keepsretains~~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 ~~bypursuant to~~by 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.cd)~~ For treatment facilities required to have a permit ~~bypursuant to~~by 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.

~~de~~d) The treated PIMW is managed in ~~complianceaccordance~~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 ~~mustshall~~must conduct an Initial Efficacy Test, ~~underpursuant 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 ~~usingby 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) ~~AOption 1 must be used for a~~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) ~~AOption 2 must be used for a~~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 ~~C 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 ~~worstworse~~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 ~~ismust in turn be~~is 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 ~~followingin accordance with~~following instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater~~, seeincorporated by reference at~~ (see 35 Ill. Adm. Code ~~1420.103~~1420.103).

f) A Document of Initial Efficacy Demonstration must be ~~keptretained~~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 ~~complianceaccordance~~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 ~~complianceaccordance~~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~~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) ~~UseAt 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~~,~~ do not need to be used.

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

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

4) Test microorganisms ~~and/~~or indicator microorganisms must be cultured and enumerated ~~compliantin accordance~~compliant with instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater~~, asincorporated 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~~,~~ 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 VerificationInitial Efficacy Test, and their qualificationsVerification 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 keptretainedkept 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 ~~unlessonly 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 ~~complianceaccordance~~compliance with 35 Ill. Adm. Code 1421.Subparts C and ~~DPart 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. ~~TheA~~The description must ~~includeof~~include the type of residuals anticipated and how they will be managed and disposed of ~~must be included~~.

b) A valid Experimental Permit ~~isconstitutes~~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 ~~thesuch~~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 ~~usingin accordance with~~using applicable manufacturer's recommendations~~,~~

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

c) ~~ProcessProcessing 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~~a minimum of five ~~(5)~~ representative grab samples ~~must be taken~~ from the processed residue of each challenge load in ~~complianceaccordance~~compliance with Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846)~~, seeincorporated by reference at~~ (see 35 Ill. Adm. Code ~~1420.103.~~1420.103). Determine ~~theThe~~the number of viable test microorganisms in each grab sample ~~usingmust be determined in accordance with~~using applicable manufacturer's recommendations, and Standard Methods for the Examination of Water and Wastewater~~, seeincorporated 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 = Log NoA - Log N1A; where Log N1A >= 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 >= 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~~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 ~~theThe~~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 = Log No - Log N2A ~~>~~= 6

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

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

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

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

d) Repeat steps (a) through (c) in this option for challenge loads Types B and C identified in ~~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 ~~oneOne~~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 ~~theThe~~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 = Log No - Log N2A ~~>~~= 6

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

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

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

d) Repeat steps (a) through (c) in this option for challenge loads Types B and C identified in ~~Section 1422.Table C of this~~ Appendix A, Table C to determine the effectiveness of the treatment unit (LB and LC, respectively).

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

~~Section 1422.APPENDIX A Initial Efficacy Test Procedures~~

Section 1422.TABLE C Challenge Loads

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

COMPOSITION OF CHALLENGE LOADS

% (w/w) A B C Moisture 5 50 Organic 70

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

Section 1422.APPENDIX B Correlating Periodic Verification Test Procedures

a) A certified microbiological indicator assay containing the test microorganisms and indicator microorganism spores is introduced into each challenge load as identified in ~~Section 1422.Table C of~~ ~~Appendix~~ Appendix A, Table C.

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

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

d) ~~CalculateThe effectiveness of the treatment unit is demonstrated by calculatingthe~~Calculate the log kill ~~(L)~~ of the test microorganisms ~~compliantin 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 = Log No - Log N2A >= 3

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

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

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

e) Repeat steps (a) through (d) for challenge loads Types B and C identified in ~~Section 1422.Table C ofAppendix~~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 _____)

Document comparison by Workshare Compare on Monday, February 25, 2019 10:01:21 AM

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Document 1 ID	file://I:\Input\Agency Rulemakings - Files Received\2019\March2019\35-1422-Agency Proposed-(issue 9).docx
Description	35-1422-Agency Proposed-(issue 9)
Document 2 ID	file://I:\Input\Agency Rulemakings - Files Received\2019\March2019\35-1422-r01(issue 9).docx
Description	35-1422-r01(issue 9)
Rendering set	Standard

Legend:	
Insertion	
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Split/Merged cell	
Padding cell	

Statistics:	
	Count
Insertions	314
Deletions	591
Moved from	0
Moved to	0
Style change	0
Format changed	0
Total changes	905

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

PART 1422
DESIGN AND OPERATION OF FACILITIES

SUBPART A: GENERAL PROVISIONS

Section

SUBPART B: STORAGE OR TRANSFER OPERATIONS

Section

SUBPART C: TREATMENT FACILITIES

Section

~~Section~~

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

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) 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.~~

1~~a~~) Legal description of the facility's location~~site at which the facility is to be located~~.

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

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

4~~d~~) Written description of the facility or facility operations with supporting documentation describing the procedures and plans that will be used at the facility to comply with the requirements of 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~~:

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

B~~2~~) The overall process to be used for treating or storing PIMW and

the anticipated performance of the process;

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

D4) The operations for initial facility startup, daily startup, and scheduled and unscheduled shutdowns;

E~~5~~) The days and hours of operation;

F~~6~~) The operating parameters for the treatment units;

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

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

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

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

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

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

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

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

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

7~~g~~) For a facility at which the owner or operator is required to conduct either

Initial Efficacy Tests or Periodic Verification Tests, a written description of procedures to be used for recordkeeping, classifying residuals, and collecting data for the Document of Initial Efficacy Demonstration and Correlating Periodic Verification Demonstration.

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 that belief.

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

Section 1422.106 PIMW Permit Application Certifications

A~~An 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~~ 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 mustshall 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 3.3303.32 of the Act, thatwhich 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 providedas prescribed by the Agency. Hand delivered applications must be delivered during the Agency's normal business hours to the offices of the Permit Section. The Agency mustshall 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 bypursuant to 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 all of the following storage requirements:

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

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

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

access.

4) Limit access to on-site storage areas to authorized employees.

5) Store ~~the~~ PIMW in a manner that affords protection from animals and does not provide a breeding place or food source for vectors. ~~(Section 56.1(e)(2)(D)(i)-(v) of the Act)~~

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

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

8) 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~~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~~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~~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~~

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

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

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 under~~required 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:

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~~

~~receiving facility~~. A~~N~~o person must not~~shall~~ falsely certify that PIMW has been treated in compliance~~accordance~~ 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.* 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~~ 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~~ with Section 1422.124.

B) Successful completion of a Periodic Verification Test must comply~~be demonstrated, in accordance~~ 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 ~~the~~ compaction and rupture of containers during handling operations*, except when compaction or rupture is an integral part of the treatment process and the treatment process is conducted without discharge of PIMW to the environment;

3) *Disposes of treatment residuals in accordance with the~~this~~ Act and Board regulations ~~adopted thereunder~~*;

4) *Provides for quality assurance programs* that must include~~, at a minimum,~~ a written plan that:

A) Designates responsibility to personnel;

B) Describes operating parameters that must be monitored to 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.

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 the~~a~~ 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

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~~.~~

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~~ a written operating record that includes~~at the treatment facility. At a minimum,~~ the following information ~~must be recorded and maintained in the operating record~~:

A) Quantities and disposition of PIMW treated;

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

C) Date and time ~~the~~ PIMW was treated;

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

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

F) Generator 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

ii) Made~~must be made~~ available at the treatment facility during normal business hours for inspection and photocopying by the Agency. ~~These records must be kept until closure of the treatment facility.~~

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

7) For a planned closure:

A) Notify the Agency of the planned closure at~~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) Certify~~Within ninety (90) days after the date the final load of PIMW is received at the treatment facility, the owner or operator shall certify~~ to the Agency that final closure has been completed in 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 _____)

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, under~~pursuant to~~ Sections 1422.124 and 1422.125~~ of this Part~~;

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

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

4) Operated with a PIMW feed rate not to exceed that which was used to

demonstrate that the infectious potential was eliminated; and

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

b) A treatment unit may be used by the owner or operator of a treatment facility not required to have a permit bypursuant 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 usesutilizes 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 compliantin accordance with the manufacturer's instructions and the requirements of Section 1422.125. Test results mustshall be keptretained and made available for inspection as required byin accordance with Section 1422.125(d) and (g); and

C) The owner or operator keepsretains 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 bypursuant to 35 Ill. Adm. Code 106.Subpart G or a site-specific rulemaking underpursuant to 35 Ill. Adm. Code 102. The petition must include a demonstration that the treatment unit meets the standards of subsection (a)(1)-(5) of this Section.

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

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

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

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

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, under~~pursuant 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

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

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

f) A Document of Initial Efficacy Demonstration must be kept~~retained~~ at the treatment facility~~,~~ and made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. The Document of Initial Efficacy Demonstration must include~~, at a minimum~~:

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

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

3) A description of quality assurance 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~~name(s)~~, date, signature,~~signature(s) and~~ title, and qualifications~~title(s)~~ of the person or persons~~person(s)~~ conducting the Initial Efficacy Test~~, and their qualifications~~; and

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

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

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

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

1) Passing the Initial Efficacy Test by using Option~~Options~~ 1, 2, or 3 (see~~of~~ Appendix A) ~~of this Part~~ (whichever is applicable). The three challenge loads described in Appendix A, Table C~~,~~ do not need to be used. The test microorganisms or indicator microorganisms must be placed in a representative load in compliance~~accordance~~ with Section 1422.124(e)(1) ~~of this Part~~. For example, an autoclave may use Option 3 (e.g., demonstrate ~~at a minimum~~ the destruction of ~~one million (~~1,000,000~~)~~ Bacillus stearothermophilus spores) to meet the Periodic Verification Test~~Tests(s)~~ requirement. In the case of an incinerator, a stainless steel pipe with threaded ends and removable caps lined with a ceramic insulation may be used to contain a glass culture vial with Bacillus subtilis spore strips. The pipe with the spore strips may be placed in a load of PIMW for the Periodic Verification Test. After the treatment, the pipe with the spore strips may be recovered and the spores may be cultured to assess whether 1,000,000~~, at a minimum, one million~~ spores have been destroyed to meet the Periodic Verification Test~~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~~ 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

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, under~~pursuant 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

was conducted. When a Periodic Verification Test is used to confirm the failure of a treatment unit, the results of the Periodic Verification Test~~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~~ with the requirements of subsection (g)~~, below~~.

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

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

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

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

3) A description of quality assurance 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 name~~names(s)~~, date, signature,~~signature(s) and~~ title, and qualifications~~title(s)~~ of the person or persons~~person(s)~~ conducting the Periodic Verification~~Initial Efficacy~~ Test~~, and their qualifications~~; and

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

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

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

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

3) Test protocols;

4) Evaluation of test results; and

5) The name~~name(s)~~, date~~dates~~, signature,~~signatures(s) and~~ title, and qualifications~~title(s)~~ of the person or persons~~person(s)~~ conducting the Periodic Verification Tests~~Test(s)~~.

h) Periodic Verification Tests~~Test(s)~~ must be conducted under the same operating conditions ~~under which~~ the treatment unit operates on a day-to-day basis. The feed rate for the treatment unit is the maximum feed rate at which the unit operates on a day-to-day basis. The feed rate must remain constant throughout the Periodic Verification Test~~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~~ 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~~ 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:

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 _____)

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

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

b) Process 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~~ applicable manufacturer's recommendations~~,~~ and Standard Methods for the Examination of Water and Wastewater~~,~~ (see~~incorporated by reference at~~ 35 Ill. Adm. Code 1420.103).

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

d) Process the~~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~~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~~disinfectant(s)~~.

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

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

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

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

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

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

If Log N1A is less than 6, then the number of viable test microorganisms introduced into the treatment unit must be increased and steps (a) through (f) in Phase 1 must be repeated until Log N1A is ≥ 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:

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

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

NoA is the number of viable test microorganisms (CFU/gram of waste solids and PFU/gram of waste solids) introduced into the treatment unit

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

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

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

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

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

a) 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 vials~~vial(s)~~. The vials~~vial(s)~~ must only contain the test microorganisms.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 1422.APPENDIX A Initial Efficacy Test Procedures

Section 1422.TABLE C Challenge Loads

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

COMPOSITION OF CHALLENGE LOADS
% (w/w)

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

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

Section 1422.APPENDIX B Correlating Periodic Verification Test Procedures

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

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

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

d) Calculate~~The effectiveness of the treatment unit is demonstrated by calculating~~ the log kill ~~(L)~~ of the test microorganisms compliant~~in accordance~~ with Option 2 of 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:

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

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

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

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

e) Repeat steps (a) through (d) for challenge loads Types B and C identified in ~~Table C of~~ Appendix A, 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 _____)