Rulemaking Addendum to the
Order of the Board
R18-29 (Rulemaking – Biological Materials)
Amendments to 35 Ill. Adm. Code Subtitle M: Biological Materials

Proposed Rule. Second Notice.

TITLE 35: ENVIRONMENTAL PROTECTION
SUBTITLE M: BIOLOGICAL MATERIALS

CHAPTER I: POLLUTION CONTROL BOARD
SUBCHAPTER b: POTENTIALLY INFECTIOUS MEDICAL WASTES

PART 1420
GENERAL PROVISIONS

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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 R91-19, at 16 Ill. Reg. 2594, effective February 3, 1992; amended in R91-20, at 17 Ill. Reg. 9947, effective June 21, 1993; amended in R18-29 at 43 Ill. Reg. _____, effective _____.

~~NOTE: Capitalization denotes statutory language.~~

Section 1420.101 Scope and Applicability

This Subtitle establishes standards for and applies to all persons who generate, transport, treat, store, or dispose of potentially infectious medical waste~~. It sets forth standards for such activities occurring in whole or in part~~ within the State of Illinois.

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

Section 1420.102 Definitions

All definitions ~~set forth~~ in this Section have the following meanings throughout this Subtitle, unless specifically stated~~provided~~ otherwise. Words and terms not defined have the meanings stated~~set forth~~ in the Act.

"6-log reduction" means a 6-decade reduction or a one millionth (0.000001) survival probability in a microbial population.

"Act" means the Environmental Protection Act ~~(Ill. Rev. Stat. 1991, ch. 111 1/2, par. 1001 et seq., as amended by P.A. 87-1097, effective January 1, 1993)~~ [415 ILCS 5/~~1 et seq.~~].

"Agency" means the Illinois Environmental Protection Agency.

"ATCC" means American Type Culture Collection.

"Board" means the ~~Illinois~~ Pollution Control Board.

"CFU" means colony forming unit.

"Chemical treatment" means using~~the treatment of PIMW in a unit that uses~~ disinfectants or chemicals as the primary means to eliminate the infectious potential of PIMW~~the waste~~. Examples include~~of chemical~~ treatment with~~are~~ ethylene oxide, chlorine, and ozone.

"Class 4 etiologic agent" means a pathogenic agent that is extremely hazardous to laboratory personnel or that may cause serious epidemic disease. Class 4 etiologic agent includes the following viral agents:

Alastrim, Smallpox, Monkey pox, and Whitepox (when used for transmission or animal inoculation experiments);

Hemorrhagic fever agents (including Crimean hemorrhagic fever (Congo), Junin, and Machupo viruses, and others not yet defined);

Herpes virus simiae (Monkey B virus);

Lassa virus;

Marburg virus;

Tick-borne encephalitis virus complex (including Absettarov, Hanzalova, HYPR, Kumlinge, Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses);

Venezuelan equine encephalitis virus (epidemic strains, when used for transmission or animal inoculation experiments); and

Yellow fever virus (wild, when used for transmission or animal inoculation experiments).

BOARD NOTE: A Class 4 Agent helps define an "isolation waste" for ~~the purposes of~~ Section 3.360(a)(6)~~3.84(a)(6)~~ of the Act and this Subtitle. This listing is derived~~derives~~ from the CDC document, "Classification of Human Etiologic Agents on the Basis of Hazard~~,~~", and is supplemented from the CDC/NIH document "Biosafety in Microbiological and Biomedical Laboratories~~.~~".

"Container" means a receptacle that does not contain PIMW.

"Detergent" means a cleansing substance that contains surface-active agents for rapid wetting, penetration, and emulsification of fats and oils, plus a sequestering agent.

"Detergent-sanitizer cleaner" means an agent that is both a detergent and sanitizer~~.~~ ~~The sanitizer must be~~ registered by the United States Environmental Protection Agency (USEPA), as identified on its label.

"Discharge" means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of waste into or on any land or water. This does not include the normal loading and unloading of PIMW from a vehicle.

"Enclosed compartment" means a compartment that protects~~provides protection~~ from the elements, prevents spillage and prevents containers from falling off the vehicle. The enclosed compartment cannot be used to meet the packaging requirements of 35 Ill. Adm. Code 1421.Subpart C.

"Equivalent log kill" ~~(T)~~ means the logarithm of the indicator microorganisms that must be killed and correlates~~, at a minimum,~~ to a 6-log reduction of viable test microorganisms.

"Highly communicable disease~~Communicable Disease~~" means those diseases identified as Class 4 etiologic agents under this Section~~Part~~. (Section 3.360(a)(6)~~3.84(a)(6)~~ of the Act)

"Indicator microorganisms" means those microorganisms listed in 35 Ill. Adm. Code 1422.Appendix A, Table B, as classified by ATCC.

"International biohazard symbol" means the symbol that is shown in 35 Ill. Adm. Code 1421.Illustration A.

"Irradiation treatment" means using~~the treatment of PIMW in a unit that uses~~ ionizing radiation as the primary means to eliminate the infectious potential of PIMW~~the waste~~. Examples include~~of irradiation~~ treatment with~~are~~ gamma (cobalt 60) and electron beam.

"Log" means logarithm to the base ~~ten (~~10~~)~~.

"Log kill" ~~(L)~~ means the difference between the logarithms of viable test microorganisms or indicator microorganisms before and after treatment.

"Oversized PIMW" means a single waste item that is too large to be placed into a ~~thirty-three (~~33~~)~~ gallon bag or container.

"Package" means a receptacle that contains PIMW.

~~"PFU" means plaque forming unit.~~

"Person" is any individual, partnership, co-partnership, firm, company, corporation, association, joint stock company, trust, estate, political subdivision, state agency, or any other legal entity, or their representative, agent, or assigns. (Section 3.315~~3.26~~ of the Act)

"PFU" means plaque forming unit.

"Potentially infectious medical waste~~Infectious Medical Waste~~" or "PIMW"~~*or "PIMW"*~~ *means the following types of waste generated in connection with the diagnosis, treatment (i.e., provision of medical services), or immunization of human beings or animals; research pertaining to the provision of medical services; or the production~~provision~~ or testing of biologicals:*

> *Cultures and stocks. This waste shall include but not be limited to cultures and stocks of agents infectious to humans, and associated biologicals; cultures from medical or pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live or attenuated vaccines; or culture dishes and devices used to transfer, inoculate, or mix cultures.*
>
> *Human pathological wastes. This waste shall include tissue, organs, and body parts (except teeth and the contiguous structures of bone and gum);~~,~~ body fluids that are removed during surgery, autopsy, or other medical procedures; or specimens of body fluids and their containers.*
>
> *Human blood and blood products. This waste shall include discarded human blood, blood components (e.g., serum and plasma), or saturated material containing free flowing blood or blood components.*

Used sharps. This waste shall include but not be limited to discarded sharps used in animal or human patient care, medical research, or clinical or pharmaceutical laboratories; hypodermic, intravenous, or other medical needles; hypodermic or intravenous syringes; Pasteur pipettes; scalpel blades; or blood vials. This waste shall also include but not be limited to other types of broken or unbroken glass (including slides and cover slips) in contact with infectious agents.

Animal waste. Animal waste means discarded materials, including carcasses, body parts, body fluids, blood, or bedding originating from animals inoculated during research, production of biologicals, or pharmaceutical testing with agents infectious to humans.

Isolation waste. This waste shall include discarded materials contaminated with blood, excretions, exudates, and secretions from humans that are isolated to protect others from highly communicable diseases, as defined in this Section. ~~*"Highly communicable diseases" means those diseases identified by the Board in rules adopted under subsection (c) of Section 56.2 of the Act. (See Section 1420.102. of this Part.)*~~

Unused sharps. This waste shall include but not be limited to the following unused, discarded sharps: hypodermic, intravenous, or other needles; hypodermic or intravenous syringes; or scalpel blades.

Potentially infectious medical waste does not include:

Waste generated as general household waste;

Waste (except for sharps) for which the infectious potential has been eliminated by treatment; or

Sharps that meet both of the following conditions:

The infectious potential has been eliminated from the sharps by treatment; and

The sharps are rendered unrecognizable by treatment.

Sharps that are managed in accordance with the following requirements:

The infectious potential is eliminated from the sharps by treatment at a facility that is permitted by the Agency for the treatment of PIMW*;*

The sharps are certified by the treatment facility as non-special waste in accordance with Section 22.48 of the *Act;*

The sharps are packaged at the treatment facility the same as required under Board rules for PIMW*;*

The sharps are transported under the custody of the treatment facility to a landfill permitted by the Agency under Section 21 of the *Act to accept municipal waste for disposal; and*

The above activities *are authorized in, and conducted in accordance with, a permit issued by the Agency to the treatment facility.* (Section 3.360~~3.84~~ of the Act)

"Putrescence" means the partial decomposition of organic matter by microorganisms that causes~~so as to cause~~ malodors, gases, or other offensive conditions, or that can provide~~is capable of providing~~ food for vectors.

"Registered professional engineer" means a person registered under the Illinois Professional Engineering Practice Act ~~(Ill. Rev. Stat. 1991, ch. 111, par. 5201 et seq.)~~ [225 ILCS 325~~/1 et seq.~~].

"Reusable container" means a receptacle that complies with~~meets the requirements of~~ 35 Ill. Adm. Code 1421.121(a) and (b); is made and repaired with materials that are corrosion resistant and non-absorbent; and designed and constructed ~~so as~~ to easily permit cleaning and disinfection in compliance~~accordance~~ with Section 1420.107~~ of this Subtitle. A reusable container is not a single-use container or is not made of cardboard~~.

"Sanitizer" means an antimicrobial agent that is intended for application to inanimate objects or surfaces for~~ the purpose of~~ reducing the microbial count to safe levels and that is~~. The sanitizer must be~~ registered by USEPA~~the United States Environmental Protection Agency~~, as identified on its label.

"Sharps" mean unused sharps and used sharps as stated in the definition of PIMW~~potentially infectious medical waste in this Section~~ with or without residual fluids.

"Significant mechanical change" means the substitution or addition of mechanical parts that result in different operating conditions. A significant mechanical change does not mean the replacement of a parts~~part(s)~~ that meets the same specifications as the original~~ part~~.

"Single-use container" means a container intended by the manufacturer for one use only~~, such as~~ (e.g., biohazard bags).

"Site" means any location, place, tract of land, and facilities, including but not limited to buildings, and improvements used for purposes subject to regulation or control by the Act or regulations thereunder. (Section 3.460~~3.43~~ of the Act) For ~~the purpose of~~ this Subtitle, every~~each campus of an~~ educational institution's campus~~institution~~ is ~~considered to be~~ a single site.

"Storage" means the containment of waste, either on a temporary basis or for a period of years, in such a manner as not to constitute disposal. (Section 3.480~~3.46~~ of the Act)

"Storage site" means *a site at which waste is stored. "Storage site" includes transfer stations.* (Section 3.485~~3.47~~ of the Act)

"Test microorganisms" means those microorganisms listed in 35 Ill. Adm. Code ~~Section~~ 1422.Appendix A, Table A, as classified by ATCC.

"Thermal treatment" means using~~the treatment of PIMW in a unit that uses~~ elevated temperatures as the primary means to eliminate the infectious potential of PIMW~~the waste~~. Examples of thermal treatment are incineration, steam sterilization, microwaving, radiowaving, infrared heating, pyrolysis, plasma systems, and laser treatments.

"Transfer station" means a site or facility that accepts waste for temporary storage or consolidation and further transfer to a waste disposal, treatment or storage facility. "Transfer station" includes a site where waste is transferred from:

~~*(1)*~~ *a rail carrier to a motor vehicle or water carrier;*

~~*(2)*~~ *a water carrier to a rail carrier or motor vehicle;*

~~*(3)*~~ *a motor vehicle to a rail carrier, water carrier or motor vehicle;*

~~*(4)*~~ *a rail carrier to a rail carrier, if the waste is removed from a rail car; or*

~~*(5)*~~ *a water carrier to a water carrier, if the waste is removed from a vessel.* (Section 3.500~~3.83~~ of the Act)

"Treatment" means any method, technique or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any waste so as to neutralize it or render it nonhazardous, safer for transport, amenable for recovery, amenable for storage, or reduced in volume. Such term includes any activity or processing designed to change the physical form or chemical composition of hazardous waste so as to render it nonhazardous. (Section 3.505~~3.49~~ of the Act)

"Unrecognizable" means relating to a sharp that has undergone physical alteration (e.g., melting, charring, corroding, or grinding) so that the sharp may no longer be used for its intended purpose.

"Vector" means any living agent, other than human, capable of transmitting, directly or indirectly, an infectious disease.

"Vehicle" means any device used to transport special waste in bulk or in packages, tanks or other containers.

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

Section 1420.103 Incorporations by Reference

The following materials are incorporated by reference. This Section incorporates no later editions or amendments.

Standard Methods for the Examination of Water and Wastewater, American Public Health Association et al. (1015 Fifteenth Street, N.W., Washington, D.C. 20005) (23rd~~18th~~ Edition, 2017~~1992~~).

Test Methods for Evaluating Solid Waste. Physical/Chemical Methods, EPA Publication SW-846 (Third Edition, Final Updates I (1993), II (1995), IIA (1994), IIB (1995), III (1997), IIIA (1999), IIIB (2005), IV (2008), and V (2015)~~1986 as amended by Update I (November, 1990)~~). SW-846 and updates~~Update I~~ are available from the Superintendent of Document, U.S. Government Printing Office, Washington, D.C. 20402, (202) 783-3238.

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

Section 1420.104 Prohibitions

No person shall:

a) *Cause or allow the disposal of any* PIMW. *Sharps may be disposed in any landfill permitted by the Agency under Section 21 of* the *Act to accept municipal waste for disposal, if both:*

1) *The infectious potential has been eliminated from the sharps by treatment; and*

2) *The sharps are packaged in accordance with* 35 Ill. Adm. Code 1421~~Part 1421, Subpart C of this Subtitle~~.

b) *Cause or allow the delivery of any* PIMW *for transport, storage, treatment or transfer except in accordance with* 35 Ill. Adm. Code 1421.Subpart C and Subpart E ~~Part 1421, Subpart C of this Subtitle~~.

c) *Cause~~Beginning July 1, 1992, cause~~ or allow the delivery of any* PIMW *to a person or facility for storage, treatment, or transfer that does not have a permit issued by the Agency to receive* PIMW under~~pursuant to~~ Section 39 of the Act, *unless no permit is required* under Section~~pursuant to subsection~~ 1420.105(c)~~ of this Part~~.

d) *Cause~~Beginning July 1, 1992, cause~~ or allow the delivery or transfer of any* PIMW *for transport unless:*

1) *The transporter has a permit issued by the Agency to transport* PIMW*, or the transporter is exempt from the permit requirement* under Section~~pursuant to subsection~~ 1420.105(b)~~ of this Part~~. ~~Permit applications must be submitted on forms provided by the Agency.~~

2) *A* PIMW *manifest is completed for the waste* unless no manifest is required under Section~~pursuant to subsection~~ 1420.105(e)~~ of this Part~~.

e) *Cause or allow the acceptance of any* PIMW *for purposes of transport, storage, treatment, or transfer except in accordance with* 35 Ill. Adm. Code 1421.Subpart C and 35 Ill. Adm. Code 1422.Subpart B~~Part 1421, Subpart C of this Subtitle and Part 1422, Subpart B of this Subtitle~~.

f) *Conduct any* PIMW *transportation operation~~Beginning July 1, 1992, conduct any~~* PIMW *~~transportation operation~~:*

1) *Without a permit issued by the agency to transport* PIMW, unless no permit is required under Section~~pursuant to subsection~~ 1420.105(b)~~ of this Part~~.

2) *In violation of any condition of any permit issued by the Agency under* the *Act*.

3) *In violation of any regulation adopted by the Board.*

4) *In violation of any order adopted by the Board under* the *Act*.

g) *Conduct~~Beginning July 1, 1992, conduct~~ any* PIMW *treatment, storage, or transfer operation:*

1) *Without a permit issued by the Agency that specifically authorizes the treatment, storage, or transfer of* PIMW under~~pursuant with~~ Section 39 of the Act, unless no permit is required under Section~~pursuant to subsection~~

1420.105(c) ~~of this Part. Permit applications must be submitted on forms provided by the Agency~~.

2) *In violation of any condition of any permit issued by the Agency under* the *Act*.

3) *In violation of any regulations adopted by the Board.*

4) *In violation of any order adopted by the Board under* the *Act*.

h) *Transport* PIMW *unless the transporter carries a completed* PIMW *manifest*, unless no manifest is required under Section~~pursuant to subsection~~ 1420.105(e) ~~of this Part~~.

i) *Offer for transportation, transport, deliver, receive or accept* PIMW *for which a manifest is required, unless the manifest indicates that the fee required under Section 56.4 of* the *Act has been paid*.

j) *Conduct~~Beginning January 1, 1994, conduct~~ a* PIMW *treatment operation at an incinerator in existence on the effective date of this Title in violation of emission standards established for these incinerators under Section 129 of the Clean Air Act* (42 USC 7429)*, as amended.* (Section 56.1 of the Act)

k) Cause or allow the discharge of PIMW from a vehicle.

l) Cause or allow the discharge of PIMW into a sanitary or combined sewer except in compliance~~accordance~~ with 35 Ill. Adm. Code~~,~~ Subtitle C. ~~No person shall cause or allow the discharge of inert or solid PIMW, or inert or solid materials resulting from the treatment of PIMW, into any sanitary sewerage system, combined sewerage system, or storm sewerage system directly or indirectly tributary to waters of the State. Such prohibition applies to, but is not limited to, absorbents, aluminum or other metallic foils, ash, bone, bedding materials, cellulose, culture dishes, garments and other cloth materials, gauze, glass, pads, plastic, sharps, shavings, straw and syringes.~~

m) Cause or allow the discharge of inert or solid PIMW, or inert or solid materials resulting from PIMW treatment, into any sanitary sewerage system, combined sewerage system, or storm sewerage system directly or indirectly tributary to waters of the State. This prohibition applies to absorbents, aluminum, or other metallic foils, ash, bone, bedding materials, cellulose, culture dishes, garments and other cloth materials, gauze, glass, pads, plastic, sharps, shavings, straw, and syringes.

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

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

Section 1420.105 Permit and Manifest Requirements and Exceptions

a) The permit and permit appeal provisions in~~of~~ Sections 39 and 40 of the Act and Board regulations adopted thereunder apply to this Subtitle.

b) A person who transports~~conducts a~~ PIMW must~~transportation operation is required to~~ obtain a PIMW hauling permit from the Agency, except:

1) *A person transporting* PIMW *generated solely by that person's activities; ~~or~~*

2) *Noncommercial transportation of less than 50 pounds of* PIMW*~~potentially infections medical waste~~ at any one time; or*

3) *The U.S. Postal Service.* (Section 56.1(f)(1)(A) through (C) of the Act)

c) A person who conducts a PIMW treatment, storage, or transfer operation must~~is required to~~ obtain a permit from the Agency, except:

1) *Any person conducting a* PIMW *treatment, storage, or transfer operation for* PIMW *generated by the person's own activities that are treated, stored, or transferred within the site where the* PIMW *is generated; ~~or~~*

2) *Any hospital that treats, stores, or transfers only* PIMW *generated by its own activities or by members of its medical staff.* (Section 56.1(g)(1) of the Act). No storage~~If the transportation of PIMW is interrupted so as not to constitute storage, no~~ permit is required under Section 56.1(g) of the Act if PIMW transportation is interrupted. For example, transportation of PIMW interrupted by vehicle repairs or inclement weather is~~does~~ not ~~constitute~~ storage.

d) A person applying for a permit for a PIMW treatment, storage, or transfer operation must~~shall~~ file an application, on forms provided by the Agency, with the Agency in compliance~~accordance~~ with ~~the requirements and procedures of~~ 35 Ill. Adm. Code 1422.105 through 1422.107.

e) Any person who transports PIMW must~~is required to~~ carry a completed PIMW manifest except for the transportation of:

1) PIMW *being transported by generators who generated the waste by their own activities, when the* PIMW *is transported within or between sites or facilities owned, controlled, or operated by that person; ~~or~~*

2) *Less than 50 pounds of* PIMW *at any one time for a noncommercial transportation activity; or*

3) PIMW *by the U.S. Postal Service.* (Section 56.1(h) of the Act)

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

Section 1420.106 Penalty Factor

In making its orders and determinations relative to penalties, if any, to be imposed for violating Section 56.1(A)(a) of the *Act, the Board, in addition to the factors in Sections 33(c) and 42(h) of* the *Act, or the court shall take into consideration whether the owner or operator of the landfill reasonably relied on written statements from the person generating or treating the waste that the waste is not* PIMW~~*potentially infectious medical waste*~~. (Section 56.1(B)~~(k)~~ of the Act)

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

Section 1420.107 Cleaning and Disinfection

a) Cleaning and disinfection includes~~comprises~~:

1) Washing with a solution of detergent used compliant~~in accordance~~ with manufacturer's instructions and agitation to remove visible contamination from each surface, followed by a clean water rinse; and

2) One of the following methods of low-level disinfection:

A) Exposure to hot water of at least 82 degrees Centigrade (180 degrees Fahrenheit) for a minimum of ~~fifteen (~~15~~)~~ seconds;

B) Rinsing with, or immersion in, a chemical disinfectant registered by the USEPA~~United States Environmental Protection Agency~~, as identified on its label and used following~~in accordance with~~ the manufacturer's instructions;

C) Rinsing with, or immersion in, a hypochlorite solution at a concentration of 50 parts per million (ppm). For example, 1/8 cup of common household bleach (5.25% sodium hypochlorite) per gallon of tap water (31 milliliters bleach to 3.78 liters of water); or

D) Other disinfection processes as approved by the Agency in writing as an equivalent to one of the methods in subsections (a)(2)(A) and (B)~~ of this Section~~.

b) A detergent-sanitizer used in conjunction with agitation to remove visible contamination may be substituted for the methods in subsection (a) ~~of this Section~~, if used following ~~in accordance with~~ the manufacturer's instructions.

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

Section 1420.120 Severability

If any provision of this Part or its application to any person is adjudged invalid, the adjudication does not affect the validity of this Part as a whole or of any portion not adjudged invalid. ~~If any Section, subsection, sentence or clause of this Subtitle is adjudged unconstitutional, invalid or otherwise not effective for any reason, such adjudication does not affect the validity of this Subtitle or of any Section, subsection, sentence, or clause thereof not adjudged unconstitutional, invalid or otherwise not effective for any reason.~~

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

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

PART 1421
ACTIVITY STANDARDS

SUBPART A: GENERAL PROVISIONS

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1421.ILLUSTRATION A International Biohazard Symbol

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. 10392, effective June 21, 1993; amended in R18-29 at 43 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 1421.101 Compliance Dates (Repealed)

~~Persons subject to this Part shall comply with its standards and criteria by June 21, 1993 (effective date).~~

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

SUBPART B: SEGREGATION

Section 1421.110 Scope and Applicability

This Subpart applies to persons who generate or transport PIMW, and to owners or operators of PIMW storage sites, transfer stations, and treatment facilities.

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

Section 1421.111 Standards and Criteria

a) Generators must~~shall~~ segregate PIMW as follows:

1) Sharps;~~,~~

2) Oversized PIMW;~~,~~ and

3) All other.

b) PIMW mixed with other waste is regulated under this Subtitle as PIMW and the mixture is not exempt from any other ~~applicable~~ regulations.

c) This Section does not prohibit ~~the~~ placing ~~of~~ previously segregated and properly packaged (compliant~~in accordance~~ with Section 1421.Subpart C ~~of this Part~~) sharps with other waste if~~, provided~~ the mixture is managed in compliance~~accordance~~ with subsection (b) ~~of this Section~~.

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

SUBPART C: PACKAGING

Section 1421.121 Standards and Criteria

a) PIMW, except for oversized PIMW, must be placed in a container, or a combination of containers. The~~Such~~ container must be:

1) Rigid~~*rigid*~~;

2) Leak-resistant~~*leak resistant*~~;

3) Impervious to moisture~~*impervious to moisture*~~;

4) Of a strength sufficient to prevent tearing or bursting under normal conditions of use and handling; and~~*of a strength sufficient to prevent tearing or bursting under normal conditions of use and handling; and*~~

5) Sealed to prevent leakage during transport.~~*sealed to prevent leakage during transport.*~~ ~~(Section 56.1(b)(2)(A))~~

b) Sharps, unless rendered unrecognizable by treatment~~pursuant to 35 Ill. Adm. Code 1422.126(a)~~, must be packaged in a container~~,~~ or a combination of containers~~,~~ that is puncture-resistant and complies with~~meets the requirements of~~ subsection (a) ~~of this Section~~.

c) Oversized PIMW must be covered or packaged in a manner that minimizes contact with transport workers and the public. Do not package sharps~~Sharps must not be packaged~~ with oversized PIMW in the same container.

d) If the outside of a container is contaminated by PIMW, ~~a person shall place~~ the container must be placed inside another container, or the container must be cleaned and disinfected in compliance~~clean and disinfect the container in accordance~~ with 35 Ill. Adm. Code 1420.107 ~~of this Subtitle~~. In either case, the container or combination of containers must comply with subsection~~meet applicable requirements of subsections~~ (a) or (b) ~~of this Section~~.

e) Once a reusable container has been cleaned and disinfected in compliance~~accordance~~ with 35 Ill. Adm. Code 1420.107 ~~of this Subtitle~~, it can be used for only waste. If a reusable container is not or cannot be cleaned and

disinfected in compliance~~accordance~~ with 35 Ill. Adm. Code~~Section~~ 1420.107~~ of this Subtitle~~, it must be regulated as PIMW under~~pursuant to~~ this Subtitle.

f) Residues from cleaning a PIMW container, or discharges from PIMW packages, are regulated under this Subtitle, except when discharged directly into a sanitary or combined sewer in compliance~~accordance~~ with 35 Ill. Adm. Code Subtitle C.

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

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

SUBPART D: LABELING AND MARKING

Section 1421.131 Standards and Criteria

a) The exterior of the outer package must be marked as follows before~~prior to~~ shipment:

1) The generator must~~shall~~:

A) Mark on two opposite sides of the outer package in lettering that is readable at a minimum distance of five ~~(5)~~ feet:

i) The International Biohazard Symbol, as shown in Illustration A, ~~ of this Part~~ and the word "Biohazard"; and

ii) The word "Sharps~~sharps~~", if the package contains sharps.

B) Mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package:

i) The generator's name;~~,~~

ii) The generator's address;~~,~~ and

iii) The generator's phone number (a 24-hour phone number, if available).

2) The transporter must~~shall~~ mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package:

A) The transporter's name;~~,~~

B) The transporter's permit number;~~,~~

C) The transporter's address;~~,~~

D) The transporter's phone number (a 24-hour phone number, if available);~~,~~ and

E) For each PIMW package, the shipment date when PIMW initially left the generator's site; or for each shipment, a unique identification number that~~which~~ directly corresponds to the initial date of shipment.

b) Except for subsection (c)~~ of this Section~~, inner packages must be marked as described in subsection (a)(1)(A)(i)~~ of this Section~~.

c) If a sharps container is packaged within an outer container, the inner sharps container must be marked with indelible ink in lettering that is legible as follows:

1) The International Biohazard Symbol, as shown in Illustration A, ~~of this Part~~ and the word "Biohazard~~biohazard~~"; and

2) The word "Sharps~~sharps~~".

d) Containers that~~which~~ are not the inner or outer containers are exempt from ~~the labeling requirements in~~ subsection (a)~~ of this Section~~. Packages may be placed in a transparent container if~~provided that~~ all required markings are legible through the transparent container. A non-rigid transparent container cannot be used as an outer container.

e) For oversized PIMW, the following requirements must be met before~~prior to~~ shipment:

1) The generator must~~shall~~:

A) Mark on one side of the outer package in lettering that is readable at a minimum distance of five ~~(5)~~ feet the International Biohazard Symbol, as shown in Illustration A, ~~of this Part~~ and the word "Biohazard~~biohazard~~".

B) Mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package:

i) The generator's name;~~,~~

ii) The generator's address;~~,~~ and

iii) The generator's phone number (a 24-hour phone number, if available).

2) The transporter must~~shall~~ mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package:

A) The transporter's name;~~,~~

B) The transporter's permit number;~~,~~

C) The transporter's address;~~,~~

D) The transporter's phone number (a 24-hour phone number, if available);~~,~~ and

E) For each PIMW package, the shipment date when PIMW initially left the generator's site; or for each shipment, a unique identification number which directly corresponds to the initial date of shipment.

f) When PIMW is transported by more than one transporter, each transporter must~~shall~~ mark with indelible ink in lettering that is legible on a water-resistant label or tag securely attached to or marked on the outer package the information listed in subsection (a)(2)~~ of this Section~~. The label, tag, or mark must not obscure any previous information on the package.

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

SUBPART E: TRANSPORTATION

Section 1421.140 Scope and Applicability

This Subpart applies to persons who transport PIMW and are required to have a PIMW hauling permit by~~in accordance with~~ 35 Ill. Adm. Code 1420.105~~ of this Subtitle~~.

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

Section 1421.141 Standards and Criteria

a) PIMW must be transported under conditions that:

1) Minimize~~to minimize~~ the effects of putrescence; and~~.~~

2) Prevent a breeding place or food source for vectors.

b) Packages of PIMW must be transported:

1) Only~~only~~ in enclosed compartments of vehicles that are secured against public access when unattended. This ~~requirement~~ does not apply to oversized PIMW, which must be handled in a manner that minimizes contact with transport workers and the public; and~~.~~

2) In a manner that:

A) Prevents compaction of packages; or

B) Does not subject them to stress that compromises the integrity of the container.

c) Vehicles and associated storage compartments, doors, piping, and valving must be:

1) Cleaned of visible PIMW contamination after each use; and

2) In good repair when transporting PIMW.

~~d) PIMW must be transported in a manner that prevents a breeding place or food source for vectors.~~

~~e) During transport, a PIMW package must not be compacted or subjected to stress that compromises the integrity of the container.~~

d~~f~~) This Subtitle regulates residues~~Residues~~ from the cleaning of vehicles contaminated by PIMW ~~are regulated under this Subtitle~~, except when discharged directly into a sanitary or combined sewer in compliance~~accordance~~ with 35 Ill. Adm. Code Subtitle C.

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

e~~g~~) Vehicles transporting PIMW must display information in compliance~~accordance~~ with the PIMW hauling permit.

f~~h~~) Emergency Response Plan.

1) The transporter must~~shall~~ develop and keep an emergency response plan in the vehicle.

2) This plan must identify the names and telephone numbers of State and local authorities who must be contacted duringin the event of an emergency or discharge of PIMW.

3) If there isIn the event of an emergency or discharge of PIMW, the transporter mustshall take immediate action in complianceaccordance with the emergency response plan to protect the health and safety of the public and the environment. In addition, each vehicle transporting PIMW must carry all equipment necessary to provide a response.

gi) Vehicles transporting PIMW must not be used to haulfor the hauling of non-waste materials, except forwith the exception of equipment and supplies intended for the use of waste management, including scales, bar coding equipment, printers, stampers, manifests, logs, dollies, load locks, conveyers, material handling equipment, plastic containers, corrugated boxes, plastic bags, tape, sharps containers, drums, labels, signs, stickers, spill kits, new PIMW containers, or PIMW containers that have been cleaned and disinfected in complianceaccordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.

hj) PIMW must not be in transport for more than ten (10) calendar days.

ik) This Subpart does not apply to the U.S.United States Postal Service.

jl) Each transporter of PIMW required to have a permit under Section 56.1(f) of the Act must file a report annually with the Agency specifying the quantities and disposition of PIMW transported during the previous calendar year. These reports must be on forms prescribed and provided by the Agency. *Commencing March 31, 1993, and annually thereafter, each transporter of PIMW required to have a permit under subsection (f) of Section 56.1 of the Act shall file a report with the Agency specifying the quantities and disposition of PIMW transported during the previous calendar year. Such reports shall be on forms prescribed and provided by the Agency.* (Section 56.3 of the Act)

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

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

SUBPART C: TREATMENT FACILITIES

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 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~~located site at which the facility is to be~~.

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;

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~~) 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 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 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 PIMW containers or facility equipment (e.g., carts, squeegees, or shovels) thatwhich 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 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

ANo person must notshall cause or allow the disposal of any PIMW whenwhere 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 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 person must notshall falsely certify that PIMW has been treated in complianceaccordance 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 successfulSuccessful 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 with Section 1422.124.

B) Successful completion of a Periodic Verification Test must complybe 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) *Each~~Commencing March 31, 1993, and annually thereafter, each~~ treatment facility for which a permit is required* by~~pursuant to~~ 35 Ill. Adm. Code1420.105 shall annually 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 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~~deseribe~~ 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,~~names(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.

d~~e~~) 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~~ 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 ~~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 loads in Appendix A, Table C~~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 names~~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 Tests~~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 Actthereunder, but only to the extent that thesuch 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 whetherTo 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 mayshall 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 includeincludes, at a minimum, the following:

1) A summary of operating data, including results of the Initial Efficacy TestsTest(s) or Periodic Verification TestsTest(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 eachEach 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 applicable manufacturer's recommendations, and Standard Methods for the Examination of Water and Wastewater, (seeincorporated by reference at 35 Ill. Adm. Code 1420.103).

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

d) Process theThe 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 disinfectantdisinfectant(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 disinfectantdisinfectant(s).

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

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

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

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

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

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

If Log N1A is less than 6, then the number of viable test microorganisms introduced into the treatment unit must be increased and steps (a) through (f) in Phase 1 must be repeated until Log N1A is $\geq$6. NoA is the inoculum size for

challenge load Type A in Phase 2 below.

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

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

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

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

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

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

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

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

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:

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

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

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

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

d) Repeat steps (a) through (c) in this option for challenge loads Types B and C identified in 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 = Log No - 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 ($\geq$ 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_____)