ILLINOIS POLLUTION CONTROL BOARD
March 25, 1993

IN THE MATTER OF:	)	
	)	
POTENTIALLY INFECTIOUS MEDICAL WASTE (PIMW): TREATMENT, STORAGE, AND TRANSFER FACILITIES and TRANSPORTATION, PACKAGING, AND LABELING (35 Ill. Adm. Code 1420, 1421, and 1422)	)	R91-20 (Rulemaking)

Proposed Rule. Second Notice.

OPINION AND ORDER OF THE BOARD (by R.C. Flemal):

This matter comes before the Board upon the mandates of the Illinois General Assembly that the Board 1) adopt rules regulating facilities for the treatment, storage, and transfer of potentially infectious medical waste (PIMW) and 2) adopt standards for the transportation, packaging, and labeling of PIMW[1]. Today the Board adopts for second notice amendments to 35 Ill. Adm. Code Part 1420 and new Parts 1421 and 1422 intended to meet these legislative mandates.

Today's second notice proposal closely follows the first notice proposal[2], which in turn closely follows the recommendations of the Governor's Medical Waste Tracking Study Group (Study Group) as that group's consensus recommendations have been presented to the Board in the proposal submitted by the Illinois Environmental Protection Agency (Agency).

The Board will not in today's opinion repeat the lengthy background materials that were presented in the first notice opinion; the interested reader is directed to the first notice opinion for this material. Rather, today the Board focuses solely on the issues raised in regard to the first notice proposal and the Board's response to these issues.

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[1] The mandates occur at Section 56.2 of the Illinois Environmental Protection Act, 415 ILCS 5/1 et seq. (formerly Ill. Rev. Stat., ch. 111½, par. 1001 et seq.).

[2] IN THE MATTER OF: POTENTIALLY INFECTIOUS MEDICAL WASTE (PIMW): TREATMENT, STORAGE, AND TRANSFER FACILITIES and TRANSPORTATION, PACKAGING, AND LABELING (35 Ill. Adm. Code 1420, 1421, and 1422), R91-20. Adopted by order of the Board on December 3, 1992. Publication of Part 1420 occurred at 16 Ill. Reg. 19625 (Dec. 18, 1992), Part 1421 at 16 Ill. Reg. 19615 (Dec. 18, 1992), and Part 1422 at 16 Ill. Reg. 20002 (December 28, 1992).

PUBLIC COMMENTS

Fourteen public comments (PC) have been filed regarding the first notice proposal. These are as follows:

PC	Author
#26	Metropolitan Water Reclamation District of Greater Chicago, by Cecil Lue-Hing
#27	Medical SafeTec, by William D. Farrington
#28	ABB Sanitec, Inc., by Suzanne E. Helton
#29	Sexton Environmental Systems, Inc., by Erich H. Pearson
#30	Isolyser Company, Inc., by Francis W. Stanton
#31	Administrative Code Division, Office of the Illinois Secretary of State, by Connie Bradway
#32	Mediclean Technology, Inc., by Joel A. Schulman
#33	City of Chicago Law Department, by Maribeth Flowers
#34	Illinois Hospital Association, by Ann Guild
#35	Stericycle, Inc., by Linda D. Lee
#36	National Solid Waste Management Association (NSWMA), by Jean Furlan
#37	Dr. Van Allen Anderson, Director, Division of Environmental Health and Safety, University of Illinois at Urbana-Champaign
#38	Ecomed, Inc., by Joseph H. Wilson
#39	Illinois Environmental Protection Agency (Agency), by Susan Schroeder

Most of the public comments are directed to the substance of the proposed rules, in many cases in response to questions posed by the Board at first notice regarding particular provisions of the proposed rules. These comments are discussed below, according to the section of the proposal to which they are addressed.

The comments of the Administrative Code Division (PC #31) address required form changes. All the changes noted by the

Administrative Code Division have been incorporated into today's second notice proposal.

All references to the Illinois Revised Statutes have also been amended by addition of the parallel citation to the Illinois Compiled Statutes. Additionally, several inadvertent occurrences of the phrase "owners and operators" have been changed to "owners or operators", which is the appropriate regulatory construct.

DISCUSSION BY SECTION

Definitions (Section 1420.102)

Low-level disinfection. The Agency recommends deletion of the definition of "low-level disinfection", noting that the term is not used in the proposal as presented at first notice. (PC #39 at 1.) The Board accepts this recommendation, and the term is accordingly deleted.

PIMW -- test kits. In response to a question regarding whether discarded unused test kits should be considered PIMW, the Board in the first notice opinion proposed that any waste containing blood components was PIMW:

> As a general rule, a waste is not a PIMW if it has no infectious potential and is otherwise not explicitly identified in the statutory definition of PIMW . . . It follows that an unused medical test kit, where the test kit is not in whole or part a culture or stock, an unused sharp, contains blood components, or somehow otherwise covered under the statutory PIMW definition, is not PIMW. (First notice opinion at p. 22, emphasis added.)

The Agency and Dr. Anderson contend that a discarded unused test kit that contains blood components should not be considered to be PIMW. The Agency observes that PIMW is by statutory definition waste generated in connection with: (1) the diagnosis, treatment or immunization of human beings or animals; or (2) research pertaining to the provision of medical services; or (3) provision or testing of biologicals. (PC #39 at 2.) The Agency further observes that unused test kits that contain blood components should not be regulated as PIMW since they are not generated in connection with any of these situations. (Id.) Dr. Anderson also observes that the blood components in test kits have been sterilized, and as such have no infectious potential. (PC #37 at 1.) These points with regard to unused test kits are well taken, and the Board accordingly today recedes from its prior proposed position on this matter.

Registered professional land surveyor and engineer. The definition for the term "registered professional engineer" has been amended to include the correct proper short name of the act cited, pursuant to the use of the short names in the Illinois Compiled Statutes. The term "registered professional land surveyor" has been deleted because it is not used (see discussion of Section 1420.105, below).

Reusable container. Stericycle, Inc., recommends deletion of the word "smooth" from the definition of "reusable container", observing that "smooth" would otherwise need to be defined. Stericycle also contends that inclusion of "smooth" might unnecessarily preclude the use of some containers made from recycled plastic. (PC #35 at 1.) The Board accepts this recommendation, and the word is accordingly deleted.

Site. The definition of "site" has presented one of the more difficult parts of this regulation, as is witnessed by the number of comments generated on this topic, both prior to and during the first notice comment period. The latter include the comments of ABB Sanitec, Inc. (ABB), the Illinois Hospital Association (IHA), Stericycle, Inc. (Stericycle), the National Solid Waste Management Association (NSWMA), Dr. Van Allen Anderson, and the Agency.

In the Board's previous opinion and order, the Board addressed the comments received prior to first notice, and a draft proposed definition was given. That proposed definition, found at Section 1420.102 is:

> "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 THIS ACT OR REGULATIONS THEREUNDER. (Section 3.43 of the Act). For the purpose of this Subtitle, each campus of an educational institution is considered to be a single site.

Several commenters continue to voice concern that the first notice proposal's definition of site is insufficient to allow flexibility in determining the nature of a site, especially in the case of hospitals. (PC #28 at 1; PC #34 at 1; PC #35 at 1; PC #36 at 1) Prior to first notice, NSWMA asked the Board to propose a definition that NSWMA had submitted:

> (1) Except for an institution of higher education owned or operated by the state of Illinois, all buildings, equipment, structures, and other stationary items which are <u>located on a single property or on contiguous or adjacent properties</u> and which are owned or operated by the same person (or by any person which

> controls, is controlled by or under common control with, such person);
>
> (2) In the case of an institution of higher education owned or operated by the state of Illinois, all buildings, equipment, structures and other stationary items located within the same county which are owned and operated by the institution of higher education. (PC #36; Exh. 53). (emphasis added).

That language is again presented to the Board by NSWMA and supported by ABB and Stericycle. The IHA supports some of the language of NSWMA, with modifications. IHA again expresses concern about the regulation of hospitals, which can have differing ownership and control arrangements.

The Board elects not to use the modifications suggested by NSWMA and IHA, for the reasons stated in the Board's previous opinion, and because the concepts are already embodied in the Act and these proposed regulations. The NSWMA definition is more restrictive since it contains the requirement that the structures, etc., be on contiguous or adjacent properties. Such location requirement goes beyond the current definition of site. The Board believes that the current definition of site would provide sufficient flexibility regarding location, without any changes.

In addition, the NSWMA definition contains the concept of ownership by a person. "Person" is already defined in the Act, and as such the definition is applicable to these regulations. To make the connection more clear, the Board today adds the definition of "person" from the Act to these regulations as follows:

> "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 3.26 of the Act)

It is probable that a hospital would be considered a person under this definition.

A reading of the definitions of person and site, and the exceptions found in the Act and repeated at Section 1420.105, shows that many hospital situations would not be overregulated as feared by IHA. The exceptions are in pertinent part:

Section 1420.105 Permit and Manifest Requirements and Exceptions

* * *

c) A person who conducts a PIMW treatment, storage, or transfer operation 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) of the Act)

* * *

e) Any person who transports PIMW 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

* * *

Regarding permits, the requirement for a treatment, storage, or transfer facility permit, pursuant to Section 1420.105(c)(1), may be excepted, if a "person" is conducting an operation for PIMW generated by that person's own activities and the wastes are treated or stored on the site where the PIMW is generated. Also, the exemption in the proposal found at Section 1420.105(c)(2), specifically for hospitals, is not limited to a particular site as in (c)(1). This means that hospitals that treat their own PIMW or PIMW generated by its medical staff are also exempted from the permit requirement.

The statutory exemption of Section 56.1(h) of the Act pertaining to manifesting requirements, contained in these regulations at Section 1420.105(e), uses plural "sites" in addition to the singular "site". This usage acknowledges the potential for multiple sites controlled by the same person. A hospital with multiple sites under common control would not be

required to manifest, pursuant to subsection (e)(1). The issue here is what "person" encompasses rather than what site is.

In addressing these issues, the Board cautions that it is not possible to cover each and every situation under a definition. For that reason the IHA suggested that the Agency be given discretion in determining what a site is based on certain criteria. The Board believes that the Agency, in the course of administering this program and in applying rules of the Board to particular situations, will most likely conclude what each site is based on these regulations. The Board does not believe any express authority is necessary to give the Agency powers it already possesses and exercises. This is not to say that there exists any implied delegation of authority, for we are not stating that the Agency can determine what defines a site.

Unrecognizable. In its first notice opinion the Board at page 26 discussed the addition, based upon an Agency recommendation, of the phrase "or perceived as usable" within the definition of "unrecognizable". The definition would thus have read:

> "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, or perceived as usable, for its intended purpose.

This addition was not included in the text of the rule. The Agency now contends, and the Board agrees, that the addition should not be adopted because of indeterminacy that the concept of perception would introduce into the definition. (PC #39 at 5.)

Also at first notice the Board discussed the encapsulation and solidification process of Isolyser Company, Inc., as a method for the treatment of sharps. (First notice opinion at p. 25.) The Board stands behind that discussion. However, based upon that discussion Isolyser now asks that "encapsulating - solidifying" be specified in the definition of "unrecognizable" as an example of physical alteration. (PC #30 at ¶1.) This the Board declines to do. The Board does not believe that the record supports a blanket endorsement of all processes that involve encapsulation or solidification.

Incorporations by Reference (Section 1420.103)

The Agency requests that the citation to the reference "Standard Methods for the Examination of Water and Wastewater" be updated from the 17th Edition, 1989, to the 18th Edition, 1992. This change is today made. (PC #39 at 4.)

Prohibitions (Section 1420.104)

Disposal of sharps. Stericycle, Inc., requests clarification regarding the issue of sharps disposal, as referenced at Section 1420.104(a). (PC #35 at 2.) Stericycle notes the absence of a requirement that sharps be rendered "unrecognizable" before disposal in a landfill. In addressing Stericycle's concern, the Board notes that there are two portions of the Illinois Environmental Protection Act and one section of the proposed regulations that address this issue. The first is the definition of PIMW[3] at Section 3.81(b) of the Act:

> (b) Potentially infectious medical waste does not include:
>
> * * *
>
> (3) sharps that meet both of the following conditions:
>
> (A) the infectious potential has been eliminated from the sharps by treatment; and
>
> (B) the sharps are rendered unrecognizable by treatment.

This definition thereby establishes that sharps that have had their infectious potential eliminated and have been treated and are rendered unrecognizable no longer meet the definition of PIMW.

It is further established at Section 56.1(a) of the Act that:

> No person shall:
>
> (a) cause or allow the disposal of any potentially infectious medical waste. Sharps may be disposed in any landfill permitted by the Agency under Section 21 of this 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:

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[3] The same definition is repeated at Section 1420.102 of the instant proposed regulations.

(A) Board regulations; or

(B) subsection (b)(2), until Board regulations relating to the packaging of potentially infectious medical waste are adopted and effective.

(emphasis added.)

The reference to sharps in this section is contained in an exception to the prohibition of disposal of PIMW in landfills. Pursuant to Section 3.81(b)(3), sharps that are unrecognizable and treated are not PIMW at the time of disposal. Thus, Section 56.1 applies only to those sharps that remain PIMW after treatment (i.e. sharps that have not been rendered unrecognizable).

Read together, these two sections of the Act therefore establish that there are two pathways by which sharps may ultimately be disposed. The first is to package, treat, and render unrecognizable the sharps. After this processing, the sharps are not considered to be PIMW and may be disposed of like any solid waste. However, if the sharps are packaged and treated appropriately but are not rendered unrecognizable, those sharps may still be landfilled under the exception provided in Section 56.1 of the Act.

This dual disposal pathway is reflected in the recommendation of the Illinois Medical Waste Study Group, the Agency's proposal, and the instant proposal at Section 1422.126:

Section 1422.126 Sharps

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

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

b) Have been:

1) Packaged, marked, and labeled in accordance with Part 1430, Subparts C and D;

2) Delivered by a transporter with a PIMW hauling permit as required by Section 1420.104 of this Subtitle, unless specifically exempted.

3) Accompanied by a PIMW manifest as required by Section 1420.104 of this Subtitle, unless specifically exempted.

(emphasis added)

The "or" in subsection 1422.126(a) indicates that either route is an acceptable handling of sharps. Therefore, the Board finds that the existing language of Section 1420.104(a) is a correct use of the statutory language and declines to append Stericycle's suggested language regarding unrecognizability.

Transportation permit. Stericycle, Inc., raises the question of whether Section 1420.104(c) should be applicable to companies transporting waste from Illinois without transfer, storage, or treatment. (PC #35 at 3.) Stericycle also suggests that a specific exemption from treatment, storage, and transfer permits be provided at Section 1420.105 for companies that do not treat, store, or transfer PIMW within Illinois (Id.).

The Board notes that the issue of applicability of the instant regulations to persons who conduct only part of their activities within Illinois is addressed at Section 1420.101:

1420.101 Scope and Applicability

a) This Subtitle 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.

(emphasis added.)

If the activity (transfer, storage, treatment) does not occur in any part within the state, the requirement for the appropriate permits does not apply, pursuant to Section 1420.101. Specific exemptions are not required to clarify this issue.

Cleaning residues. At first notice at the recommendation of the Metropolitan Water Reclamation District of Greater Chicago (MWRDGC) the Board added a provision found at Section 1420.104(l) that prohibits the discharge of PIMW into sewers. The MWRDGC additionally asks that an explicit reference be added at several subsequent portions of the PIMW[4] regulations identifying that cleaning residues from PIMW treatment are also prohibited from discharge into sewers; MWRDGC "is concerned that these wastes could contain, in part at least, the same inert or solid PIMW

[4] Sections 1421.121(f), 1421.141(f), 1422.111(a)(9), and 1422.122(b)(1).

prohibited from discharge under Section 1420.104(l)". (PC #26 at 2.)

The Board believes that the prohibition at Section 1420.104(l) should be sufficient to address the consideration raised by the MWRDGC, as far as the instant regulation is concerned.

The Board also notes that it today changes the "Board Note" that follows Section 1420.104(l) and is repeated at other similar parts of the regulations[5] to read "Interested persons should note that discharges to sewer systems can also be regulated by units of local government." This change is made to clarify that it is units of local government that may also have regulations relating to discharges to sewer systems.

Permit and Manifest Requirements and Exceptions (Section 1420.105)

A new subsection (a) is inserted today that make explicit that the permit provisions of Section 39 and 40 of the Illinois Environmental Protection Act apply to PIMW permits. This specification is requested by the Agency. (PC #39 at 13-18.) This changes requires relettering of the remaining subsections of Section 1420.105.

The language of subsection (d) is also today modified to conform to the additions made at Sections 1422.105 through 1422.107 (see following discussion).

Both ABB Sanitec, Inc., (PC #28 at 1) and Isolyser Company, Inc., (PC #30 at ¶4) request clarification of how the permit requirements of Section 1420.105(c) cover mobile treatment units[6]. The Board's reads the Act at Section 56.1(g), from which the Section 1420.105(c) language is repeated, as requiring a permit for a mobile treatment unit, unless operation of the unit somehow falls under the exceptions listed at Section 56.1(g); each possible exception would have to analyzed on a case-by-case basis. The generator of PIMW who treats, stores, or transfers PIMW -- whether using the services of a mobile treatment unit or otherwise -- is similarly required to have a permit, unless qualifying for an exception under Section 56.1(g).

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[5] Sections 1421.121(f), 1421.141(f), 1422.121(f), and 1422.141(f).

[6] A mobile treatment unit is a treatment facility that travels between PIMW generators to treat PIMW onsite.

Cleaning and Disinfection (Section 1420.107)

Use of abbreviations. The Agency recommends that the terms "liter" and "milliliter" as used at Section 1420.107(a)(2)(C) be written out rather than abbreviated so as to eliminate possible confusion over the meaning of the abbreviated forms. (PC #39 at p. 18.) This recommendation is accepted.

Hypochlorite concentration. Stericycle, Inc., also requests clarification as to whether the concentration of hypochlorite cited is intended to be 50 ppm or 500 ppm. (PC #35 at 3.) The intended concentration is 50 ppm, the number used in the Agency proposal and at first notice. (See Tr2[7]. at 64 and 243-5.)

Packaging Standards and Criteria (Section 1421.121)

At first notice the Board proposed the requirement that packaging of oversized PIMW be done in a manner "so as to avoid contact with transportation workers and the public". This language was chosen to impart a high degree of specificity to the requirement.

Dr. Anderson recommends that the wording be "that minimizes contact with transportation workers and the public". He observes that this was the language originally recommended by the Agency and Study Group, as well as the language retained at first notice in the parallel construction found in the transportation subpart at Section 1421.141(b). (PC #37 at 1.) Dr. Anderson observes:

> The wording "that minimizes" was chosen to provide flexibility in the handling of oversize wastes that cannot be packaged in a conventional sense (e.g., boxed) to totally avoid contact with transport workers. A specific example of such a waste would be large animals "inoculated during research, production of biologicals, or pharmaceutical testing with agents infectious to humans" (See definition of Animal Waste, Section 1420.102). The carcasses of these animals are considered PIMW. Trying to "package" a large animal carcass would increase the handling of the carcass, thereby increasing contact with the material. Other types of oversized PIMW could be equally difficult to "package". (PC #37 at 1-2.)

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[7] Citation to the pages of transcripts are in the same form today as used at first notice. That is, the inquiry hearing are in the form "Tr1. at ____"; citations to the transcripts of the merit hearings, which are consecutively numbered, are in the form "Tr2. at ___".

The Board accepts Dr. Anderson's observations, and today uses the "that minimizes" construction at Section 1421.121(c).

Labeling and Marking (Section 1421.130)

Stericycle, Inc., requests clarification as to whether the "unique identification number" described at Section 1421.130(a)(2) is one assigned to a full trailer on the date that the trailer is removed from the generator. (PC #35 at 4.) Stericycle observes that this interpretation would "eliminate the need for labeling each container on the trailer with a shipment date" (Id.).

The concept behind the "identification number" is indeed intended as Stericycle conceives it. The Agency addressed this matter at hearing in the testimony of Dr. Shirley Baer:

> The use of a unique identification number for the shipment date was recommended by Mr. Karls (Attachment 13). It is common for a truck to be parked in a specific location at a hospital ... Essentially the truck acts as a storage unit at the hospital. Once the truck is full, the PIMW is transported off-site ... It would be burdensome, as well as costly, to mark each outer container with the shipment date, since it would probably require [rehandling of each individual PIMW .parcel]. (Tr2. at 97-8.)

Transportation Requirements (Section 1421.141)

Manifests. The Environmental Protection Act sets out various requirements of PIMW handlers that are met through the use of manifests. Most specifics regarding the form and use of these manifests are either statutory or statutorily within the purview of the Agency[8]. This notwithstanding, the Board at first notice raised the issue of whether, for the sake of clarity within the instant proposal, some additional presentation of the use of manifests is needed in the proposed rule. None of the commenters have risen to this issue[9], which the Board accepts as endorsement of the manifest provisions as presented at at first notice.

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[8] See, for example, the Act at Sections 56.1(d)(2), 56.1(h), and 56.4,

[9] The Agency has presented an addendum to its view of how the manifest system in intended to work on pages 19-20 of its public comment (PC #39). Interested persons are directed to this document.

NSWMA requests that the term "manifest" be replaced with the term "shipping paper", wherever the former appears in today's rule, so as to distinguish it from the manifests required under some federal law. (PC #36 at 3.) The Board sympathizes with problems arising from different meanings applied to the same word. However, "manifest" is the term used for shipping paper in the PIMW statute (see 415 ILCS 5/Subtitle XV), and references in today's proposal are to this same statutory manifest. The Board is not empowered to alter the use in the statute, and believes it unwise to use a term in the regulations different from that used in the statute.

Dedicated vehicles. As proposed at first notice the regulations at Section 1421.141(i) contain a prohibition against the transportation of non-PIMW materials in vehicles otherwise used to transport PIMW. However, the Board did, based upon concern from trucking interests, request comment on whether alternating of loads might be made permissible under some circumstances (e.g., backhauling if preceded by decontamination). Sexton Environmental Systems, Inc. (PC #29 at 5), Stericycle, Inc. (PC #35 at 4), and the NSWMA (PC #36 at 2) each responded in opposition to any exception beyond those already specified within 1421.141(i). On this basis the Board does not today alter the language of the first notice proposal.

Permit Applications (Sections 1422.105 through 1422.107)

At first notice the Board raised an issue concerning the need for further specificity and clarification in the regulations regarding the procedures for, and contents of, applications for permits for treatment, storage, or transfer operations. (First notice opinion at p. 18-19.) The Agency in response (while questioning the need for specificity) has submitted recommended provisions addressing these application requirements. (PC #39 at 5-12.)

Today's proposal contains new Sections 1422.105, 1422.106, and 1422.107 that respond to the Agency's recommendation. The additions are gathered into three new sections for the purpose of organizational clarity.

The specific language in these sections in large measure draws upon the Agency's recommendations. However, there are some suggested requirements in the Agency comment that are not utilized in the Board's proposed regulations because they could constitute new showings or restrictions not previously "aired" in this rulemaking. Examples include certain location standards and mapping requirements that would not apply to PIMW facilities unless those requirements are already mandated elsewhere, such as in other regulations.

Storage Requirements (Section 1422.111)

"Elevated" storage. Stericycle, Inc. (PC #35 at 4), inquires of the meaning of the word "elevated" used in the requirement of Section 1422.111(b)(3):

> Cardboard packages must be elevated and stored in an enclosed area.

This issue was addressed in the testimony of the Agency as presented Mr. Theodore Dragovich:

> Cardboard packages must be elevated during storage to insure that their structural integrity is not compromised by moisture resulting from spills or normal housekeeping activities, such as floor mopping. ... If packages are stored directly on the floor, the opportunity for contact with moisture is much higher than in situations where the packages are elevated. (Tr2. at 167.)

"Elevated" is accordingly equivalent to "above the floor". To insure that this meaning is clear to all, the Board today revises Section 1420.111(b)(3) as follows:

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

Personnel training. As regards the personnel training requirement of Section 1422.111(b)(8)[10], ABB Sanitec, Inc., contends that not all personnel at a PIMW storage facility (e.g., clerical staff) would seemingly need PIMW training. (PC #28 at 2.) The Board disagrees. Every employee of a PIMW facility should be made aware of at least the basic guidelines of PIMW management. This is not, however, to say that all personnel need to receive the same depth of the training. As the Agency observed in presenting the rationale for this training provision:

> The amount of training involved depends upon the person's job but must be adequate to insure that they can safely perform their job, avoid occupational exposure and respond properly during emergency situations. (Tr2. at 170.)

Stericycle, Inc., also inquires whether the personnel training requirement of Section 1422.111(b)(8) applies only to permitted facilities. (PC #35 at 4.) The answer is "yes".

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[10] The same question is raised by ABB with regard to proposed Section 1422(c)(3); the Board's response is the same.

Section 1422.111(b) specifies that "storage operations required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle must also comply with the following requirements . . ." Subsection (b)(8) is one of these requirements.

Time limit for storage. Section 1422.111(b)(12) sets limits[11] on the time that PIMW may be stored. Stericycle, Inc., noting that an intent of this provision is to avoid putrescence, questions whether it is necessary to prescribe a storage time limit as long as the waste has not become putrescent. (PC #35 at 4.) The Board believes that the time limit is necessary to avoid common occurrences of putrescence; setting the test for continued storage at the presence of putrescence would surely and needlessly increase the instances of PIMW being kept until it became putrescent. Moreover, the purpose of the storage time limit is broader than just avoidance of putrescence. It is also intended to prevent indefinite storage from being used as a means of disposal. (Tr2. at 173.)

Treatment Facility Certification (Section 1422.121)

Isolyser, Inc., reads Section 1422.121 as requiring a generator/treatment facility operator to supply a landfill with documentation of efficacy of the treatment unit; Isolyser contends that this is inappropriate. (PC #30 at ¶2.) The Board believes that Isolyser reads more into this section than has been intended. The crux of the provision at issue is that a treater of PIMW must be prepared to demonstrate to the disposer that the PIMW has been properly treated, including, if requested, data verifying efficacy of the treatment unit.

Nevertheless, the Board appreciates that clarification of this provision is appropriate. Accordingly, today the Board amends the second last sentence of the Section as follows:

> Data to verify the efficacy of the treatment unit must be made available to the receiving facility upon request of the receiving facility.

Treatment Facility Design and Operation (Section 1422.122)

Applicability of Section 1422.122 requirements. Stericycle, Inc., requests clarification of whether the requirements of this section apply only to permitted facilities or to anyone treating PIMW. (PC #35 at 5.) The answer is found at Section 1422.120,

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[11] The time limits specified are those recommended by the Illinois Medical Waste Study Group (Tr2. at 174): 72 hours for unrefrigerated PIMW and 30 days for refrigerated PIMW. It is further specified that either or both of these limits may be set differently by permit.

which is the Scope and Applicability Statement for the whole of Subpart C, including Section 1422.122. Pursuant to Section 1422.120 the Subpart C requirements apply to the owner or operator of any PIMW treatment facility.

Elimination of infectious potential. The first notice proposal at Section 1422.122(a)(1) provided an operational definition of the statutory phrase "eliminates the infectious potential of the waste":

> ELIMINATES THE INFECTIOUS POTENTIAL OF THE WASTE. Proof that the infectious potential is eliminated must be demonstrated by the Initial Efficacy Test and Periodic Verification Test(s), pursuant to Sections 1422.124 and 1422.125 of this Part. Mechanical treatment may only be conducted as an integral step of the treatment process.

However, given the large amount of concern generated by the general issue of the treatment standard (see first notice opinion at pp. 14-18, 34-40), the Board requested interested persons to focus on this definition (Id. at 18). Several commenters responded, including the National Solid Waste Management Association, which proposes alternative language of the following form:

> ELIMINATES THE INFECTIOUS POTENTIAL OF THE WASTE. The infectious potential is eliminated by treatment in a process that results in a 6-log reduction in vegetative organisms and, at a minimum, a 3-log reduction in bacterial spores as indicated by the Initial Efficacy Test and Periodic Verification Test conducted pursuant to Sections 1422.124 and 1422.125 of this Part. (PC #36 at 3).

Stericycle, Inc., proposes similar language, although it recommends a standard for bacterial spores of a 6-log reduction. (PC #35 at 5.) Ecomed, Inc., recommends that the first notice language be left intact. (PC #38 at 3.)

As it did at first notice, the Board affirms its intention to retain the treatment standards proposed by the Agency as reflected in the first notice proposal. The language proposed by NSWMA more clearly reflects those standards and more clearly articulates the specific standards that constitute elimination of infectious potential. For these reasons, the Board today replaces Section 1422.122(a)(1) with the language recommended by NSWMA.

Compaction and rupture exception. At Section 1422.122(a)(2) the first notice proposal contained the following language:

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

* * *

2) PREVENTS THE COMPACTION AND RUPTURE OF CONTAINERS DURING HANDLING OPERATIONS, except when the package is in a treatment unit;

The Board observed at first notice that the exception clause at the end of this subsection was based on the principle that:

> Mechanical treatment of PIMW is allowed only if it is an integral step in the treatment process; this is to minimize the dispersion of airborne particles (Tr2. at 33). (First notice opinion at p. 35.)

Both Stericycle, Inc. (PC #35 at 5), and the National Solid Waste Management Association (PC #36 at 3-4) observe that the language in the exception clause presents possible difficulties. NSWMA contends, for example, that emissions to the environment would not be excluded under the language in question.

The Board agrees with Stericycle's and the NSWMA's observations and today's amends Section 1422.122(a)(2) as recommended by the NSWMA as follows:

2) PREVENTS THE COMPACTION AND RUPTURE OF CONTAINERS DURING HANDLING OPERATIONS, except when <u>compaction or rupture is an integral part of the treatment process and the treatment process is conducted without discharge of PIMW to the environment</u> ~~the package is in a treatment unit~~;

<u>Recordkeeping requirements</u>. Stericycle, Inc., suggests that the recordkeeping requirements at Section 1422.122(c)(5) "seem to be somewhat redundant", and that they be at least partially deleted. (PC #35 at 5.) The Board disagrees. The requirements are fairly standard and of the type that have been useful in tracking wastes.

<u>Treatment Units (Section 1422.123)</u>

In the first notice opinion at pages 35-37 the Board discussed and expressed concern regarding the proposed provisions that address use of treatment units at permit-exempt treatment facilities. These provisions are found at Section 1422.123(b) of the first notice proposal, as follows:

* * *

b) A treatment unit may be used by a treatment facility not required to have a permit pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle, if

the requirements of subsection (b)(1) or (2) below are met.

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

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

   B) The treatment unit is mechanically identical to one previously permitted in Illinois for the treatment of PIMW, is operated under the same operating conditions and feed rate, and uses the same Periodic Verification Test method and frequency.

2) The Board has granted the owner's or operator's petition for an adjusted standard pursuant to 35 Ill. Adm. Code 106.Subpart G or a site-specific rulemaking pursuant to 35 Ill. Adm. Code 102. In considering a petition, the Board will determine whether the treatment unit meets, at a minimum, the standards of subsection (a)(1)-(5) of this Section.

The record shows that the Study Group and the Agency proposed these provisions to allow easy consideration for new technologies that do not fit the definition of chemical, thermal, or irradiation treatment. The Board supports this concept.

Several commentors have added additional perspective to the Section 1422.122(b) provisions. Among these are observations regarding the degree of oversight proposed for permit-exempt facilities. The City of Chicago, for example, is concerned that "municipalities could be burdened by the regulation of these unpermitted facilities if the State fails to adequately regulate these facilities' treatment units". (PC #33 at 2.) Ecomed, Inc., observes, in part to the concerns of the City of Chicago, that "[a]s the manufacturer of low cost on-site treatment technology, it is critical for us to be able to satisfy the permit requirements of specific units on a multi-site basis". (PC #38 at 1.) The Illinois Hospital Association encourages the Board to retain the Agency-proposed mechanism noting that although, "no specific permit would be required, there is still regulatory oversight by multiple state agencies. These [instant] rules specify operational parameters and require all operators to ensure that treatment units are operating effectively through monthly periodic verification tests." (PC #34 at 3.)

A second issue is that of the use of adjusted standards. The Agency expresses concern that "[i]t would be overly burdensome for the Board, industry and the IEPA to conduct adjusted standards for identical treatment units because the IEPA anticipates that thousands of identical treatment units will be used by the medical community". (PC #39 at 21.) The Board notes that the Agency appears to interpret citation to the adjusted standard procedure in this section as limited to site-specific adjusted standards. Although requests to the Board for adjusted standards have generally been of a site-specific nature[12], an adjusted standard can also be technology-specific, and that is the sort that the Board has envisioned here.

The Board emphasizes that it is sympathetic with the concerns of the Agency regarding the administrative burden of adjusted standards. An adjusted standard proceeding is resource consuming not only for the Board, but for the Agency and the petitioning party as well. Accordingly, reliance on the adjusted standard process must be contemplated with care that an unnecessary and onerous administrative burden is not created.

As a final matter regarding Section 1422.123(b), Dr. Anderson recommends alternative language (PC #37 at 2) that addresses many of the concerns raised by the Board at first notice and by the first notice commentors. The Board accepts this recommendation with some changes, and accordingly today substitutes the following language:

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

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[12] The statutory requirements governing the adjusted standard procedure are articulated at Section 28.1 of the Act. Section 28.1(a) allows the Board to grant an adjusted standard for persons who can justify such adjustment consistent with Section 27(a) of the Act. Section 27(a) requires the Board, among other things, to consider existing physical conditions, the character of the area, surrounding land uses, zoning classification, environmental conditions etc., when granting an adjusted standard.

By requiring the Board to grant adjusted standards consistent with Section 27(a), the statute requires the Board to consider the implications of certain site-specific conditions when granting an adjusted standard. However, the statute does not prohibit the Board from granting a technology-specific adjusted standard. As long as informational requirements are met to the extent applicable, a technology-specific adjusted standard may be granted.

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

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

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

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

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

Initial Efficacy Test (Section 1422.124)

Waiver of test. Stericycle recommends that today's proposal contain a provision that would allow the Agency to waive the Initial Efficacy Test where a treatment unit could be shown to meet the more stringent efficacy standards of another state. (PC #35 at 6.) This the Board declines to do. Aside from problems of whether this would constitute an unacceptable delegation of authority to another state, there is no adequate record before the Board upon which the Board could find that the requirements of any other state are consistent with the requirements laid down in today's regulations.

Model number. Several commentors noted difficulties with equating "the same model number" with the concept of mechanical identity, as found at Section 1422.124(a)(2) of the first notice proposal. Isolyser, for example, notes that its treatment unit uses batch numbers rather than model numbers. (PC #30 at ¶5.) Both ABB Sanitec, Inc. (PC #28 at 2), and Ecomed, Inc. (PC #38 at 3), note that model number is an artificial construct of the manufacturer, and may have little relationship to the technology

involved. ABB Sanitec cites the example of a manufacturer differently numbering units depending upon how the units are house or mounted. (PC #28 at 2.) Ecomed observes that a manufacturer may choose to use different model numbers depending upon marketing outlet. (PC #38 at 3.)

The Board agrees that model number is only weakly associated with the concept of mechanical identity. Accordingly, the model number provision is today deleted.

Manufacturer's instructions. In its first notice opinion, the Board asked for clarification regarding the term "applicable manufacturer" found in first notice Sections 1422.124(e)(2) and 1422.125(b)(4). The Agency responded that the "methods to be used in culturing and enumerating the microorganisms are prescribed by the commercial or clinical laboratory providing the test and/or indicator microorganisms". (PC #39 at 22.) ABB and Ecomed each responded that the treatment unit manufacturer should supply the owner or operator with the necessary methods (PC #28 at 2; PC #38 at 3, respectively).

The Board defers to the Agency's interpretation as the authors of the subsections in question and accordingly today replaces the term "applicable manufacturer's recommendations" with "instructions provided by the supplier of the microorganisms".

Document of Initial Efficacy. At first notice the Board observed and questioned as follows:

> Section 1422.124(f) requires that the Document of Initial Efficacy Demonstration be prepared by and retained by the treatment facility. Since it is the manufacturer of a treatment unit that is responsible for conducting the Initial Efficacy Test, is this requirement reasonable?

Ecomed, Inc., observes that a copy of the Document of Initial Efficacy is obtainable from manufacturers. (PC #38 at 3.) The Agency further notes that "IEPA discussions and written correspondence with many treatment unit manufacturers" indicates that the Document of Initial Efficacy can easily be provided to an owner/operator. (PC #38 at 22.)

The Board notes that, pursuant to these comments, the Document of Initial Efficacy Demonstration is generally prepared by the manufacturer rather than the treatment facility. The Board has accordingly altered subsection (f) by deleting the phrase "prepared by", thereby requiring that the treatment facility only retain the Document of Initial Efficacy Demonstration. Thus, a treatment facility must take the

responsibility of obtaining the document from the manufacturer so that it is available at any time for reference and inspection.

Periodic Verification Test (Section 1422.125)

Commercially-available spore test kits. The Illinois Hospital Association proposes an addition at Section 1422.125(a) addressing the use of a commercially available spore test kit for periodic verification testing:

> Using a commercially available test kit which will demonstrate a 6-log reduction of the indicator microorganism using the relevant treatment process. Commercially available test kits must be used according to manufacturers instructions. (PC #34 at 4.)

It is the Board's understanding that the periodic verification test is to be performed with a spore test kit containing one of the indicator organisms given in Section 1422.Appendix B. The owner or operator of the treatment unit is responsible for determining that the test kit will show the appropriate spore reduction as related to the reduction of vegetative microorganisms in the Initial Efficacy Test. Because the manufacturer of a treatment unit will most likely determine the correlation between the Periodic Verification Test and the Initial Efficacy Test, the owner or operator should be able to refer to the manufacturer for recommendations regarding the appropriate commercial test kit and operating instructions. The Board also notes that because initial efficacy can be proven using a 6-log reduction of spores, nothing prohibits an owner or operator of a treatment unit from demonstrating periodic verification using a commercial test kit.

Incinerator alternative verification. The proposal at Section 1422.125(a)(3) provides an example of an alternative verification method (i.e., visual inspection of ash) applicable only to incinerators. The Illinois Hospital Association observes that "incineration is a common treatment method for PIMW" for which "the efficacy of treatment . . . is well established". (PC #34 at 4.) On this basis the IHA recommends that these regulations not require case by case Agency approval for visual ash inspection, and that periodic verification for incinerators be split out into a separate subsection. (Id.)

Ecomed, Inc., in contrast, recommends retention of the language as presented at first notice as the best method of assuring that new, innovative technologies can be accommodated. (PC #38 at 3.)

The Board is not inclined to provide blanket alternatives to periodic verification tests as suggested by IHA for incinerators. The standards established by these rules and the methods by which

compliance is determined are applicable to every treatment technology unless the owner, operator, or manufacturer can provide scientific data to prove otherwise.

Notification of results. IHA has expressed concern regarding the requirements of Section 1422.125(d):

> Results of the Period Verification Test(s) must be received, verified, and available for inspection by the Agency within two weeks of when the test was conducted, except in the case of when a Periodic Verification Test is used to confirm the failure of a treatment unit. In this case, the results of the Periodic Verification Test(s) must be received, verified, and available for inspection by the Agency within one week of when the test was conducted.

IHA notes that this subsection, read in conjunction with Section 1422.125(g), could be interpreted to require an owner or operator of a treatment unit to send the Agency the results of the Periodic Verification Test within two weeks of when the test was conducted. (PC #34 at 4.) The Board reads these subsections as requiring the owner or operator to receive the results (in the case where the test is analyzed elsewhere), verify the results, and make those results available to the Agency within two weeks. To clarify this point, the Board today changes the wording of Section 1422.125(d) as follows:

> Results of the Periodic Verification Test(s) must be received, verified, and made available for inspection by the Agency within two weeks of when the test was conducted~~., except in the case of~~ ~~w~~When a Periodic Verification Test is used to confirm the failure of a treatment unit~~. In this case~~, the results of the Periodic Verification Test(s) must be received, verified, and made available for inspection by the Agency within one week of when the test was conducted. Results of Periodic Verification Tests must be made available in accordance with the requirements of subsection (g), below.

"Log-reduction" efficacy standard. At first notice, the Board requested comment on whether a "log-reduction" or "log-kill" standard was appropriate for these rules. (First notice opinion at 17.) Extensive comment was filed on this issue, including by Sexton Environmental Systems, Inc. (PC #29 at 1-5), City of Chicago (PC #33 at 1), the National Solid Waste Management Association (PC #36 at 4), and Dr. Anderson (PC #37 at 3). All voice support for the "log-reduction" standard and calculations proposed by the Agency and by the Board at first notice. No comments supporting "log-kill" have been tendered during the first notice comment period. Accordingly, the Board

stands by its first notice decision to retain the standard and calculations proposed by the Agency.

Initial Efficacy Test Procedures (Section 1422.Appendix A)

Treatment efficacy standard. Based on the extensive record developed on the issue, the Board at first notice declined to alter the proposed efficacy standard to focus on bacterial spores, as was then recommended by Sexton Environmental Systems. (see first notice opinion at p. 15-16.) Dr. Anderson (PC #37 at 3), Ecomed, Inc. (PC #38 at 2), and the Agency (PC #39 at 23-28) add additional record on this matter, which further reinforces the Board's determination as proposed at first notice.

Substitution liquid. The dilution provisions of the Phase I of Option I provided at first notice that the dilutant be sterile saline solution or phosphate buffer solution. Medical SafeTec recommends that "tap water not be prohibited from selection as the substitution liquid. The use of tap water may not be appropriate in all instances, but neither should it be prohibited." (PC #27 at 2.) Ecomed, Inc., also observes that "[t]ap water is perfectly acceptable, as that is what the systems are going to use in normal operation". (PC #38 at 4.) The Agency now supports the use of any liquid because the "effect of the liquid will impact the quantity of microorganisms that will need to be used in Phase 2." (PC #39 at 23). Because the number of organisms recovered in Phase 1 must be greater than 6-log, any reduction of organisms by substitution liquid will require a larger inoculum prior to testing. The Board has accordingly altered this section of Section 1422.Appendix A to read:

> The container of test microorganisms and challenge loads must be processed together without the physical and/or chemical agents designed to kill the test microorganisms. For example, in treatment units that use chemical disinfectant(s) an equal volume of liquid (e.g., sterile saline solution (0.9%, volume/volume) ~~or,~~ phosphate buffer solution, or tapwater) must be substituted in place of the chemical disinfectant(s).

Alternative organisms. Mediclean Technology, Inc., requests that the Board allow submission of efficacy test data on other organisms of resistance equivalent to or greater than those listed in Section 1422.Appendix A, Tables A and B, as approved by an appropriate Illinois governmental agency. (PC #32 at 1.) The Board notes that the Agency addressed this issue at hearing, observing that "no alternatives will be permitted to [the] proposed rules since it was the consensus of the study group that all treatment technologies be evaluated by the same standards" (Tr2. at 231). The Board supports the Agency and the Study Group

position in this matter and will not modify the rule as requested by Mediclean.

ECONOMIC IMPACT

The Board is charged under the Act to take into account the technical feasibility and economic reasonableness of all regulatory proposals before it. (Act at Section 27(a).) Compliance can be achieved with existing technology, so the technical feasibility of reducing this type of pollution is not an issue in this proceeding. Therefore, by this discussion the Board examines the economic reasonableness of reducing this particular type of pollution by considering the information presented in the record on this topic.

In general, a small percentage of the testimony and comments address economic matters. A summary of that information is given below.

Affected Facilities and Costs

The record contains information on the facilities that generate medical waste as approximately: 2,500 health care facilities (including hospitals, long term care facilities, local health clinics), 24,000 physicians, 6,500 dentists[13], and 3,906 funeral directors. (Exh. 5[14] at 10, appendix 2). It is estimated that 103 Illinois colleges have programs that potentially generate medical waste. (Exh. 37 Att. 16). The Agency submitted a 63 page list of 1400 special waste haulers that may or may not opt to haul medical waste. A list of haulers who contacted the Agency requesting information on the requirements of commercial transportation of PIMW prior to submittal of the proposal was also included in the record (See, Exh. 37 Atts. 11 and 12). The Agency also states that there are currently seven off-site transfer/storage/treatment facilities permitted for PIMW by the Bureau of Land. There are 191 hospital incinerators and 148 sites and 88 ethylene oxide units at 56 sites currently permitted by the Bureau of Air. (See, Exh. 37 Atts. 14 and 15). All these facilities and businesses are estimated to be affected to some degree by these rules.

The Report to the Governor discusses costs of PIMW disposal as follows:

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[13] Robert A. Rechner, Illinois Dental Association, estimates that 7,000 dentists practice in Illinois. (Exh. 41).

[14] Report to the Governor, The Regulation of Potentially Infectious Medical Waste in Illinois, June 1991, Medical Waste Tracking Study Group.

> The Study Group recognized the problem of escalating health care costs and the increasing difficulty of access to health care. It is the intent of the Study Group that the effect of waste handling on health care costs be limited as much as possible.
>
> The cost to dispose of PIMW in Illinois depends on several factors and obviously will vary within the state. However, based on the waste management companies polled, a common pricing arrangement is to charge larger generators, such as hospitals, on a per pound basis and the smaller ones per pickup or per carton. A common conversion in comparing the weight and volume of PIMW is 4.5 to 5.0 pounds/cubic foot.
>
> * * *
>
> A May 1989 American Hospital Association estimate placed the range of costs for PIMW disposal for a 200 bed hospital to be between $63,000 and $173,000 per year. Other factors could increase costs such as the recent Clean Air Act amendments, regulatory changes, etc.
>
> (Exh. 5).

Throughout the hearing, members of the Study Group urged the Board to be sensitive to costs. (Exh 45 at 7; Tr1. at 109).

In addition, the NSWMA submitted a document it entitled an Economic Impact Analysis. NSWMA states that its intent and that of the Medical Waste Tracking Study Group has been to minimize cost impact the health care community in developing these regulations. NSWMA states that the proposed PIMW regulations will have little appreciable economic impact on currently regulated hospital generators. Although the PIMW regulations will expand the scope of generators regulated beyond the hospitals currently regulated, NSWMA states that these generators "should be able to reduce the collection fee and treatment cost burden by employing one of the several on-site treatment options, or by transporting the limited quantity of PIMW they generate to a hospital with which they are affiliated for treatment. NSWMA estimates that 40 to 50% of these newly regulated small quantity generators will be able to utilize on-site or off-site hospital treatment." (Exh. 37 Att. 10).

NSWMA gives other estimates of economic impact as follows:

> The economic impact for the estimated remaining 17,500 generators, who select commercial management of PIMW, should be negligible for two reasons. First, PIMW is defined by the new regulations in a way that permits generators to be more selective in the types of waste

requiring PIMW management. Overall, this should reduce the volume of PIMW. Second, increased competition has reduced the cost for commercial PIMW management, and this trend should continue.

(Exh. 37 Att. 10).

Finally, NSWMA estimates that efficient waste segregation, increased competition, and increased employee safety and awareness should all serve to reduce costs. (Exh. 37 Att. 10).

Robert A. Rechner of the Illinois Dental Society estimated that the costs of purchasing sharps containers and outer packages, and the pick-up fee increases costs to dentists approximately $25.00 per month. He also estimated that the periodic verification tests, assuming the tests were conducted monthly for one autoclave for 2 dentists in the state would result in costs of $4,410,000 for all the dentists in the state. (Exh. 41).

Cost-Benefit Analysis

The benefit to the rule, put most simply, is the lessening of the public health risks of infection from medical waste. The information in the record indicates that the costs associated with the proposed rule have been minimized to the extent possible.

In addition to the discussion above, it is worth noting that the costs of these rules would be additionally offset when compared with similar programs already in place at health care facilities. The Agency states that OSHA's Occupational Exposure to Bloodborne Pathogens Rule (29 CFR 1910.1030 (1991)) (Exh. 37 Att. 6) contains requirements for segregation, packaging, labeling, marking, transportation, storage, and treatment of regulated medical waste that meets or exceeds the requirements for these proposed rules. (Exh. 37 at 3).

The Board has considered the information in the record pertaining to the economic reasonableness of these rules, including comments, testimony, and exhibits. Actual dollar figures of the costs associated with these proposed rules has been difficult to ascertain from the record. However, the Board concludes that the record supports the finding that the instant rule will not be economically unreasonable.

ORDER

The Board hereby directs that second notice of the following proposed amendments to 35 Ill. Adm. Code 1420 and the following

new Parts 35 Ill. Adm. Code 1421 and 1422 be submitted to the Joint Committee on Administrative Rules.

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

PART 1420
GENERAL PROVISIONS

Section
1420.101 Scope and Applicability
1420.102 Definitions
1420.103 Incorporations by Reference
1420.104 Prohibitions
1420.105 Permit and Manifest Requirements and Exceptions
1420.106 Penalty Factor
1420.107 Cleaning and Disinfection
1420.120 Severability

AUTHORITY: Implementing and authorized by Sections 56.2~~(e)~~ and 27 of the Environmental Protection Act (Ill. Rev. Stat. 198991, ch. 111 1/2, pars. 1056.2~~(e), as added by P.A. 87-752 effective January 1, 1992~~, as amended by P.A. 87-1097, effective January 1, 1993, and 1027) [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 _____ Ill. Reg. _____, effective _____.

NOTE: Capitalization denotes statutory language.

1420.101 Scope and Applicability

~~a)~~This Subtitle 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.

~~b) This Part sets forth definitions that apply throughout this Subtitle except as specifically provided otherwise.~~

~~BOARD NOTE: Section 56.2(d) requires the Board to repeal pre-existing rules for handling medical wastes by January 1, 1992. Section 56.2(e) requires the Board to adopt by January 1, 1992 a list of Class 4 etiologic agents, which lends operative meaning to "isolation waste," as that term is used in the statutory definition of potentially infectious medical waste at~~

~~Section 3.81. Section 56.2(a) and (c) require the Board to adopt standards for the transportation, packaging, segregation, labelling, and marking of potentially infectious medical waste by January 1, 1993. Section 56.2(f) authorizes additional rules to promote the purposes of Title XV of the Environmental Protection Act (Ill. Rev. Stat. 1989 ch. 111½, par. 1001 et seq., as amended by P.A. 87-752, effective January 1, 1992).~~

Section 1420.102 Definitions

All definitions set forth in this Section ~~shall~~ have the following meanings throughout this Subtitle, unless specifically provided otherwise. Words and terms not defined have the meanings 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. 198991, ch. 111 1/2, par. 1001 et seq., as amended by P.A. 87-1097, effective January 1, 1993~~-752 and P.A. 87-650, both effective January 1, 1992~~) [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 the treatment of PIMW in a unit that uses disinfectants or chemicals as the primary means to eliminate the infectious potential of the waste. Examples of chemical treatment 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 other not yet defined)

Herpesvirus 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)

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 3.8~~1~~4(a)(6) of the Act and this Subtitle. This listing derives from the CDC document, "Classification of 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, 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 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" MEANS THOSE DISEASES IDENTIFIED AS CLASS 4 ETIOLOGIC AGENTS under this Part. (Section 3.8~~1~~4(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 the treatment of PIMW in a unit that uses ionizing radiation as the primary means to eliminate the infectious potential of the waste. Examples of irradiation treatment are gamma (cobalt 60) and electron beam.

~~"ISOLATION WASTE" MEANS DISCARDED WASTE MATERIALS CONTAMINATED WITH BLOOD, EXCRETIONS, EXUDATES, AND SECRETIONS FROM HUMANS THAT ARE ISOLATED TO PROTECT OTHERS FROM HIGHLY COMMUNICABLE DISEASES. (Section 3.81(a)(6) of the Act)~~

"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 3.26 of the Act)

"POTENTIALLY INFECTIOUS MEDICAL WASTE" 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 PROVISION OR TESTING OF BIOLOGICALS:

~~ANIMAL WASTE;~~

~~CULTURES AND STOCKS;~~

~~HUMAN BLOOD AND BLOOD PRODUCTS~~

~~HUMAN PATHOLOGICAL WASTES;~~

~~ISOLATION WASTE; AND~~

~~UNUSED SHARPS.~~

~~USED SHARPS;~~

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. "HIGHLY COMMUNICABLE DISEASES" MEANS THOSE DISEASES IDENTIFIED BY THE BOARD IN RULES ADOPTED UNDER SUBSECTION (e) 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 ~~THE FOLLOWING~~:

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. (Section 3.8~~1~~4 of the Act)

"Putrescence" means the partial decomposition of organic matter by microorganisms so as to cause malodors, gases, or other offensive conditions, or that 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 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 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. The sanitizer must be registered by the United States Environmental Protection Agency, as identified on its label.

"Sharps" mean unused sharps and used sharps as stated in the definition of 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 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 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 THIS ACT OR REGULATIONS THEREUNDER. (Section 3.43 of the Act). For the purpose of this Subtitle, each campus of an educational 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 3.46 of the Act)

"STORAGE SITE" means A SITE AT WHICH WASTE IS STORED. "STORAGE SITE" INCLUDES TRANSFER STATIONS. (Section 3.47 of the Act)

"Test microorganisms" means those microorganisms listed in Section 1422.Appendix A, Table A, as classified by ATCC.

"Thermal treatment" means the treatment of PIMW in a unit that uses elevated temperatures as the primary means to eliminate the infectious potential of 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 3.83 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 3.49 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.

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) (18th Edition, 1992).

Test Methods for Evaluating Solid Waste, Physical/Chemical Methods, EPA Publication SW-846 (Third Edition, 1986 as amended by Update I (November, 1990)). SW-846 and Update I are available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 783-3238,

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 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 Part 1421,Subpart C of this Subtitle.

c) 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 pursuant to Section 39 of the Act, UNLESS NO PERMIT IS REQUIRED pursuant to subsection 1420.105(c) of this Part.

d) 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 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 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 Part 1421, Subpart C of this Subtitle and Part 1422, Subpart B of this Subtitle.

f) 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 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) 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 pursuant with Section 39 of the Act, unless no permit is required 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 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) 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 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.

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

Section 1420.105 Permit and Manifest Requirements and Exceptions

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

b) A person who conducts a PIMW 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 POTENTIALLY INFECTIOUS MEDICAL WASTE AT ANY ONE TIME; OR

3) THE U.S. POSTAL SERVICE. (Section 56.1(f) of the Act).

c) A person who conducts a PIMW treatment, storage, or transfer operation 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) of the Act). 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. For example, transportation of PIMW interrupted by vehicle repairs or inclement weather does not constitute storage.

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

e) Any person who transports PIMW 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 FORE A NONCOMMERCIAL TRANSPORTATION ACTIVITY; OR

3) PIMW BY THE U.S. POSTAL SERVICE. (Section 56.1(h) of the Act)

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) 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 POTENTIALLY INFECTIOUS MEDICAL WASTE. (Section 56.1(k) of the Act)

Section 1420.107 Cleaning and Disinfection

a) Cleaning and disinfection comprises:

1) Washing with a solution of detergent used 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 United States Environmental Protection Agency, as identified on its label and used in accordance with the manufacturer's instructions;

C) Rinsing with, or immersion in, a hypochlorite solution at a concentration of 50 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 in accordance with the manufacturer's instructions.

Section 1420.120 Severability

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 as a whole or of any Section, subsection, sentence or clause thereof not adjudged unconstitutional, invalid or otherwise not effective for any reason.

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

Section
1421.101 Compliance Dates

SUBPART B: SEGREGATION

Section
1421.110 Scope and Applicability
1421.111 Standards and Criteria

SUBPART C: PACKAGING

Section
1421.120 Scope and Applicability
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SUBPART D: LABELING AND MARKING

Section
1421.130 Scope and Applicability
1421.131 Standards and Criteria

SUBPART E: TRANSPORTATION

Section
1421.140 Scope and Applicability
1421.141 Standards and Criteria

Section 1421.Illustration A

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

SOURCE: Adopted in R91-20, at _____ Ill. Reg. _____, effective _____.

NOTE: Capitalization denotes statutory language.

SUBPART A: GENERAL PROVISIONS

Section 1421.101 Compliance Dates

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

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.

Section 1421.111 Standards and Criteria

a) Generators 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 (in accordance with Subpart C of this Part) sharps with other waste, provided the mixture is managed in accordance with subsection (b) of this Section.

SUBPART C: PACKAGING

Section 1421.120 Scope and Applicability

This Subpart applies to persons who package PIMW for off-site transportation.

Section 1421.121 Standards and Criteria

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

1) RIGID;

2) LEAK-RESISTANT;

3) IMPERVIOUS TO MOISTURE;

4) OF A STRENGTH SUFFICIENT TO PREVENT TEARING OR BURSTING UNDER NORMAL CONDITIONS OF USE AND HANDLING; AND

5) SEALED TO PREVENT LEAKAGE DURING TRANSPORT. (Section 56.1(b)(2)(A))

b) Sharps must be packaged in a container, or a combination of containers, that is puncture-resistant and 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. 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 inside another container, or clean and disinfect the container in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle. In either case, the container or combinatior of containers must meet applicable requirements of subsections (a) or (b) of this Section.

e) Once a reusable container has been cleaned and disinfected in 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 accordance with Section 1420.107 of this Subtitle, it must be regulated as PIMW 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 accordance with 35 Ill. Adm. Code Subtitle C.

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

SUBPART D: LABELING AND MARKING

Section 1421.130 Scope and Applicability

This Subpart applies to persons who package PIMW for off-site transportation or who accept packages of PIMW from off-site.

Section 1421.131 Standards and Criteria

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

1) The generator 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 Section 1421.Illustration A of this Part and the word "Biohazard"; and

ii) The word "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 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.

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 Section 1421.Illustration A of this Part and the word "biohazard"; and

2) The word "sharps".

d) Containers 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 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 prior to shipment:

1) The generator 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 Section 1421.Illustration A of this Part and the word "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 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 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.

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 in accordance with 35 Ill. Adm. Code 1420.105 of this Subtitle.

Section 1421.141 Standards and Criteria

a) PIMW must be transported under conditions to minimize the effects of putrescence.

b) Packages of PIMW must be transported 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.

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 subject to stress that compromises the integrity of the container.

f) 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 accordance with 35 Ill. Adm. Code Subtitle C.

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

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

h) The transporter shall develop and keep an emergency response plan in the vehicle. This plan must identify the names and telephone numbers of state and local authorities who must be contacted in the event of an emergency or discharge. In the event of an emergency or discharge of PIMW, the transporter shall take immediate action in accordance 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.

i) Vehicles transporting PIMW must not be used for the hauling of non-waste materials, with 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 accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle.

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

k) This Subpart does not apply to the United States Postal Service.

l) 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)

Section 1421.Illustration A

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

PART 1422
DESIGN AND OPERATION OF FACILITIES

SUBPART A: GENERAL PROVISIONS

Section
1422.101 Compliance Date
1422.105 PIMW Permit Application Contents
1422.106 PIMW Permit Application Certifications
1422.107 PIMW Permit Application Filing Requirements

SUBPART B: STORAGE OR TRANSFER OPERATIONS

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

SUBPART C: TREATMENT FACILITIES

Section

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

Section
1422.Appendix A Initial Efficacy Test Procedures
Table A Test Microorganisms
Table B Indicator Microorganisms
Table C Challenge Loads
1422.Appendix B Correlating Periodic Verification Test Procedures

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

SOURCE: Adopted in R91-20, at _____ Ill. Reg. _____, effective _____.

NOTE: Capitalization denotes statutory language.

SUBPART A: GENERAL PROVISIONS

Section 1422.101 Compliance Date

Persons subject to this Part shall comply with its requirements by _____, 1993 (effective date).

Section 1422.105 PIMW Permit Application Contents

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

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

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

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

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

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

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

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

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

5) The days and hours of operation;

6) The operating parameters for the treatment units;

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

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

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

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

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

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

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

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

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

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

Section 1422.106 PIMW Permit Application Certifications

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

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

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

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

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

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

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

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

e) The applicant must state whether the facility is a new regional pollution control facility, as defined in Section 3.32 of the Act, which is subject to the site location suitability approval requirements of Sections 39(c) and 39.2 of the Act. If such approval by a unit of local government is required, the application must identify the unit of local government with jurisdiction. The application must contain any approval issued by that unit of local government. If

no approval has been granted, the application must describe the status of the approval request.

Section 1422.107 PIMW Permit Application Filing Requirements

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

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

SUBPART B: STORAGE OR TRANSFER OPERATIONS

Section 1422.110 Scope and Applicability

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

Section 1422.111 Design and Operating Standards and Criteria

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5) Adequate aisle space, as specified in the permit, must be maintained between packages to allow inspection of at least one (1) side of each package. Packages must be stacked so that labels are readable. A vehicle containing PIMW is exempt from the above aisle space requirement:

   A) When loading or unloading a vehicle; or

   B) When a fully-loaded vehicle is on a site.

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

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

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

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

9) Storage operations must have a written contingency plan and the applicable sections must be implemented in the event of a discharge or personal injury. The contingency plan must describe the actions that personnel shall take in response to emergency situations such as, but not limited to, personal injury, discharges of PIMW, rupture of plastic bags, and equipment failure. This contingency plan must, at a minimum, include a list of all emergency equipment at the storage operation, an up-to-date list of names, addresses and phone numbers (office and home) of all persons

qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue, repackaging of PIMW, and alternate arrangements for PIMW storage and transfer. A copy of the contingency plan must be maintained at the storage operation. Emergency phone numbers and a brief description of the emergency procedures must be posted at the storage operation.

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

A) Quantities and disposition of PIMW stored or transferred;

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

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

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

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

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

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

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

11) The records required by subsections (b)(8) and (10) of this Section must be retained by and kept at the storage operation and must be made available at the storage operation during normal

business hours for inspection and photocopying by the Agency. These records must be kept until closure of the storage operation. The retention period is extended automatically during the course of any unresolved enforcement action regarding the storage operation or as requested in writing by the Agency.

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

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

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

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

SUBPART C: TREATMENT FACILITIES

Section 1422.120 Scope and Applicability

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

Section 1422.121 Treatment Facility Certification

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

person shall falsely certify that PIMW has been treated in accordance with this Part.

Section 1422.122 Design and Operating Standards

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

1) ELIMINATES THE INFECTIOUS POTENTIAL OF THE WASTE. The infectious potential is eliminated by treatment in a process that results in a 6-log reduction in vegetative organisms and, at a minimum, a 3-log reduction in bacterial spores as indicated by the Initial Efficacy Test and Periodic Verification Test conducted pursuant to Sections 1422.124 and 1422.125 of this Part;

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

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

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

A) Designates responsibility to personnel;

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

C) Identifies monitoring devices;

D) Insures monitoring devices are operating properly;

E) Establishes appropriate ranges for all operating parameters;

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

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

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

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

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

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

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

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

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

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

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

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

4) COMMENCING MARCH 31, 1993, AND ANNUALLY THEREAFTER, EACH TREATMENT FACILITY FOR WHICH A PERMIT IS REQUIRED pursuant to 35 Ill. Adm. Code 1420.105 of this Subtitle and EACH FACILITY NOT REQUIRED TO HAVE A PERMIT pursuant to Section 1420.105 of this Subtitle THAT TREATS MORE THAN 50 POUNDS PER MONTH OF POTENTIALLY INFECTIOUS MEDICAL WASTE SHALL FILE A REPORT WITH THE AGENCY

SPECIFYING THE QUANTITIES AND DISPOSITION OF POTENTIALLY INFECTIOUS MEDICAL WASTE TREATED DURING THE PREVIOUS CALENDAR YEAR. SUCH REPORTS SHALL BE ON FORMS PRESCRIBED AND PROVIDED BY THE AGENCY. (Section 56.3 of the Act)

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

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

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

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

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

4) Treatment facilities must have a written contingency plan and the applicable sections must be implemented in the event of a discharge, equipment failure or personal injury. The contingency plan must describe the actions that personnel shall take in response to emergency situations such as, but not limited to, personal injury, discharges of PIMW, and equipment failure. This contingency plan must, at a minimum, include a list of all emergency equipment at the treatment facility, an up-to-date list of names, addresses and phone numbers (office and home) of all persons

qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue, alternative arrangements for PIMW treatment. A copy of the contingency plan must be maintained at the treatment facility. Emergency phone numbers and a brief description of the emergency procedures must be posted at the treatment facility.

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

A) Quantities and disposition of PIMW treated;

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

C) Date and time the PIMW was treated;

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

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

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

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

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

6) The records required by subsections (c)(3) and (c)(5) of this Section must be retained by and kept at the treatment facility and must be made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. These records must be kept until

closure of the treatment facility. The retention period is extended automatically during the course of any unresolved enforcement action regarding the treatment facility or as requested in writing by the Agency.

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

Section 1422.123 Treatment Units

a) A treatment unit must be:

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

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

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

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

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

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

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

A) The treatment unit utilizes a thermal, chemical, or irradiation treatment, as

defined in 35 Ill. Adm. Code 1420.102 of this Subtitle; or

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

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

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

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

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

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

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

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

Section 1422.124 Initial Efficacy Test

a) The manufacturer, owner, or operator of a treatment unit shall conduct an Initial Efficacy Test, pursuant to Appendix A of this Part, for each model prior to its operation. If significant mechanical changes are made to a treatment unit, the Initial Efficacy Test must be repeated. Treatment units are considered to be the same model if they:

1) Are manufactured by the same company;

2) Have the same capacity; and

3) Have no significant mechanical changes.

b) The Initial Efficacy Test must be conducted by the use of Options 1, 2 or 3 of Appendix A of this Part, and the challenge loads as described in Table C of Appendix A of this Part. If any of the challenge loads fails the Initial Efficacy Test, the operating conditions must be revised and the Initial Efficacy Test must be repeated for all challenge loads. The Initial Efficacy Test must also meet the requirements of this Section.

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

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

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

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

3) Option 3 can only be used for a thermal treatment unit that maintains the integrity of the container of indicator microorganism spores (e.g., autoclaving, incinerating). The log kill (L) of

indicator microorganism spores after treatment must be greater than or equal to six (6).

c) Composition of Challenge Loads

1) For treatment units designed to treat all types of PIMW, all three (3) types of challenge loads must be used in conducting the Initial Efficacy Test. The three (3) types of challenge loads represent PIMW with a high moisture content, low moisture content, and high organic content. The quantity of each challenge load must equal 100% of the maximum capacity of the treatment unit. Each challenge load must include, at a minimum, 5% of each of the following categories: blood/broth cultures, fibers, metals, sharps, plastics, pathological waste, glass, non-woven fibers, and bottles of liquids. Table C of Appendix A of this Part contains the moisture and organic content requirements that must be met in each type of challenge load.

2) For treatment units designed to treat only select categories of PIMW (e.g., a sharps treatment unit), a modification in the composition of the challenge load(s) may be used if approved by the Agency in writing.

d) The Initial Efficacy Test must be conducted under the same operating conditions under which the treatment unit operates on a day-to-day basis. The feed rate for the treatment unit must remain constant throughout the Initial Efficacy Test. This feed rate must never be exceeded during the operation of the treatment unit.

e) The Initial Efficacy Test must be performed so that:

1) Each container of test microorganisms and/or indicator microorganism spores is placed in the load to simulate the worse case scenario (i.e., that part of the load that is the most difficult to treat). For example, the worst case scenario for an autoclave would be to place the container of test microorganisms and/or indicator microorganism spores within a sharp container tha 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 accordance with instructions provided by the supplier of the microorganisms and Standard

Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.

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

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

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

3) A description of quality assurance/quality control procedures and practices for the culture, storage, and preparation of test and/or indicator microorganisms (including, but not limited to, organism history, source, stock culture maintenance, and enumeration procedures). The purity of the test microorganisms and/or indicator microorganism spores must be certified by a commercial or clinical laboratory;

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

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

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

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

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

Section 1422.125 Periodic Verification Test(s)

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

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

2) Correlating the log kill (L) of the test microorganisms in the Initial Efficacy Test to an equivalent log kill (T) of the indicator microorganism spores in accordance with Appendix B of this Part. The equivalent log kill (T) of the indicator microorganism spores must be used for all subsequent Periodic Verification Tests. The correlation must be done with the three (3) challenge loads identified in Table C of Appendix A of this Part. (See subsection (b) of this Section for further requirements); or

3) Submitting and obtaining written approval by the Agency for a procedure that is equivalent to subsection (a)(2) of this Section. Examples of alternatives include, but are not limited to, use of another indicator microorganism or measurement of disinfectant concentrations in the treated residue. For incinerators only, an example of an alternative is visually inspecting the ash from

each load of treated PIMW to insure that all PIMW within the load is completely combusted. The approval of an alternative by the Agency may require more frequent testing and/or monitoring of the treatment unit.

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

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

2) The fraction of surviving indicator microorganisms that correlates to a log kill (L) of six (6) for each test microorganism must be used in future Periodic Verification Test(s). (For example, if a log kill (L) of four (4) for the indicator microorganism spores per gram of waste solids is achieved during this demonstration, then a population of ten thousand (10,000) of the indicator microorganism must be used in all future Periodic Verification Test(s)). For future Periodic Verification Tests, the three challenge loads described in Appendix A, Table C, do not need to be used. The test microorganisms or indicator microorganisms spores must be placed in a representative load in accordance with Section 1422.124(e)(1) of this Part;

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

4) Test microorganisms and/or indicator microorganisms must be cultured and enumerated in accordance with instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater, incorporated by reference at 35 Ill. Adm. Code 1420.103.

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

c) If a load of PIMW fails a Periodic Verification Test(s), the Periodic Verification Test(s) must be

repeated. The operator shall implement the quality assurance program (in Section 1422.122 (a)(4) of this Part) and contact the manufacturer, if applicable, to identify and correct the problem(s) until the unit can eliminate the infectious potential of the PIMW. If the operating parameters are altered, another Initial Efficacy Test must be performed to demonstrate the effectiveness of the unit and, if applicable, another Periodic Verification Test correlation, pursuant to subsection (a) of this Section, must also be repeated. Loads of PIMW that were first processed prior to receiving results showing a failure of the Periodic Verification Tests are considered treated. A second Periodic Verification Test must be run immediately after the first Periodic Verification Test indicates a failure. The second Periodic Verification Test is to determine whether or not the treatment unit is eliminating the infectious potential of the waste. After the second Periodic Verification Test shows a failure of the treatment unit, the processed waste is considered PIMW and must be managed in accordance with this Subtitle.

d) Results of the Periodic Verification Test(s) must be received, verified, and made available for inspection by the Agency within two weeks of when the test was conducted. When a Periodic Verification Test is used to confirm the failure of a treatment unit, the results of the Periodic Verification Test(s) must be received, verified, and made available for inspection by the Agency within one week of when the test was conducted. Results of Periodic Verification Tests must be made available in accordance with the requirements of subsection (g), below.

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

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

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

with description of data handling, and a presentation and interpretation of final test results;

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

3) A description of quality assurance/quality control procedures and practices for the culture, storage, and preparation of test and/or indicator microorganisms (including, but not limited to, organism history, source, stock culture maintenance, and enumeration procedures). The purity of the test microorganisms and/or indicator microorganism spores must be certified by a commercial or clinical laboratory;

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

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

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

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

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

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

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

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

3) Test protocols;

4) Evaluation of test results; and

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

h) Periodic Verification Test(s) must be conducted under the same operating conditions under which the treatment unit operates on a day-to-day basis. The feed rate for the treatment unit is the maximum feed rate at which the unit operates on a day-to-day basis. The feed rate must remain constant throughout the Periodic Verification Test(s). This feed rate must never be exceeded during the operation of the treatment unit.

Section 1422.126 Sharps

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

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

b) Have been:

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

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

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

Section 1422.127 Experimental Permits

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

b) A valid Experimental Permit constitutes a prima facie defense to any action brought against the permit holder for a violation of the Act or regulations promulgated

thereunder, but only to the extent that such action is based upon the failure of the process or technique.

c) All Experimental Permits have a duration not to exceed two (2) years. These permits can only be renewed once.

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

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

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

2) A discussion of how the equipment performed;

3) A discussion of how residuals were managed; and

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

Section 1422.APPENDIX A INITIAL EFFICACY TEST PROCEDURES

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

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

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

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

b) Each test microorganism must be processed in separate runs through the treatment unit. Prior to each run, the number of viable test microorganisms in each container must be determined in accordance with

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

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

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

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

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

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

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

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

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

If Log N1A is less than 6, then the number of viable test microorganisms introduced into the treatment unit

must be increased and steps (a) through (f) in Phase 1 must be repeated until Log N1A is ≥ 6. NoA is the inoculum size for challenge load Type A in Phase 2 below.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 1422.APPENDIX A: Initial Efficacy Test Procedures
Table A: Test Microorganisms

1. Staphylococcus aureus (ATCC 6538)

2. Pseudomonas aeruginosa (ATCC 15442)

3. Candida albicans (ATCC 18804)

4. Trichophyton mentagrophytes (ATCC 9533)

5. MS-2 Bacteriophage (ATCC 15597-B1)

6. Mycobacterium smegmatis (ATCC 14468)

Section 1422.APPENDIX A: Initial Efficacy Test Procedures
Table B: Indicator Microorganisms

1. Bacillus subtilis (ATCC 19659)

2. Bacillus stearothermophilus (ATCC 7953)

3. Bacillus pumilus (ATCC 27142)

Section 1422.APPENDIX A: Initial Efficacy Test Procedures

Table C: Challenge Loads

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

COMPOSITION OF CHALLENGE LOADS
% (w/w)

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

Section 1422.APPENDIX B: Correlating Periodic Verification Test Procedures

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

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

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

d) The effectiveness of the treatment unit is demonstrated by calculating the log kill (L) of the test microorganisms in accordance with Option 2 of Appendix A of this Part. The equivalent log kill (T) of the indicator microorganism spores is calculated by subtracting the log of viable cells after treatment from the log of viable cells introduced into the treatment unit as the inoculum as follows:

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

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

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

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

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

IT IS SO ORDERED.

I, Dorothy M. Gunn, Clerk of the Illinois Pollution Control Board, hereby certify that the above opinion and order was adopted on the 25th day of March, 1993, by a vote of 6-0.

Dorothy M. Gunn

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board