ILLINOIS POLLUTION CONTROL BOARD
June 17, 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)

Adopted Rule. Final Action.

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 amendments to 35 Ill. Adm. Code Part 1420 and new Parts 1421 and 1422 to meet these legislative mandates.

The Board is charged under the Illinois Environmental Protection Act (Act) to "determine, define and implement the environmental control standards applicable in the State of Illinois"[2]. The Board is thereby responsible for promulgating the State's substantive environmental regulations, such as represented by today's action. More generally, the Board's rulemaking authority is based on the system of checks and balances integral to Illinois environmental governance: the Board is charged with the rulemaking and principal adjudicatory functions and the Illinois Environmental Protection Agency (Agency) is charged with carrying out the principal administrative functions.

Today's regulations closely follow the recommendations of the Governor's Medical Waste Tracking Study Group (Study Group) as that group's consensus has been proposed to the Board by the Agency. Today's regulations also are identical to the regulations adopted for second notice, with the exception of a modification at subsection 1422.122(a)(1) and several format and nonsubstantive modifications made at the recommendation of the Joint Committee on Administrative Rules (JCAR).

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[1] The mandates occur at Section 56.2 of the Illinois Environmental Protection Act (Act), 415 ILCS 5/1 et seq.

[2] Act at Section 5(b).

The Board wishes to acknowledge the special contributions made to this proceeding by staff scientist LouAnn Burnett in her roles as technical consultant and participant in regulatory meetings with the Study Group, and to Board attorney Michelle C. Dresdow in her roles as hearing officer, contact person, and advisor in drafting of the several opinions and orders. The Board also expresses its appreciation for the quality and magnitude of the contributions made by the members of the Study Group and other participants, and for the leadership provided by the Agency.

HISTORY

Prior to discussing the particulars of the instant regulations, it is instructive to place their development in historical perspective. Although concern about infectious materials is long standing, the impetus to today's particular action is more recent, with antecedents at both the federal and state level.

National Concern with Medical Wastes

Broad public and national concern about medical waste reached a heightened consciousness after medically-related material washed up on beaches on the east coast during the summer of 1987 and again on the east coast and on the Michigan shores of Lake Michigan in the summer of 1988. In addition to general health and aesthetic concerns, fear of AIDS contributed heavily to the public's anxiety regarding these wastes. (Exh. 7 at iii.)

Following the second season of wash-ups, Congress passed Public Law 100-582, the Medical Waste Tracking Act of 1988 (MWTA). The MWTA has a research and information component that has provided for an expanded understanding of the nature and hazards associated with medical wastes[3].

In addition, the MWTA requires that the United States Environmental Protection Agency promulgate regulations to establish a demonstration tracking system for medical waste. Several states along the Atlantic Coast (Connecticut, New York, New Jersey) were required to participate in the demonstration program. Participation of states bordering the Great Lakes was made optional.

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[3] Among the important MWTA documents is "The Public Health Implications of Medical Waste: A Report to Congress", prepared by the Agency for Toxic Substances and Disease Registry (ATSDR) of the Public Health Service, U.S. Department of Health and Human Services. This document is Exhibit 7 in the instant record.

All of the Great Lakes States elected to opt out of the federal MWTA demonstration program. Governor James R. Thompson outlined several reasons for Illinois' choice not to participate (Exh. 5 at 8):

1. Illinois already had a system in place which tracked the potentially infectious waste from hospitals. It was estimated at that time that approximately 60 percent of the potentially infectious waste generated in Illinois came from hospitals.

2. The intent of the MWTA was to prevent beach closings, yet even USEPA concluded that the program would have a very limited effect on the beaches.

3. No funding would be available from USEPA to implement the program in Illinois.

Medical Waste Tracking Study Group

Governor Thompson recognized, however, that there was need for additional study and planning for Illinois' medical waste program. Accordingly, on December 28, 1989, he announced the formation of the Medical Waste Tracking Study Group. The Study Group consisted of elected officials[4] and representatives of state agencies[5], the health community[6], academia[7], waste handling groups[8], agriculture[9], and the City of Chicago[10].

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[4] State Senators Judy Baar Topinka, Margaret Smith, and Virginia MacDonald, and State Representative Myron Kulas.

[5] The Agency, the Board, and Illinois Department of Public Health. Board Member Joan Anderson participated initially.

[6] Including the Illinois State Medical Society (Dr. Larry A. Von Behren), the veterinary community (Dr. Raymond O. Hill), Illinois Council on Long Term Care (Mr. Peter P. Peters), the Illinois Hospital Association (Ms. Ann Guild), public health departments (Mr. J. Maichle Bacon), the Association for Practitioners in Infectious Control (Ms. Carol Mason), and the Illinois Dental Society (Dr. Robert Colantino).

[7] Dr. Van Allen Anderson, University of Illinois Urbana-Champaign, and John Klaire, University of Chicago Hospital.

[8] Including Waste Management, Inc. (Ms. Janet S. Emmerman), Sexton Environmental Services (Mr. Larry Lawrence), National Environmental Services Corp. (Mr. Bill Smith), Browning-Ferris Industries (Mr. Francis J. O'Brien), and Compliance Resources,

The Study Group met on many occasions and reviewed a large number of scientific, technical and legal materials preparatory to issuing its findings. (Exh. 5 at cover letter.) The culmination of these activities was the submission to Governor Jim Edgar on June 10, 1991 of the Study Group's report entitled "The Regulation of Potentially Infectious Medical Waste in Illinois"[11]. The report contains background information on the scope of the PIMW problem and recommendations for managing PIMW in Illinois. These recommendations are directed to modifications of law, as well as educational and voluntary actions. The recommendations with respect to the law formed the basis for subsequent legislative actions and for the regulations today adopted.

Members of the Study Group have continued to participate in PIMW legislative and regulatory developments, including presentation of much of the proposal, testimony, and general record upon which today's action is based.

Legislative Action

During the spring 1991 legislative session, the Illinois General Assembly in House Bill 2491 adopted a variety of amendments to the Illinois Environmental Protection Act (Act) in response to the Study Group's recommendations. These were signed into law on September 26, 1991 by Governor Edgar as Public Act 87-752, effective January 1, 1992.

One of the cornerstones of P.A. 87-752 is the definition for potentially infectious medical waste[12]; its greatest importance is that it specifically limits the types of waste to which PIMW regulations apply.

P.A. 87-752 also added to the Act new *Title XV: Potentially Infectious Medical Waste*. This title consists of seven sections, numbered Sections 56 through 56.6. Section 56 consists of the findings of the General Assembly on the matter of PIMW and the statement of purpose for Title XV. In its entirety Section 56 reads:

Inc. (Mr. Ed Juracek).

[9] Mr. Richard P. Myers.

[10] Ms. Nancy Marren.

[11] This report is found in the instant record as Exhibit 5.

[12] The definition was originally placed at Section 3.81 of the Act. Pursuant to P.A. 87-1097 it was renumbered to Section 3.84.

a. The General Assembly finds:

1. that potentially infectious medical waste, if not handled properly, may constitute an environmental or public health problem.

2. that potentially infectious medical waste, if not handled properly, may present a health risk to handlers of the waste at the facility where the waste is generated, during transportation of the waste, and at the facility receiving the waste.

b. It is the purpose of this Title to reduce the potential environmental and public health risks associated with potentially infectious medical waste by establishing statutory and regulatory requirements to ensure that such waste will be handled in a safe and responsible manner.

Section 56.1 is a lengthy[13] section consisting of a list of prohibitions against PIMW activities. The principal prohibitions are against:

1. Disposal of any PIMW (Section 56.1(a));

2. The landfill disposal of sharps unless their infectious potential has been eliminated and they are properly packaged (Section 56.1(a));

3. The delivery of PIMW for transport, storage, treatment, or transfer except where the PIMW is properly packaged (Section 56.1(b));

4. The delivery of PIMW to a person or facility that does not have an Agency-issued permit for storage, treatment, or transfer of PIMW, where such permit is required (Section 56.1(c));

5. The delivery or transfer of PIMW unless the transporter has an Agency-issued permit, where such permit is required (Section 56.1(d));

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[13] A substantial portion of the length of Section 56.1 arises from the inclusion of various effective dates (all now past except for the incineration date found at Section 56.1(j)) plus interim regulations which are to be in effect until the adoption of the instant regulations.

6. The delivery or transfer of PIMW unless a PIMW manifest is completed for the waste, where such manifest is required (Section 56.1(d));

7. The acceptance of any PIMW for transport, storage, treatment, or transfer except where the PIMW is properly packaged (Section 56.1(e));

8. The conducting of any PIMW transportation operation without an Agency-issued permit (where such permit is required), in violation of any permit condition, or in violation of a Board regulation or order (Section 56.1(f));

9. The conducting of any PIMW treatment, storage, or transfer operation without an Agency-issued permit (where such permit is required), in violation of any permit condition, or in violation of a Board regulation or order (Section 56.1(g));

10. The transport of unmanifested PIMW, where a manifest is required (Section 56.1(h)); and

11. The incineration of PIMW after January 1, 1994 at an existing incinerator in violation of standards established under Section 129 of the Clean Air Act (Section 56.1(j)).

Section 56.2 consists principally of mandates to the Board, including the mandates under which the instant action is being undertaken[14]. The first of these mandates is found at Section 56.2(a), and requires that the Board adopt regulations "prescribing design and operating standards and criteria for all potentially infectious waste treatment, storage, and transfer facilities". The mandate also directs that the Board, "at a minimum" require that PIMW be treated at a facility that:

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[14] In addition to the mandates to which today's action is addressed, Section 56.2 also requires at subsection (d) that the Board repeal its previous infectious waste regulations and at subsection (e) that the Board adopt the list of Class 4 etiologic agents. These two actions have been completed. The first was undertaken as In the Matter of: Repeal of 35 Ill. Adm. Code 809.Subpart I: Hazardous (Infectious) Hospital Waste, R91-18, Final Order December 19, 1991. The second was undertaken as In the Matter of: Potentially Infectious Medical Wastes: Etiologic Agents, R91-19, Final Order January 23, 1992.

1. eliminates the infectious potential of the waste;

2. prevents compaction and rupture of containers during handling operations;

3. disposes of treatment residuals in accordance with this Act and regulations adopted thereunder;

4. provides for quality assurance programs;

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.

The second mandate that today's action addresses occurs at Section 56.2(c). It specifies that the Board shall adopt regulations "prescribing standards and criteria for transporting, packaging, segregating, labeling, and marking potentially infectious medical waste".

Sections 56.3, 56.4, 56.5, and 56.6 of Title XV generally deal with the Agency's direct role in PIMW matters, including reporting, manifesting, permit issuance, and fee collection. Some of these matters bear peripherally on today's action.

In the spring 1992 legislative session, the General Assembly revisited P.A. 87-752 for the purpose of making certain corrective amendments. These were proposed as House Bill 3666 and signed into law as P.A. 87-1097 on September 15, 1992. Among pertinent provisions, P.A. 87-1097 clarified the definition of PIMW, clarified various exceptions to the prohibitions of Section 56.1, and specified July 1, 1993 as the required date of completion of the instant rulemaking.

Actions before the Board

In anticipation of the need to take action in the PIMW arena, the Board on August 9, 1991 reserved several rulemaking dockets within which it intended to conduct the various rulemakings. On August 23, 1991 the Board called a public hearing (inquiry hearing), which was held on September 18, 1991.

The purpose of this hearing was to determine the proper scope of the regulations to be developed under the Section 56.2 mandates.

On August 26, 1991 the Board issued orders formally opening the dockets. Included were separate dockets for the rulemaking covering treatment, storage, and transfer facilities (R91-20) and for the rulemaking covering transportation, packaging, and labeling (R91-21).

At the inquiry hearing testimony was received from Mr. Henry Henderson from the City of Chicago, Dr. Van Allen Anderson of the University of Illinois at Urbana-Champaign and the Study Group; Ms. Ann Guild of the Illinois Hospital Association and the Study Group; Dr. Larry Von Behren of the Illinois State Medical Society and the Study Group; Mr. Joe Suchecki from Waste Management of Illinois, Inc.; Mr. Francis J. O'Brien from Browning Ferris Industries Medical Waste Systems and the Study Group; Ms. Jacquelyn Flora from Browning Ferris Industries Medical Waste Systems; and Mr. Larry Lawrence of Sexton Environmental Systems and the Study Group. Testimony and questioning included the implementation provisions of the legislation requiring segregation, packaging, marking and labeling, transporting, storing and treating of PIMW (Tr1.[15] at 98-144).

Based upon the inquiry hearing and in recognition that matters of PIMW facilities and transportation, packaging, and labeling overlapped, the Board on February 27, 1992 ordered dockets R91-20 and R91-21 to be consolidated, docket R91-21 to be closed, and the materials in docket R91-21 to be incorporated into R91-20 for the purpose of all subsequent considerations.

On April 27, 1992 the Agency filed the draft proposal upon which the merit hearings have been held and upon which today's adopted rules are based; the Agency has also subsequently acted as proponent for the instant rulemakings. Accordingly, for purposes of the following discussions, the Board will identify the April 27 draft proposal in short form as the "Agency Proposal". It is to be acknowledged, however, that the Study Group and other interested persons contributed to the development of the Agency Proposal, and moreover that the Agency undertook extensive outreach and regulatory development meetings[16] prior to

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[15] Citations to the pages of transcripts of 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 ___".

[16] Meetings were held on December 10 and 19, 1991, January 7, 23, and 24, 1992, and February 6, 7, and 24, 1992. Participants included members of the Study Group in addition to other interested persons. Ms. LouAnn Burnett and Mr. Philip Van Ness,

formalizing and filing its proposal. The Board extends its appreciation to the Agency and its personnel for the quality of its leadership role.

On April 27, 1992 the Agency also filed a recommendation (Exh. 37), pursuant to then Section 27 of the Act[17], that an Economic Impact Study (EcIS) not be conducted; on May 11, 1992 the Illinois Department of Energy and Natural Resources joined in that recommendation (PC #7)[18]. On June 4, 1992 the Board issued an order finding that the EcIS need not be conducted. The Board noted:

> The Agency states that representative members of the regulated community* have participated in the development of the Agency's proposal, and that these representatives will attend the hearings and present information on the economic reasonableness of the rule. The Agency has also presented some economic information with its proposal (see Attachments 1-10), and will present additional information at hearing. The Department concurs in the Agency's comments, and further states that interested parties will have "ample opportunity to present testimony regarding technical feasibility and economic reasonableness during the Board's merit hearings." (P.C.#7 at 1). The Department further states that additional economic information will be available from the Agency at or before hearing.
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> > Some of these representatives also participated on the Medical Waste Tracking Study Group (Study Group) formed by Governor Thompson. The Study Group was instrumental in drafting the legislation mandating the adoption of medical waste regulations.

Board staff, also participated in these meetings. Minutes of these meetings are included in this record as Exhibits 38-5, 38-13, 38-35, 38-64, 38-65, and 38-66.

[17] PA 87-860, effective July 1, 1992, deleted those portions of the Act that required economic impact studies for this type of rulemaking. The Board's EcIS determination aside, the need for a formal EcIS study is accordingly now moot.

[18] Public comments are cited to in this opinion in the form "PC #x at ___".

The Board has held three merit hearings. These were held on June 16, 1992 in Bloomington, Illinois, and on July 14, 1992 and August 25, 1992 in Chicago, Illinois.

The June 16, 1992 hearing was devoted to presentation of the Agency Proposal and the taking of questions on the proposal. Providing testimony on behalf of the Agency were three members of the Permit Section of the Agency's Bureau of Land: Mr. Douglas Clay, Manager of the Disposal Alternatives Unit; Dr. Shirley Baer, Co-coordinator of the PIMW waste program, Disposal Alternatives Unit, and Mr. Theodore Dragovich, Permit Reviewer. Among persons posing questions to the Agency were ABB Sanitec, Inc., Sexton Environmental Systems (Sexton), Winfield Environmental Corporation, the National Solid Waste Management Association (NSWMA), Chemical Waste Management, Isolyser Company, and the Board.

The July 14, 1992 hearing focused on testimony directed to the merits of the Agency Proposal. Among those testifying were Dr. Cecil Lue-Hing of the Metropolitan Water Reclamation District of Greater Chicago; Dr. Van Allen Anderson of the University of Illinois, Urbana-Champaign and the Study Group; Dr. Edward Cohen of University of Illinois, Chicago, on behalf of Sexton; Mr. Travis Honeycutt of Isolyser Company; Mr. Robert Rechner of the Illinois State Dental Society and the Study Group; Ms. Ann Guild of the Illinois Hospital Association and the Study Group; Dr. Larry Von Behren of the Illinois State Medical Society and the Study Group. Drs. Anderson and Von Behren, Mr. Rechner, and Ms. Guild each spoke to the general support they and their organizations give to the Agency Proposal, with Dr. Anderson providing additional documentation in support of the position. The other presenters generally spoke to specific concerns.

The August 25, 1992 hearing continued the opportunity for testimony regarding the Agency Proposal and response testimony to that given at the July 14 hearing. Witnesses included Ms. Jean Furlan of the National Solid Waste Management Association; Mr. Corrie Frank of Rose Cartage; Mr. Harry Eiler of Recovery Corporation of Illinois; Ms. Carol Mason of the Association for Practitioners in Infection Control and the Study Group; Dr. John Keene from the Society for Hospital Epidemiology of America; Mr. Joseph Wilson of Ecomed; and Mr. Larry Eastep of the Agency and the Study Group. Dr. Cohen also testified again. Ms. Mason noted the support of her association for the Agency Proposal. The other presenters generally spoke to specific concerns.

Public Comments

Thirty-nine public comments have been filed with the Board, including nineteen filed subsequent to the start of merit hearings and fourteen filed in the post-first notice comment period. These are dominantly expansions upon or responses to

matters addressed at hearing or raised in the first notice opinion. The Board has reviewed all public comments, with citations herein where pertinent.

The Board notes that it recently received comment from Medx Inc. and Custom Compactors Corporation. These comments were received on May 10, 1993 and May 13, 1993, respectively, three months after the February 11, 1993 close of the public comment period and well after the Board adopted today's rules for second notice (see below). The Board is not able to react to such late-filed comments; the Board is statutorily prohibited from altering any proposal subsequent to second notice, except at the recommendation of JCAR (see below).

First and Second Notices

Based on the record as then developed, the Board on December 3, 1992 adopted the first notice proposal[19]. The proposed rules were accompanied by a 39-page opinion, the major elements of which are repeated in the instant opinion. In its outlines and particulars, the first notice proposal closely tracked the Agency Proposal.

On March 25, 1993 the Board adopted the second notice proposal. The changes adopted for second notice were few and generally were of the nature of giving greater specificity to the regulations. The second notice proposal was accompanied by an opinion of 28 pages, the major elements of which are incorporated into today's opinion.

Among changes made at second notice was adoption of a recommendation of the National Solid Waste Management Association that the operational definition of "eliminates the infectious potential of the waste" found at Section 1422.122 (a)(1) be clarified (PC #36 at 3). The intent was to provide a definition that "more clearly reflects [the treatment] standards and more clearly articulates the specific standards that constitute elimination of infectious potential". (Second Notice Opinion at 17.) The NSWMA comment, plus a similar comment from Stericycle (PC #35), were filed prior to the end of the public comment period, and prior to the time the Agency filed its comment. The Agency, however, did not address this issue until after today's rules had gone to JCAR.

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[19] 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).

Action Before JCAR

Immediately upon adoption of the second notice rules, the Board on March 26, 1993 forwarded them to JCAR pursuant to the Illinois Administrative Procedure Act (5 ILCS 100/1-1 et seq.); JCAR set the matter for consideration at its May 11, 1993 meeting.

On May 10, 1993 the Agency asked JCAR to object to adoption of these rules on the basis that the modification made to Section 1422.122(a)(1) -- see above -- at second notice resulted in an internal inconsistency between that subsection and some other portions of Part 1422[20]. On May 11 JCAR voted the objection. Under the terms of an objection, the Board is required to address the objection.

This objection presented a number of concerns for the Board. The first was that the objection delayed the adoption of the entire set of rules pending resolution of the objection. Moreover, it is statutorily required that this rulemaking process be completed by July 1, 1993, further necessitating that action be expeditious.

A second whole area of concern for the Board is that the Board is statutorily and by its own rules and established practices bound to the principle of equitable and impartial hearing of the concerns of all interested parties on the public record. Accordingly, if any person, the Agency included, wishes the Board to modify the Board's rules, it has available to it clearly established public procedures by which petition may be made.

Given the circumstances of the objection, the Board at its first opportunity on May 20, 1993 ordered a special and short public comment period to address solely the matter of the appropriate language for subsection 1422.122(a)(1). To expedite the matter, the Board suggested language that it believed would address the JCAR concern. Further, the Board both invited comment on the new proposed language and invited acceptable alternatives; only the Agency responded.

On June 3, 1993 the Board voted adoption of the language today found at subsection 1422.122(a)(1) (see discussion below for specifics), and submitted that language to JCAR via a Board resolution as the Board's response to the JCAR objection.

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[20] The Agency's letter to JCAR requesting that an objection be voted has not been served upon the Board; the Board nevertheless takes official notice of it as a public document. At no time, in fact, has the Agency addressed any of its perceived problems with subsection 1422.122(a)(1) on the record.

GENERAL CONSIDERATIONS

In addition to the history of PIMW matters, there are a number of general considerations necessary to put today's regulations into perspective.

Immediacy of the PIMW Problem

While it is generally conceded that PIMW presents a real problem, it is also generally conceded that the problem should be addressed by a reasoned consideration of existing rules and regulations and awareness of the professional practices employed in those fields where PIMW is generated and handled. It was in recognition of this situation that Illinois opted out of the MWTA program (see above). It was also in recognition of this situation that the broad interests represented in the Study Group were brought together to recommend a concerted PIMW program.

It is also worth noting that the ATSDR's report to Congress (Exh. 7), made in accordance with the MWTA (see above), observed that the general public's health is not likely to be adversely affected by medical waste generated in the traditional health care setting and that OSHA's "Occupational Exposure to Bloodborne Pathogens" rule should decrease workplace medical waste-related injuries and infections nationwide. (Exh. 7 at E.9.) ATSDR also concluded that medical waste can be effectively treated by chemical, physical, or biological means and that research indicates that medical waste does not contain any greater quantity or different types of microbiological agents than does residential waste. Medical waste is approximately 0.3% of the solid wastestream in the U.S. (Exh. 7 at E.11.)

Design of Rules

Today's rules are designed as a multi-pronged attack on the chain of events leading to infection and disease. For infection to occur, each of these events must take place:

1) A person must come in contact with medical waste;

2) An injury must occur following this contact, thereby creating an appropriate portal of entry, or a portal of entry must already exist; and

3) A sufficient number of viable infectious agents must enter a susceptible individual via this portal of entry, then cause infection.

Infection does not always result in disease. (Exhs. 7 at E.5, 38-26, and 39-30 at 3.)

Appropriate segregation of PIMW from other wastes allows a generator to apply more extensive safety measures to a smaller waste stream. Proper packaging should nearly eliminate the possibility of contact (Tr2. at 84) or the creation of a portal of entry (i.e., packaging sharps in a puncture-proof container). Storage and transportation requirements also help limit the exposure of handlers or the general public to potentially infectious agents. Treatment reduces the number of potentially infectious agents, thereby reducing the possibility of infection if contact and injury does occur. Any of these preventive methods applied individually should reduce the possibility of infection, but used in concert and properly, the entire PIMW management system should reduce the possibility of infection almost completely. (Tr2. at 113.)

Today's rules are also designed to complement the Occupational Safety and Health Administration rules issued December 6, 1991 that contain provisions requiring employers to protect their employees from bloodborne pathogens through training, engineering controls, work practices, personal protective equipment, recordkeeping, and Hepatitis Type-B virus vaccinations (Exhibit 37-6; Tr2. at 72, 84).

Definition of Potentially Infectious Medical Waste (PIMW)

The definition of potentially infectious medical waste, or PIMW, is set by statute at Section 3.84 of the Act. In its entirety, that definition is as follows:

a. "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:

   1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

b. Potentially infectious medical waste does not include:

1. waste generated as general household waste;

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

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.

Early in the history of this proceeding there was concern raised by various persons about the appropriateness of this definition. A portion of that concern was addressed by the corrective amendments undertaken in P.A. 1097; these amendments limited the types of waste that are PIMW[21].

The remaining questions regarding the PIMW definition are largely concerned with interpretation and implementation of certain phrases used within the definition, as, for example, the meaning of "rendered unrecognizable" found in the last subsection of the definition. These will be discussed in context in the following part-by-part analyses.

The Treatment Standard

The fundamental provision around which the instant regulations are built is the provision of treatment to render waste non-PIMW. Because a waste that is PIMW may not be disposed of in Illinois, and because treatment is the process by which a waste ceases to be PIMW[22], the ultimate disposition of PIMW depends upon its being treated.

Suitably, treatment standards and criteria form the largest single portion, Subpart B of Part 1422, of today's regulations. Moreover, treatment has been the single greatest focus of participant interest, both at hearing and in public comments. Much of that interest has focused on the question of what constitutes successful treatment.

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[21] The principal changes were to eliminate the phrase "... but not limited to ..." prior to the lists of materials included in the definitions of human pathological wastes, human blood and blood products, and isolation waste, and to rephrase the definition of animal waste.

[22] A partial exception occurs for sharps. These must be both treated and "rendered unrecognizable" in order to leave the PIMW wastestream. "Recognizable" sharps, which remain PIMW, may be disposed of provided that they are both treated and packaged, pursuant to Section 1422.126. See discussion of the term "recognizable" in the part-by-part discussion, below.

Today's regulations follow the Agency Proposal in requiring two demonstrations of treatment efficacy. The first is the Initial Efficacy Test[23], in which it is required that the manufacturer assure that six types of "test" microorganisms[24] that are surrogates for pathogens be reduced to very low concentrations (a 6-log reduction[25]) by the treatment process.

The second demonstration is made by operators of individual treatment units. They are required to verify that the manufacturer-demonstrated efficacy continues by conducting Periodic Verification Tests[26]. These are accomplished by showing that concentrations of bacterial spores (typically the most resistant forms of microorganisms) are reduced to a number that correlates with the 6-log reduction of the organisms used in the manufacturer's efficacy test.

This program represents the consensus view of members of the Study Group, and the program which today is adopted in its major provisions. Nevertheless, several issues regarding treatment standards constituted major areas of debate during the course of this proceeding.

Among such issues have been the stringency of the efficacy standard, whether the standard is properly a "log-kill" or "log-reduction" standard, and which organisms should be used or allowed in efficacy determinations. Greater detail regarding these issues has been presented in the first notice opinion at pages 15-18 and 34-40 and the second notice opinion at pages 16-26.

ORGANIZATIONAL CONSIDERATIONS

The Board has established the following organizational scheme to accommodate the PIMW and related regulations.

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[23] See Section 1422.124.

[24] *Staphylococcus aureus* (representative of gram-positive bacteria), *Pseudomonas aeruginosa* (representative of gram-negative bacteria), *Candida albicans* (representative of vegetative fungi--yeast), *Trichophyton mentagrophytes* (representative vegetative fungi--mold), MS-2 bacteriophage (hepatitis virus surrogate, and *Mycobacterium smegmatis* (tuberculosis bacteria surrogate).

[25] At various places in the record this term is also given as "6log". The hyphenated form is used here and in the text of the regulations.

[26] See Section 1422.125.

Subtitle M, which is to consist of the 1400-1499 series of 35 Ill. Adm. Code, is reserved for regulations that control specific biological materials; currently, the only Board regulations within Subtitle M are the instant PIMW regulations.

As is the general scheme with 35 Ill. Adm. Code regulations, parts numbered 1400 to 1449 (Chapter I) are reserved for regulations promulgated by the Board, and parts numbered 1450 to 1499 (Chapters II and III) are reserved for regulations promulgated by the Agency or the Department of Energy and Natural Resources.

Today's specific regulations are collected into subchapter b, the PIMW subchapter. This subchapter, in turn, is subdivided into three parts to efficiently house general provisions (Section 1420), and the regulations today adopted in response to the separate Section 56.2(a) and 56.2(c) mandates of the Act (Sections 1421 and 1422)

PART-BY-PART ANALYSIS - Part 1420

In this portion of our opinion, the Board presents an explanatory analysis of today's regulations, beginning with Part 1420. Emphasis is on issues that have required Board resolution[27].

Part 1420 is the only one of the three parts in today's regulatory package that is not entirely new. Part 1420 originated in the Board's first PIMW proceeding, R91-19, that dealt with etiologic agents[28]. It is expanded to house general provisions pertaining to PIMW.

Scope and Applicability (Section 1420.101)

The Scope and Applicability statement for the PIMW regulations was adopted in R91-19. At first notice the Board proposed, and today adopts, the deletion of both subsection (b) and the Board Note as no longer reflective of the overall content of either Part 1420 or the PIMW subchapter.

It is to be noted that, through the operation of Section 1420.101, the instant regulations are applicable to activities occurring in whole or in part within the State of Illinois. Thus, that part of any PIMW wastestream activity (e,g.,

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[27] The interested person is directed to the testimony of Dr. Baer, Tr2. at 52-153, and Mr. Dragovich, Tr2. at 154-191, for a more extensive explanation of particular provisions.

[28] See footnote #14.

transporting) that takes places in Illinois is subject to these regulations, even if some portion of the PIMW wastestream activity (e.g., disposal) does not.

Definitions (Section 1420.102)

General definitions that apply to the three PIMW parts are found in Section 1420.102. Most of these definitions are standard, and need not be specifically discussed here. However, there are several around which question has been raised.

"PIMW". The full statutory definition of PIMW has been presented and discussed above. It is also presented within the body of the rule at Section 1420.102[29]. As noted above, there have been some concerns raised regarding this definition that have now been addressed by the General Assembly. The Board has no authority to modify the statutory definition.

In response to a question raised by Chemical Waste Management (CWM) regarding whether discarded unused test kits should be considered PIMW (Tr2. at 282-305; PC #22), the Board in its 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.)

During the post-first notice comment period, two commenters observed that a discarded unused test kit that contains blood components should not be considered to be PIMW. The Agency observed 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 observed 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 observed that blood components in test kits have been sterilized, and as such have no infectious potential. (PC #37 at 1.) In its second

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[29] It is to be noted that, in accord with standard construction, statutory language in the regulations is denoted by capitalization.

notice opinion, page 3, the Board noted that these points with regard to unused test kits are well taken, and accordingly receded from its first notice proposed position on this matter.

"Site". The term "site" appears in many places within the today's regulations, including within other definitions ("storage site" and "transfer station"), within provisions defining the circumstances under which permits and manifests are required[30] and within various provisions defining on- and off-site circumstances[31]. There is thus a special importance to having the definition be clear and precise.

The following definition was offered in the Agency Proposal:

> "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). In the case of a hospital or an educational institution, the Agency shall determine what constitutes a site based on location, ownership, operation, charter or license.

The first, capitalized part of this definition is identical to the definition of "site" found in the Act. It has not been at issue.

However, the second, lower case part of the definition has been of concern. The purpose of the language is to allow for flexibility in determining the geographic bounds of a site, particularly in the circumstance where an organization (epitomized by hospitals and universities) may consist of geographically separated buildings and structures. The intent is that such organizations need not necessarily acquire separate permits for each structure or manifest all loads transferred between buildings. The Agency's resolution of this matter was to allow a case-by-case determination under its supervision.

The problem with this resolution is that it constitutes a delegation of authority of questionable validity. Accordingly, the Board at first notice declined to propose the lower case language of the Agency Proposal. Instead, at the lead of several participants, the Board observed that the term "campus" has sufficient ordinary meaning as to itself be explicit, and

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[30] Sections 1420.105(c)(1) and (e)(1).

[31] Sections 1421.120, 1421.130, 1421.131(a)(2)(E), 1421.131(e)(2)(E), 1422.111(a), 1422.111(a)(4), and 1422.111(b)(5)(B).

therefore proposed to address the matter by replacing the lower case language with:

> For the purpose of this Subtitle, each campus of an educational institution is considered to be a single site.

This resolution did not explicitly address the issue of hospitals. However, based on additional comments received in the post-first notice comment period, the Board at second notice concluded that it would be both unnecessary and unwise to attempt more explicit consideration of hospitals within the definition of "site". This conclusion is based, among other matters, on the special mention made of hospitals, and the permits required by them, both in the statute and within the main body of the instant regulations. (See second notice opinion at p. 4-7.) The Board today affirms its analysis as presented at second notice.

Unrecognizable. Pursuant to the definition of PIMW at Section 3.84 of the Act all sharps are considered to be PIMW unless they meet both of the conditions:

> The infectious potential has been eliminated from the sharps by treatment; and
>
> The sharps are rendered unrecognizable by treatment.

This definition has raised the question of how the phrase "rendered unrecognizable" is to be interpreted[32]. The issue is significant in that it factors into a determination of when a sharp no longer is a PIMW, and hence is no longer subject to PIMW treatment and disposal limitations[33].

In the original Agency Proposal it is recommended that the term "unrecognizable" be included within the general definitions, as follows:

> "Unrecognizable" means physical alteration (i.e., melted, charred, corroded, or ground) so that the sharp may no longer be used for its intended purpose.

As the Board concluded at first notice, an effect of this recommendation is to incorporate into the definition the concept of usability. The Board also concluded that this incorporation

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[32] The meaning of infectious potential being "eliminated" has also been raised in this proceeding. A discussion of this matter is found in the "General Considerations" portion of this opinion, above.

[33] See discussion of Section 1420.104, below.

is consistent with the PIMW threat posed by sharps and the circumstance under which that threat is allayed. The Board accordingly adopted the concept[34]. (See first notice opinion at p. 25.) The Board today affirms these conclusions.

Also at first notice the Board discussed the encapsulation and solidification process of Isolyser Company, Inc., as a method for the treatment of sharps[35]. (First notice opinion at p. 25.) For second notice Isolyser asked that "encapsulating/solidifying" be specified in the definition of "unrecognizable" as an example of physical alteration. (PC #30 at ¶1.) This the Board declined to do because it believes that the record does not support a blanket endorsement of all processes that involve encapsulation or solidification. (Second notice opinion at p. 7.) The Board today affirms these analyses.

Incorporations by Reference (Section 1420.103)

Incorporations by reference for the full PIMW subchapter occur at Section 1420.103. All incorporations are placed in one section to simplify future amendments and updates, and for more ready reference.

Today's regulations contains two incorporations by reference. They are Standard Methods for the Examination of Water and Wastewater (18th Edition) and Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (EPA SW-846)[36].

Prohibitions (Section 1420.104)

Section 1420.104 sets out the PIMW prohibitions. Much of the section is statutory, as found at Section 56.1 of the Act.

Disposal of sharps. In a post-first notice public comment Stericycle, Inc., requested clarification of sharps disposal, as

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[34] The actual language adopted was slightly modified for grammatical reasons. See first notice opinion at p.26.

[35] Under the Isolyser process sharps are treated and bound into a polymer matrix. During the binding process pressure forces the polymer into the barrels of syringes and needles, with the whole enclosed in an opaque container. Isolyser contends that this process renders the sharps no longer usable (Tr2. at 279; 663-94).

[36] The former is referenced in the Initial Efficacy Test procedures at Section 1422.124(e)(2) and 1422.Appendix A, and in the Periodic Efficacy Test procedures at Section 1422.125(b)(4). The latter is referenced in the Initial Efficacy Test procedures at 1422.Appendix A.

referenced at Section 1420.104(a). (PC #35 at 2.) Stericycle noted 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 regulations that reflect on the disposal of sharps. The first is in the definition of PIMW[37] 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 <u>potentially infectious medical waste</u>. 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:
>
> (A) Board regulations; or

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

(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 the sharps unrecognizable. After this processing, the sharps are not considered to be PIMW and may be disposed of in a manner the same as that of 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 Study Group, the Agency Proposal, and the instant regulations 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.

Disposal into sewers. Among the changes made to Section 1420.104 during the course of this proceeding has been the addition at subsection (l) of an explicit prohibition against the discharge of PIMW into sewers.

This action arose from concerns of the Metropolitan Water Reclamation District of Greater Chicago (MWRDGC) and the Illinois Association of Wastewater Agencies that the practice of flushing ground/shredded inert medical solid wastes into sewers is an inappropriate use of the public sewerage system, and that the public sewerage system is neither designed to function as a landfill nor as a depository for inert solid wastes regardless of origin. (Tr2. at 468-493; Exh. 43 and 44; PC #6, 11, and 12.) MWRDGC also observed difficulties posed to the biological treatment system of a sewage treatment plant and sludges when such solid materials are received in the waste stream. (Tr2. at 478-80.)

Permit and Manifest Exceptions, Penalty Factor, and Cleaning and Disinfection (Sections 1420.105, 1420.106, and 1420.107)

The first two of these sections basically present language from the PIMW statute. The third contains at a single location language required in support of various other sections[38].

The three sections have remained basically unaltered from the Agency Proposal, although conforming and minor amendments have been made, as discussed in the first notice opinion at page 28-29 and in the second notice opinion at page 11-12.

Severability (Section 1420.120)

Section 1420.120 contains severability language as found generally in Board regulations.

PART-BY-PART ANALYSIS - Part 1421

Part 1421 is a new part intended to address the mandate of Section 56.2(c) of the Act regarding the prescription of "standards and criteria for transporting, packaging, segregating, labeling, and marking potentially infectious medical waste". The

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[38] Within the definition of "reusable container" at Section 1420.102, as well as at Sections 1421.121(d), 1421.121(e), 1421.141(i), 1422.111(a)(8), 1422.111(a)(11), and 1422.122(b)(5).

part is divided into five subparts, each addressing one of the natural divisions of the topic. Part 1421 also has an Appendix A that contains the International Biohazard Symbol.

The entire part is adopted today with only minor, generally nonsubstantive modification from the Agency Proposal.

General Provisions (Subpart A)

This short subpart contains a single section specifying that the date for compliance with Part 1421 is the effective date of the part. That is, compliance is required immediately upon the regulation becoming effective; that, in turn, will be upon the acceptance by the Office of the Illinois Secretary of State of the filing by the Board of today's action.

Waste Segregation (Subpart B)

Subpart B consists of two sections that apply to all PIMW generators, transporters, storage sites, transfer stations, and treatment facilities (Section 1421.110).

A principal requirement, found in Section 1421.111(a), is that generators segregate PIMW into sharps, oversized PIMW (a single waste item that is too large to be placed into a 33-gallon bag or container), and all other. These three categories are derived from similar categories used in Section 56.1 of the Act, including the interim PIMW regulations found there.

Subsections 1421.111(b) and (c) specify that properly packaged and labeled sharps and mixed waste must be handled as though the entire wastestream originated as PIMW. They do not, however, preclude the applicability of other regulations. For example, if a hazardous substance is also PIMW, both the hazardous waste and PIMW rules are intended to apply.

This latter provision has raised the question of whether rules that govern a waste as PIMW and rules that govern the same waste under another categorization (e.g., hazardous waste) could be incompatible. (Tr2. at 252-268.) The Board does not immediately see that this presents a problem. As the Agency indicates, a waste that is both PIMW and a hazardous waste may occur, but is likely to be rare. (Tr2. at 271-276.) Where overlap does occur, compliance with rules applicable to both PIMW and hazardous wastes is required.

Packaging (Subpart C)

Subpart C consists of standards and criteria for packaging that apply to any person who packages PIMW for off-site transportation. (Section 1421.120.)

The standards and criteria, which are found in Section 1421.121, are designed to prevent discharge and protect handlers from contact with PIMW (Tr2. at 27). They include packaging requirements for all PIMW, with different standards for sharps and oversized PIMW. Also included are standards for reusable containers, standards for the management of the outside of containers that are contaminated by PIMW, and standards for residues from the cleaning of PIMW containers or discharges from packages.

It is broadly believed that packaging is a critical element in PIMW management, and that Subpart C correctly addresses that matter. Subpart C is fashioned on the premise that performance standards, rather than design standards, provide the most effective method of assuring good PIMW management (Tr1. at 100, 137; Exhs. 38-5, 38-13, 38-35, 38-64, 38-65, and 38-66).

Labeling and Marking (Subpart D)

This subpart applies to any person who packages PIMW for off-site transportation or who accepts packages from off-site. The specific standards for labeling and marking are found in Section 1421.131. Among these are requirements for marking the exterior of the outer package by the generator and transporter(s), and different standards for marking sharps containers and oversized PIMW.

Transportation (Subpart E)

This subpart applies to transporters required to have a PIMW hauling permit. It contains requirements regarding the conditions under which PIMW can be transported, including the condition of the vehicle, the management of the packages, the information that must be displayed on the vehicle, the emergency response plan that is required to be kept, and a 10 calendar-day limitation for the transportation of PIMW.

Dedicated vehicles. At hearing the issue was raised as to whether it was necessary to require "dedicated vehicles" for PIMW transportation[39]. (Tr2. 776-814; Exh. 54.) In particular, it was asked whether "long-haul" vehicles (i.e., those vehicles that engage in interstate transport) should be allowed to backhaul "hardgoods" (paint, water seal stains, plastic, etc.) after the

[39] Subsection (i) reads: "Vehicles transporting PIMW cannot be used for the hauling of non-waste materials, with the exception of equipment and supplies intended for the use of waste management, new PIMW containers or PIMW containers that have been cleaned and disinfected in accordance with 35 Ill. Adm. Code 1420.107 of this Subtitle".

vehicle has been decontaminated in accordance with the procedures given in Section 1420.107. (Tr2. at 796, 805.)

At first notice the Board proposed to follow the recommendation of the Study Group and the Agency by requiring "dedicated vehicles". At second notice the Board again addressed the issue, and observed that post-first notice public comments uniformly contended that no exceptions to the prohibition against hauling non-PIMW loads should be allowed beyond those already specified within 1421.141(i). (See second notice opinion at p. 14.)

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[40]. This notwithstanding, the Board at first notice raised the issue of whether, for the sake of clarity within the instant regulations, some additional presentation of the use of manifests is needed. (First notice opinion at p. 32.) None of the post-first notice public comments rose to this issue, and accordingly no further consideration of manifests within the bounds of today's rules has been entertained by the Board.

PART-BY-PART ANALYSIS - Part 1422

Part 1422 is addressed to the mandate of Section 56.2(a) of the Act regarding the prescription of "design and operating standards and criteria for all potentially infectious waste treatment, storage, and transfer facilities". Like Part 1421, Part 1422 is a new part.

Effective Date (Section 1422.101)

This section specifies that the date for compliance with Part 1422 is the effective date of the part. That is, compliance is required immediately upon the regulation becoming effective[41].

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

[41] This provision notwithstanding, it should be noted that in certain circumstances the requirements for an existing unit are different than those for a unit that begins operation after the effective date. An example is the Initial Efficacy Test requirement for an autoclave, incinerator, or ethylene oxide unit at Section 1422.123(c).

Permit Applications (Sections 1422.105 through 1422.107)

At first notice the Board raised an issue concerning the need for greater 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 submitted recommended provisions addressing application requirements. (PC #39 at 5-12.)

The Board accordingly at second notice added three new sections, Sections 1422.105, 1422.106, and 1422.107, that track the Agency's recommendation. The first section deals with content of the application, the second with application certifications, and the third with application filing requirements. In each case, the provisions closely track similar permit application provisions found in the Board's landfill regulations at 35 Ill. Adm. Code 812.

The addition of Sections 1422.105 through 1422.107 also required collateral amendments at Section 1420.105(a) and (d).

Storage/Transfer Operations (Subpart B)

Subpart B consists of two sections that apply to the owner or operator of any PIMW storage operation[42]. The subpart is adopted today without substantive modification from the Agency Proposal.

Design and operating requirements, which occur at Section 1422.111, constitute the principal standards and criteria of the subpart. Standards and criteria applicable to any person who stores PIMW prior to treatment or disposal on-site or transport off-site are contained in subsection (a); these apply whether or not a permit is required for the storage operation. Many of these standards are repeated from Section 56.1(e) of the Act, including requirements for maintaining the integrity of the packages, limiting access to the storage operation, maintaining the PIMW in a nonputrescent state, and protecting the PIMW from animals and vectors. Other requirements in this subsection include the management of reusable PIMW containers and residues, retention of manifest copies, and closure of the storage operation.

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[42] For the purpose of 1422.Subpart B a storage operation is defined at Section 1422.110 to collectively include a "storage site" or a "transfer station". The latter two terms are defined in the Act at Sections 3.47 and 3.83, respectively, and repeated in the instant regulations in the definitions at Section 1420.102.

Subsection 1422.111(b) contains additional standards for those storage operations that are required to have a permit. These generally are facilities that receive waste from off-site. (Tr2. at 30.) The standards include more detailed requirements regarding to operating records, aisle space, the manner of storage, signs, personnel training, contingency plan, storage time limitations, and notification of closure. As the Agency notes:

> These requirements are necessary to meet the intent of the Act to reduce the potential environmental and public health risks associated with PIMW, since the permitted storage operation is not normally the generator of the waste. The owner or operator of the storage operation does not possess the same knowledge of the waste as the generator and does not maintain the same control over what is placed in the packages as the original generator. In addition, safeguards are necessary because PIMW is stored for varying lengths of time and under varying conditions. (Tr2. at 165-75.)

Treatment (Subpart C)

This subpart applies to all facilities that treat PIMW to eliminate its infectious potential.

PIMW may not be disposed of in Illinois unless it has been treated in accordance with the standards of this subpart; the standards apply whether the treatment occurred at a facility located in Illinois or elsewhere (Section 1422.120).

At Section 1422.121 it is required that there be certification of the treatment:

> 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 shall be made available to the receiving facility. No person shall falsely certify that PIMW has been treated in accordance with this Part.

Design and operating requirements for PIMW treatment facilities occur in Section 1422.122. Subsections (a) and (b) apply to all treatment facilities, including those that do not require a permit. Requirements include proper management of residues, filing of an annual report, and the cleaning and

disinfection of the facility upon closure. 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).

The (a)(1) portion of Section 1422.122 has undergone particular evolution during the course of this proceeding. 1422.122(a)(1) is intended to provide an operational definition of the statutory term "eliminates the infectious potential of the waste", which is critical to the whole concept of treatment of PIMW. Initially in the Agency proposal and in the first notice proposal the definition was attempted by directing the interested person to Sections 1422.124 and 1422.125. By the time of second notice, however, it was apparent that this device did not provide very much useful instruction and moreover was a source of confusion to at least some of the affected persons (see PC #35, #36, and Second Notice Opinion at p. 17). Accordingly, at second notice and at the recommendation of the National Solid Waste Management Association (PC #36 at 3), the Board modified the language in a manner that it thought to be consistent with the whole of Part 1422.

The Agency later objected to the amendment of its favored language and sought to have JCAR reinstate that language (see discussion above). Reinstatement was not acceptable either to other participants or the Board.

Today's final subsection (a)(1) language is language adopted by the Board on June 3, 1993 in its resolution responding to the JCAR objection (see discussion above). The language continues to provide an "upfront" operational definition of "eliminates the infectious potential", in addition to providing direction to the testing procedures of Sections 1422.124 and 1422.125.

Subsection (c) of Section 1422.122 contains additional requirements that apply to those treatment facilities for which a permit is required. These include personnel training, a written contingency plan, and a written operating record to be kept at the facility.

Section 1422.123 contains standards for treatment units. The emphasis is on performance standards rather than on authorization of particular techniques or technologies. Most fundamentally, the treatment unit must be designed and operated to eliminate the infectious potential of PIMW (subsection (a)(1)). It must also be operated in modes determined by manufacturer's specifications and under the same conditions that are used in the efficacy demonstrations (subsections (a)(2) to (a)(5)). The same level of treatment is required whether Agency permits are required or not.

Subsection (b) of 1422.123 allows treatment units to be used by treatment facilities not required to have permits if the unit meets certain requirements of the subsection or if the Board has granted an adjusted standard.

A principle underlying the Section 1422.123(b) provisions has been to allow for easy consideration of new technologies that do not fit the definition of chemical, thermal, or irradiation treatment. To achieve this end, participants and the Board have addressed these provisions in some detail, with resolution not achieved until second notice (see second notice opinion at pages 18-21).

The Initial Efficacy Test requirements are set out in Section 1422.124, with supporting materials present in Section 1422.Appendix A. The Initial Efficacy Test is a one-time demonstration made for each model of a particular treatment unit that demonstrates that the unit will achieve a 6-log reduction of all vegetative microorganisms. (Tr2. at 34.) If the Initial Efficacy Test is undertaken by the unit's manufacturer or some person other than the treatment facility, the treatment facility is responsible for obtaining and making available for inspection at any time documentation of the test.

Section 1422.125, supported by Section 1422.Appendix B, sets out the requirements of the Periodic Verification Tests. These are tests that are designed to be performed on an ongoing basis to ensure that treatment efficacy continues.

Section 1422.126 sets out those conditions, in addition to elimination of infectious potential, that are necessary before a sharp may be landfilled.

Section 1422.127 also allows the Agency to issue an experimental treatment permit for a period of up to two years, renewable once. Experimental permits are for processes or techniques that do not otherwise satisfy the standards of Subpart C. Residues from a treatment unit with an experimental permit may or may not be considered PIMW, depending on the experimental permit conditions.

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[43], and 3,906 funeral directors. (Report to the Governor, Exh. 5 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:

> 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.

* * *

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

> 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 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 (Id.):

> 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.

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 today's regulations 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 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 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 Clerk of the Board is directed to submit the text of the following regulations to the Secretary of State for final notice pursuant to Section 6 of the Administrative Procedure Act.

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. 1989~~91~~, 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 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).~~

(Source: Amended at 17 Ill. Reg. _____, effective _____)

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. 19~~89~~91, 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 others 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~~14~~(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 THE 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.

(Source: Amended at 17 Ill. Reg. _____, effective _____)

Section 1420.103 Incorporations by Reference

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

Standard Methods for the Examination of Water and Wastewater, American Public Health Association et al. (1015 Fifteenth Street, N.W., Washington, D.C. 20005) (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.

(Source: Added at 17 Ill. Reg. _____, effective _____)

Section 1420.104 Prohibitions

NO PERSON SHALL:

a) CAUSE OR ALLOW THE DISPOSAL OF ANY PIMW. SHARPS MAY BE DISPOSED OF 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.

(Source: Added at 17 Ill. Reg. _____, effective _____)

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)

(Source: Added at 17 Ill. Reg. _____, effective _____)

Section 1420.106 Penalty Factor

IN MAKING ITS ORDERS AND DETERMINATIONS RELATIVE TO PENALTIES, IF ANY, TO BE IMPOSED FOR VIOLATING SECTION 56.1(a) 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)

(Source: Added at 17 Ill. Reg. _____, effective _____)

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.

(Source: Added at 17 Ill. Reg. _____, effective _____)

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.

(Source: Added at 17 Ill. Reg. _____, effective _____)

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

PART 1421
ACTIVITY STANDARDS

SUBPART A: GENERAL PROVISIONS

SUBPART B: SEGREGATION

SUBPART C: PACKAGING

SUBPART D: LABELING AND MARKING

SUBPART E: TRANSPORTATION

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

SOURCE: Adopted in R91-20, at _____ 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 unless treated and rendered unrecognizable pursuant to 35 Ill. Adm. Code 1422.126, 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 combination 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 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 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 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 subjected 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

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1422.105 PIMW Permit Application Contents
1422.106 PIMW Permit Application Certifications
1422.107 PIMW Permit Application Filing Requirements

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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, pars. 1056.2 and 1027) [415 ILCS 5/56.2 and 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 filed with the Agency on forms as prescribed by the Agency. Hand delivered applications must be delivered during the Agency's normal business hours to the offices of the Permit Section. The Agency shall provide a dated, signed receipt of filing only if the applicant requests. The date of filing must be that recorded by the Agency, unless proven otherwise by a dated, signed receipt.

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

SUBPART B: STORAGE OR TRANSFER OPERATIONS

Section 1422.110 Scope and Applicability

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

Section 1422.111 Design and Operating Standards and Criteria

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1) Storage operations shall weigh in pounds the amount of PIMW received, unless previously weighed by the transporter. PIMW must be weighed with a device for which certification has been obtained under the Weights and Measures Act (Ill. Rev.

Stat. 1991, ch. 147, pars. 101 et seq.) [225 ILCS 470].

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

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

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

5) Adequate aisle space, as specified in the permit, must be maintained between packages to allow inspection of at least one (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.

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

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

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

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

9) Storage operations must have a written contingency plan and the applicable sections must be implemented in the event of a discharge or personal injury. The contingency plan must describe the actions that personnel shall take in

response to emergency situations such as, but not limited to, personal injury, discharges of PIMW, rupture of plastic bags and equipment failure. This contingency plan must, at a minimum, include a list of all emergency equipment at the storage operation, an up-to-date list of names, addresses and phone numbers (office and home) of all persons qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue, repackaging of PIMW and alternate arrangements for PIMW storage and transfer. A copy of the contingency plan must be maintained at the storage operation. Emergency phone numbers and a brief description of the emergency procedures must be posted at the storage operation.

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

A) Quantities and disposition of PIMW stored or transferred;

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

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

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

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

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

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

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

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

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

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

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

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

SUBPART C: TREATMENT FACILITIES

Section 1422.120 Scope and Applicability

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

Section 1422.121 Treatment Facility Certification

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

Section 1422.122 Design and Operating Standards

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

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

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

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

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

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

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

2) PREVENTS THE COMPACTION AND RUPTURE OF CONTAINERS DURING HANDLING OPERATIONS, except when compaction

or rupture is an integral part of the treatment process and the treatment process is conducted without discharge of PIMW to the environment;

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

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

A) Designates responsibility to personnel;

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

C) Identifies monitoring devices;

D) Insures monitoring devices are operating properly;

E) Establishes appropriate ranges for all operating parameters;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   A) Quantities and disposition of PIMW treated;

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

C) Date and time the PIMW was treated;

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

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

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

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

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

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

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

Section 1422.123 Treatment Units

a) A treatment unit must be:

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

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

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

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

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

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

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

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

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

C) The owner or operator retains any notification from the manufacturer of the

permitted commercially available treatment unit of a permit modification.

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

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

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

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

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

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

Section 1422.124 Initial Efficacy Test

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

1) Are manufactured by the same company;

2) Have the same capacity; and

3) Have no significant mechanical changes.

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

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

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

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

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

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

c) Composition of Challenge Loads

1) For treatment units designed to treat all types of PIMW, all three (3) types of challenge loads must be used in conducting the Initial Efficacy Test. The three (3) types of challenge loads represent PIMW with a high moisture content, low moisture content and high organic content. The quantity of each challenge load must equal 100% of the maximum capacity of the treatment unit. Each challenge load must include, at a minimum, 5% of each of the

following categories: blood/broth cultures, fibers, metals, sharps, plastics, pathological waste, glass, non-woven fibers and bottles of liquids. Table C of Appendix A of this Part contains the moisture and organic content requirements that must be met in each type of challenge load.

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

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

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

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

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

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

1) A detailed description of the test procedures used, including all test data generated, with

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

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

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

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

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

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

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

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

Section 1422.125 Periodic Verification Test(s)

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

1) Passing the Initial Efficacy Test by using Options 1, 2, or 3 of Appendix A of this Part (whichever is applicable). The three challenge loads

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

2) Correlating the log kill (L) of the test microorganisms in the Initial Efficacy Test to an equivalent log kill (T) of the indicator microorganism spores in accordance with Appendix B of this Part. The equivalent log kill (T) of the indicator microorganism spores must be used for all subsequent Periodic Verification Tests. The correlation must be done with the three (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 microorganism spores must be placed in a representative load in accordance with Section 1422.124(e)(1) of this Part;

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

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

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

c) If a load of PIMW fails a Periodic Verification Test(s), the Periodic Verification Test(s) must be repeated. The operator shall implement the quality assurance program (in Section 1422.122 (a)(4) of this Part) and contact the manufacturer, if applicable, to identify and correct the problem(s) until the unit can eliminate the infectious potential of the PIMW. If the operating parameters are altered, another Initial Efficacy Test must be performed to demonstrate the effectiveness of the unit and, if applicable, another Periodic Verification Test correlation, pursuant to subsection (a) of this Section, must also be repeated. Loads of PIMW that were first processed prior to

receiving results showing a failure of the Periodic Verification Tests are considered treated. A second Periodic Verification Test must be run immediately after the first Periodic Verification Test indicates a failure. The second Periodic Verification Test is to determine whether or not the treatment unit is eliminating the infectious potential of the waste. After the second Periodic Verification Test shows a failure of the treatment unit, the processed waste is considered PIMW and must be managed in accordance with this Subtitle.

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

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

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, signature(s) and title(s) of person(s) conducting the Periodic Verification Test(s).

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

Section 1422.126 Sharps

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

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

b) Have been:

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

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

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

Section 1422.127 Experimental Permits

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

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

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

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

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

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

2) A discussion of how the equipment performed;

3) A discussion of how residuals were managed; and

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

Section 1422.APPENDIX A INITIAL EFFICACY TEST PROCEDURES

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

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

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

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

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

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

d) The container of test microorganisms and challenge loads must be processed together without the physical and/or chemical agents designed to kill the test microorganisms. For example, in treatment units that use chemical disinfectant(s), an equal volume of liquid (e.g., sterile saline solution (0.9%, volume/volume), phosphate buffer solution, 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 = Log NoA - Log N1A; where Log N1A $\geq$ 6

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

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

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

If Log N1A is less than 6, then the number of viable test microorganisms introduced into the treatment unit must be increased and steps (a) through (f) in Phase 1 must be repeated until Log N1A is $\geq$ 6. NoA is the inoculum size for challenge load Type A in Phase 2 below.

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

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

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

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

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

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 17th day of June, 1993, by a vote of 7-0.

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board