ILLINOIS POLLUTION CONTROL BOARD
December 3, 1992

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

Proposed Rule. First Notice.

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

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

Today's first notice proposal closely follows the recommendations of the Governor's Medical Waste Tracking Study Group as that group's consensus recommendations have been presented to the Board in the proposal submitted by the Illinois Environmental Protection Agency (Agency). The few substantive departures from that proposal are identified and discussed in today's opinion.

Pursuant to the Illinois Administrative Procedure Act, a 45-day public comment period will commence upon publication in the *Illinois Register* of today's proposal. Persons interested in providing additional comment on this proposal, or in responding to inquiries posed by the Board herein, should submit such response in writing to the Clerk of the Board prior to the expiration of this 45-day period.

## HISTORY

Prior to discussing the particulars of today's proposal, it is instructive to place the proposal in historical perspective.

[1] The Board is today proposing that the three parts that comprise the PIMW subchapter be consecutively numbered. This is reflected in the caption of the instant action. The organizational plan for Subtitle M is discussed later in this opinion.

Although concern about infectious materials is long standing, the impetus to today's particular action is more recent, and threads through both federal and state actions.

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, which has provided for an expanded understanding of the nature and hazards associated with medical wastes[2].

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 bordering a portion of 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.

All of the Great Lakes States have elected to opt out of the federal MWTA demonstration program. Governor James R. Thompson explained the reasons that Illinois chose 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.

[2] 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.

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 the Illinois' medical waste program. Accordingly, on December 28, 1989, he announced the formation of the Medical Waste Tracking Study Group (Study Group). The Study Group consisted of elected officials[3] and representatives of state agencies[4], the health community[5], waste organizations[6], academia[7], agriculture[8], and the City of Chicago[9].

The Study Group met on many occasions and reviewed many 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"[10]. The report contains background information on the scope of the PIMW problem and recommendations for managing PIMW in Illinois. These

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

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

[5] 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).

[6] 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, Inc. (Mr. Ed Juracek).

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

[8] Mr. Richard P. Myers.

[9] Ms. Nancy Marren.

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

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 under consideration.

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. The Board expresses its appreciation for the quality and magnitude of these contributions.

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") (Ill. Rev. Stat. 1991, ch. 111½, par. 1001 et seq.) 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.

A definition[11] for potentially infectious medical waste is one of the cornerstones of P.A. 87-752; its 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:

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.

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

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[12] 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));

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

[12] 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.

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[13]. 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:

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;

[13] 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.

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 clarifies the definition of PIMW, clarifies various exceptions to the prohibitions of Section 56.1, and specifies July 1, 1993 as the required date of completion of the instant rulemaking[14].

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. 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

[14] The amendments of P.A. 87-1097 are not effective until January 1, 1993. For the purposes of this first notice action, however, the Board will treat the amendments as if they are in force since they will become effective well before the instant rulemaking is completed.

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 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 further considerations.

On April 27, 1992 the Agency filed the draft proposal upon which the merit hearings have been held and upon which today's first notice proposal is 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 formalizing and filing its proposal. The Board extends its appreciation to the Agency and its personnel for the quality of its leadership role.

[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, 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.

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). On June 4, 1992 the Board issued an order finding that the EcIS need not, at that time, 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.
>
> *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.

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

[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.

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 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, as will be discussed in subsequent sections of this opinion.

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, as also will be discussed in subsequent sections of this opinion.

Public Comments

Twenty-four public comments have been filed with the Board, including nineteen filed subsequent to the start of merit hearings. These are dominantly expansions upon or responses to matters addressed at hearing. The Board has reviewed all public comments, with citations[18] herein where pertinent.

## GENERAL CONSIDERATIONS

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

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

Immediacy of the PIMW Problem

While it is generally acceded that PIMW presents a real problem, it is also generally acceded 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 proposed 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 proposed PIMW management system should reduce the possibility of infection almost completely. (Tr2. at 113.)

Today's proposed 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 is PIMW[19].

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 proposed 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[20], 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 proposal. 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.

Today's proposal follows the Agency Proposal in requiring two demonstrations of treatment efficacy. The first is the Initial Efficacy Test[21], in which it is required that the

[19] 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.

[20] 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 proposed Section 1422.126. See discussion of the term "recognizable" in the part-by-part discussion, below.

[21] See proposed Section 1422.124.

manufacturer assure that six types of "test" microorganisms[22] that are surrogates for pathogens be reduced to very low concentrations (a 6-log[23] reduction) 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[24]. 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 the Study Group. Nevertheless, there have been several questions raised regarding particulars of the program, notably by Sexton Environmental Systems (Sexton), Dr. Eugene Cole, and Winfield Environmental Corporation (Winfield).

Sexton believes that "the efficacy standards for PIMW treatment processes which are contained in the proposed regulations are inadequate to insure that the infectious potential of the PIMW will be eliminated". (PC #21 at 1.) It also contends that:

> [a] requirement that efficacy should be demonstrated using vegetative microorganisms which are surrogates for human pathogens is both more complicated and less reliable. Any PIMW treatment process which is capable of a 6-log bacterial spore reduction will result in even greater reductions in test microorganism populations and thereby will insure that "all" of the vegetative pathogenic microorganisms present in the waste will be killed. (PC #21 at 3.)

Sexton also argues that the Agency and Sexton disagree on the definition of "high-level disinfection". Sexton cites Dr.

[22] *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).

[23] 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.

[24] See proposed Section 1422.125.

Van Anderson's testimony that "... high level disinfection ... means that it destroys all forms of microbial life except high numbers of bacterial spores" (Tr2. at 503). Sexton cites Dr. Edward Cohen's belief that "high-level disinfection" is achieved by a 6-log reduction in bacterial spores (PC #21 at 3). Sexton further states that neither Dr. Cohen nor Sexton propose that PIMW should be sterilized (PC #21 at 4).

Sexton believes that in order to adopt treatment standards within the mandates of the Act, to "eliminate the infectious potential" of the waste, the Board must require that a treatment unit demonstrate a 6-log reduction of bacterial spores. Sexton also states that "no representative from the infectious waste management industry other than Mr. [Joseph] Wilson of Ecomed, testified that any existing or planned PIMW treatment facility could not meet a 6-log spore reduction standard" (PC #21 at 9).

Most of the participants in this proceeding, aside from Sexton, argue that there is very little extra benefit afforded by a treatment standard that focuses on bacteria spores as the microorganism upon which the 6-log reduction must be demonstrated (e.g., Tr2. at 500-5, 695-6, 706, 894, 952, 982; Exh. 45 at 2, 14-16; Exh. 45-6). They also emphasized that treatment is only one aspect of today's proposal. (Tr2. at 505-10, 514-5, 697, 704, 726, 896.) In light of this very strong and diverse support for maintaining the treatment standard as presented in the Agency Proposal, the Board today declines to alter this facet of the Agency Proposal. We also note that, upon review of the extensive record in this proceeding, the scientific consensus for what constitutes "high-level disinfection" is comparable to the Agency's proposal rather than that asserted by Sexton. (Tr2. at 910-11, 952-4; Exhs. 38-8, 38-12, 38-71, and 45-6.)

The issue of how the phrase "eliminate the infectious potential" is to be interpreted is also raised by Dr. Cole[25]. One of Dr. Cole's primary concerns is the proposal's use of a 6-log reduction standard to determine treatment efficacy. Dr. Cole contends that the correct standard is a $10^6$ kill (a destruction of one million organisms per gram of waste). Winfield (PC #8) commented similarly.

The treatment efficacy standard proposed by the Agency at Section 1422.124(b) requires the "log kill" for each test microorganism after treatment to be greater than or equal to 6

[25] Dr. Cole has authored two public comments. The first (PC #16), submitted to the Board by National Solid Waste Association, is a report entitled, "Assessment of Illinois EPA Proposed Rules for the Treatment of Potentially Infectious Medical Waste". The second public comment (PC #23) contains comments to the Board from Dr. Cole.

(6-log reduction). The Board notes that the term "log kill" as used by the Agency incorporates the concept of "log reduction" which is different than the interpretation proposed by Dr. Cole. "Log reduction" means the logarithm of the number of times the initial concentration of test microorganisms is reduced by treatment. Therefore, the proposed efficacy standard requires at least a 6-log reduction which means a reduction of initial concentration of test microorganisms by a magnitude of 6 orders or 1 million times. Under the Agency's proposal, log kill is calculated as follows:

$$\text{log kill} = \log (\text{NoA}/\text{N1A}) = \log \text{NoA} - \log \text{N1A} \geq 6$$

where:

NoA=number of organisms/gram before treatment;
N1A=number of organisms/gram surviving treatment.

According to Dr. Cole, "log kill" means the logarithm of number of microorganisms inactivated or killed by treatment. Therefore, the efficacy standard proposed by Dr. Cole would require at least a 6-log kill which corresponds to inactivation of at least one million test organisms per gram of waste. According to Dr. Cole's interpretation, log kill is determined as follows:

$$\text{log kill} = \text{Log} (\text{NoA} - \text{N1A}) \geq 6$$

The difference between the efficacy standards proposed by the Agency and Dr. Cole may be illustrated by example. If waste containing $10^7$ organisms/gram (10 million) is treated and reduced by $10^6$ organisms/gram (1 million), $9.0 \times 10^6$ (9 million) organisms\gram survive. Under the Agency's proposal, the treatment yields a log kill of 0.05 which fails to meet the proposed standard of 6. On the other hand, under Dr. Cole's interpretation, the above example yields a log kill of 6 which meets the efficacy standard. In the above example, for the treatment process to meet Agency's proposed standard, only 10 or less test microorganisms may survive after treatment; this equals a kill 9.99999 million organisms/gram.

The Board will retain the Agency's language and calculations, but solicits comments as to whether a log-reduction calculation is appropriate to determine efficacy and whether the definition regarding log-reduction is sufficiently straightforward.

Dr. Cole also suggests a direct definition of "eliminates the infectious potential", thusly:

ELIMINATES THE INFECTIOUS POTENTIAL OF THE WASTE. The infectious potential is eliminated and indicated by the

> consistent kill of at least 1 X $10^6$ per gram of waste solids for at least one of each of the following: vegetative bacteria, vegetative fungi, fungal spores, viruses, and mycobacteria; and the kill of 1 X $10^3$ bacterial spores per gram of waste solids. (PC #16 at 4.)

This contrasts with the concept definition provided in the Agency Proposal at Section 1422.122(a)(1):

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

The Board reserves judgement on this definitional matter, and requests that interested persons address it in public comment.

Dr. Cole also recommends the use of alternate types of microorganisms rather than the specific species identified in Section 1421.Appendix A.Table A. The Agency has stated, in response to a similar comment from Winfield (PC #8), that no substitutes for the specific organisms will be accepted in order to provide a consistent standard for all treatment technologies (Tr2. at 231). The Board agrees with the Agency.

Permitting

The Agency submitted draft permit applications in Dr. Shirley Baer's testimony (Exhs. 38-1B and 38-3). Review of these draft permit applications reveals that some of the requirements for permitting would not flow from the proposed rules, and in part are inconsistent with them.

For example, in the draft Agency permit application and instructions, the paraphrase of treatment is different (Exh. 38-3 at 11) from the statutorily-derived definition in Section 1420.101; the requirements for land surveyor and engineer certification, and for demonstrating compliance with referenced federal CFR packaging standards[26] (Exh. 38-3 at 2, 11) are not reflected in the proposed rules; the Initial Efficacy Test demonstration does not appear to allow the owner or operator to provide for manufacturer documentation (Exh. 38-3 at 6), as the proposed rules allow; the narrative paragraph addressing the Periodic Verification Test (Exh. 38-3 at 6) does not fully

[26] It is unclear whether this is the proper CFR reference.

comport with the detailed regulations; regarding waste types, required identification, such as by generation process and by percent weight of components such as sharps, plastics, noncombustibles, and cellulosic solids (Exh. 38-3 at 4) appear to be at odds with Subpart B of the proposal, which only requires segregation by sharps, oversized PIMW, and all other.

The need to avoid such problems of nonconformance is the reason why many of the Board's regulations are quite specific regarding the information required to be submitted on a permit application and the conditions under which the Agency may request modification or deny a permit[27]. In many instances here, desired provisions can be included in the proposed regulations so as to provide the necessary authority for their implementation and enforcement. As a first step, the Board today proposes to include the registered land surveyor and registered professional engineer certification requirements and to define those terms. However, one fundamental difficulty in reaching such conclusions is draft permit applications' virtual lack of citation to, or otherwise no utilizing the language of, the proposed regulations. The Board believes that the best approach is to attach 35 Ill. Adm. Code 812.Subpart A of the Board's landfill regulations to this opinion for further guidance and to solicit comment regarding the need for greater specificity or clarification in the rules in light of these draft permit requirements.

Further discussion regarding permitting can be found in the part-by-part discussion below.

Manifesting and Agency Objection

The PIMW manifest requires classification of PIMW into the categories used/unused sharps, human pathological wastes, and animal wastes. (Exh. 38-2.) This classification is not required in the rule. PIMW is considered PIMW and, with the exception of a few extra provisions for sharps, is identical for each classification. Human pathological wastes and animal wastes are not required to be segregated from the other PIMW, as sharps are. Mr. Corrie Frank of Rose-Cartage, Inc., expressed concern at the August hearing that the labeling requirements in the proposed rule did not provide what he needed to know for his manifest. The Agency objected to Mr. Frank's testimony on the grounds that it deals with manifesting requirements. (Tr2. at 821.)

The Board overrules the objections of the Agency to the extent that the testimony relates to the issue of the clarity of

[27] For permits, for example, see 35 Ill. Adm. Code 807.Subpart B, 809.Subpart B, or Part 812; for Agency certification or waste classification requirements see 35 Ill. Adm. Code 745.Subpart B and 808.Subpart D.

the proposed rules. The Agency is correct that the legislature mandated that the Agency prescribe and provide manifest forms. (Section 56.4 of the Act). However, the Board is mandated to adopt regulations prescribing, among other things, standards and criteria for transporting, packaging, segregating, labeling, and marking PIMW. (Section 56.2 of the Act.) The Board solicits further comment on the issue of clarity of the labeling requirements and other provisions of the proposed rules in light of the manifest requirements.

Non-Substantive Format Changes

The proposal as today sent to first notice contains a number of modifications made for organizational, formatting, grammatical, etc., reasons. Many of these consist of errata offered by the Agency (Exhs. 42, 67, and 68). Because these are generally non-substantive, most of them will not be discussed in the text of this opinion.

One general modification that is noteworthy, however, is the change in numbering of the two new parts. The Board notes that it had earlier recommended that Parts 1430 and 1440 be used for the Section 56.2 regulations, and that the Agency has adopted this scheme in presenting the Agency Proposal. However, upon both review of that proposal and consideration of possible future additions to Subtitle M, the Board now believes that the PIMW subchapter is best placed in consecutively numbered parts, as a matter of the most economical use of Subtitle M (see discussion below). This scheme is used today.

Another general modification to be noted is the editing of the proposal to establish a uniform usage with respect to "shall", "must", "will", and "may". "Shall" is used when the subject of a sentence has to do something. "Must" is used when someone has to do something, but that someone is not the subject of the sentence. Typical usage of the latter occurs where an object is required to have some condition or property, as for example in: "the map must show the location of all facilities". "Will" is used when the Board obliges itself to do something. "May" is used when a provision is optional. The Board does not intend to make any substantive change in the rules by way of these changes.

Additionally, the Board has made several nonsubstantive format changes to the Appendices.

## ORGANIZATIONAL CONSIDERATIONS

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

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 proposed 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 proposal, beginning with Part 1420. Emphasis is on issues that have required Board resolution and on substantive modifications of the Agency Proposal that the Board proposes today[28].

Part 1420 is the only one of the three parts in today's proposal that is not entirely new. Part 1420 originated in the Board's R91-19 proceeding. Today 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. Although no modification of this section was offered in the Agency Proposal, the Board today proposes to strike both subsection (b) and the Board Note as no longer reflective of the overall content of either Part 1420 or the PIMW subchapter.

### Definitions (Section 1420.102)

General definitions that apply to the three PIMW parts are found in Section 1420.102. Most of these definitions are

[28] 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.

standard, and need not be specifically discussed here. However, there are several around which question has been raised.

**"Registered Land Surveyor"** and **"Registered Professional Engineer"** As observed above under the "Permitting" discussion, the Board today adds definitions for registered land surveyor and registered professional engineer. These definitions are the same as the definitions in the Board's landfill regulations at 35 Ill. Adm. Code 810.103 and groundwater regulations at 35 Ill. Adm. Code 615.102.

**"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 a few concerns raised regarding this definition, some of which have now been addressed by the General Assembly. The Board as no authority to modify the statutory definition.

Chemical Waste Management (CWM) has raised a question regarding the role that the source of a material plays in determining whether a material is PIMW (Tr2. at 282-305; PC #22). CWM specifically asks that the Board clarify the definition of PIMW regarding whether unused, discarded test kits that contain sterilized and not free-flowing blood components should be considered PIMW. The Agency has stated that it does not believe such a waste is PIMW because it is not waste from a health facility. (Tr2. at 299.)

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, its source notwithstanding. 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.

**"Site"** The term "site" appears in many places within the instant proposal, 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

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

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

circumstances[31]. There is thus a special importance to having the definition be clear and precise.

The following definition is 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. There is, however, concern with the lowercase, Agency-proposed language. The purpose of the lowercase 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 to assure 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 is 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 today declines to propose the lowercase language.

Several alternative resolutions have been proposed. Among these is the proposal of the National Solid Waste Management Association (Exh. 53), which offers the following definition of "site":

> (1) Except for an institution of higher education owned or operated by the state of Illinois, all buildings, equipment, structures, and other stationary items which are located on a single property or on contiguous or adjacent properties and which are owned or operated by the same person (or by any person which controls, is controlled by or under common control with, such person);
>
> (2) In the case of an institution of higher education owned or operated by the state of Illinois, all

[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).

> buildings, equipment, structures and other stationary items located within the same county which are owned and operated by the institution of higher education.

Ms. Ann Guild has also suggested that all activities that fall under a single institutional license should be considered a single site (Exh. 51; Tr2. at 708-9).

Dr. Van Anderson presented language that would address the particular concerns of the four campuses of the University of Illinois, by explicitly defining each as a separate site:

> The campuses and facilities of the University of Illinois under the management and control of the Board of Trustees as specified in 144 Ill. Rev. Stats. 22 et seq., at the following locations: (1) Urbana-Champaign, (2) Chicago, (3) Rockford, and (4) Peoria.

The Board recognizes that the matter of campuses as single entities is worth explicit consideration in these regulations. Accordingly, the Board today adds language specifying that each campus constitutes a single site. The Board believes that the term "campus" has sufficient ordinary meaning as to itself be explicit. The result is as follows:

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

The Board requests comment as to whether there are any other aggregates of facilities, hospitals for example, which need also to be specifically identified at this portion of the regulations. In this regard, the Board requests comment on whether the "single institutional license" description is more workable for hospitals than the proposed language offered by the NSWMA. While NSWMA's language appears to cover hospital "campus" situations, it may be too restrictive.

**"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.

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.[33]

It may be observed that an effect of this recommendation is to incorporate into the definition the concept of usability. The Board believes that this incorporation is consistent with the PIMW threat posed by sharps and the circumstance under which that threat is allayed.

Isolyser Company has questioned how the usability concept would apply to sharps treated by their encapsulation-solidification process. (Tr2. at 277-8.) 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). The Board concludes that such treatment renders sharps unrecognizable for the purposes of these regulations.

Although the Board accepts the Agency's concept of the definition of "unrecognizable" as contained in its proposal, it notes that the definition needs a technical correction. As proposed, the definition is that of a noun, although the word "unrecognizable" is an adjective. Similarly, "alteration" is a noun, and those terms that are examples of "alteration" must also be nouns.

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

[33] The Agency later proposed adding "and the sharp cannot be easily identified" to this definition. (Exh. 67.) The Agency posed this change in response to Board inquiries and suggestions at hearing. The Board believes the Agency's original language satisfies these concerns.

As a final matter, the Agency in reponse to Board inquiries at hearing, proposed in its errata (Exh. 67) to add the phrase "and the sharp cannot be easily identified" at the end of the original definition. The Board today retains this concept, but in a rephrased form. In sum, the Board today proposes the definition modified as follows:

> "Unrecognizable" means relating to a sharp that has undergone physical alteration (~~i.e., melted, charred, corroded, or ground~~e.g., melting, charring, corroding, or grinding) so that the sharp may no longer be used, or perceived as usable, for its intended purpose.

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 proposal contains two incorporations by reference. They are Standard Methods for the Examination of Water and Wastewater (17th Edition) and Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (EPA SW-846)[34]. When asked at hearing, Agency witness Dr. Shirley Baer testified that Part 9000 of the Standard Methods reference discusses microbiological examinations and Chapter 9 of SW-846 describes sampling protocols such as those necessary for the tests required by this proposal (Tr2. 241, 398-400). The Board today proposes these incorporations as presented in the Agency Proposal. However, in observation that both references are fairly lengthy, the Board does ask whether greater specificity, such as citation to those more specific parts cited by Dr. Baer, would be useful and how this could be accomplished in the rule.

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. Today Section 1420.104 is presented without modification from the Agency Proposal, except as noted in the following.

Subsections (d)(1) and (g)(1) contain prohibitions against transporting, treating, storing, or transferring PIMW without permits. The Board has deleted the phrase referring to forms

[34] 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.

which reads "and completed in accordance with permit application instructions and guidelines" from subsections (d)(1) and (g)(1). The Board believes that this phrase conceivably could be the basis for an enforcement action for failure to complete permit applications according to Agency guidelines and instructions. The Board does not intend to propose enforcement of Agency instructions or guidelines since these are not rules nor are intended to be rules.

In its errata submissions, the Agency proposed adding a additional prohibition at subsection (l), as follows:

> [No person shall:] Cause or allow the discharge of PIMW into a sanitary or combined sewer except in accordance with 35 Ill. Adm. Code.Subtitle C and local ordinances.

This proposal arises from concerns of the Metropolitan Water Reclamation District of Greater Chicago (MWRDGC) and the Illinois Association of Wastewater Agencies. (Tr2. at 468-493; Exh. 43 and 44; PC #6, 11, and 12.) MWRDGC explains 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. MWRDGC discussed the 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.) MWRDGC accordingly asked the Board to include a specific prohibition of the discharge of inert or solid PIMW into the sewerage system:

> [No person shall:] Cause or allow the discharge of any inert or solid PIMW, or an 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.

In response the City of Chicago points out that MWRDGC may, under the authority given it by the legislature, enact its own ordinance to cover the situation of solid PIMW. (PC #18.) However, the Board is charged under Section 56.2 of the Act to prescribe design and operating standards and criteria for all potentially infectious medical waste treatment, storage, and transfer facilities, which must include treatment that disposes of treatment residuals in accordance with the Act and Board regulations adopted thereunder. The Board believes that disposal

of such treatment residuals is within the province of these regulations and a prohibition involving sewage disposal may then be necessary.

The question next becomes whether the Agency's proposed prohibition or MRWDGC's prohibition is proper for these regulations. The Board believes that both the general prohibition proposed by the Agency and the specific prohibition covering solid PIMW are necessary in order to assure that any discharge of PIMW will be done in accordance with the Act and Board regulations. The record indicates that there are unique problems associated with the disposal of solid PIMW into sewage systems, such as possible damage to the biological treatment system and difficulties in applying sludges to land, that require the more specific prohibition. (See, Tr2. at 491-496.) For these reasons, the Board today proposes to add to the Agency proposal at Section 1420.105(l) underlined language as follows:

> l) Cause or allow the discharge of PIMW into a sanitary or combined sewer except in accordance with 35 Ill. Adm. Code.Subtitle C. <u>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.</u>

Having so noted, the Board solicits further comment on this issue, particularly on the matter of whether this prohibition is sufficiently inclusive but yet allows flexibility for new treatment technologies. The Board also deletes the phrase "and local ordinances" from the Agency proposed language at this subsection and at proposed Sections 1421.121(f), 1421.141(f), 1422.111(a)(9), and 1422.122(b)(1) because the Board has no authority to enforce local ordinances. The Board adds a "Board note" to the rule text alerting interested persons of local ordinances covering sewer discharges.

<u>Permit and Manifest Exceptions and Penalty Factor (Sections 1420.105 and 1420.106)</u>

These two sections basically present language from the PIMW statute. Although the sections are critical, they hence are not amenable to substantive modification at the Board level.

As explained above under the "permitting" discussion, the Board is proposing to insert in Section 1420.105 a new subsection (c). The new subsection (c) requires that engineering features of plans, specifications, and reports in permit applications be certified by a registered professional engineer and must bear the engineer's seal and signature along with the signature and/or seal of a registered land surveyor.

Cleaning and Disinfection (Section 1420.107)

Cleaning and disinfection are general actions required at several places in the PIMW subchapter, including within the definitions ("reusable container") and Parts 1421 and 1422[35]. Section 1420.107 provides for a single location at which the elements of cleaning and disinfection are presented.

No questions have been raised regarding the content or form of Section 1420.107. However, the Board today adds the metric equivalent for the household bleach/sodium hypochlorite solution at subsection (a)(2)(C). The Board also adds at subsection (a)(2)(B) the phrase "as identified on its label", pertaining to the chemical disinfectant registered by the United States Environmental Protection Agency. The same phrase is used elsewhere in the Agency Proposal[36].

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 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 proposed today without substantive modification from the Agency Proposal.

[35] Sections 1421.121(d), 1421.121(e), 1421.141(i), 1422.111(a)(8), 1422.111(a)(11), and 1422.122(b)(5).

[36] See definitions of "detergent-sanitizer" and "sanitizer" and Section 1420.102.

General Provisions (Subpart A)

This short subpart contains a single section that specifies 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.

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. The Board deletes the phrase "that minimizes" from the

Agency proposal at subsection 1421.121(c), and replaces it with "so as to avoid".

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.

No questions have been raised regarding the content of Subpart D; it is proposed today substantively as recommended in the Agency Proposal.

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.

Mr. Harry Eiler of Recovery Corporation of Illinois Precision Energy Systems, Inc. (Recovery Corporation), expressed concern regarding the proposed requirement for "dedicated vehicles" for PIMW management for "long-haul" vehicles[37]. (Tr2. 776-814; Exh. 54.) Recovery Corporation also filed a public comment on the issue. (PC #24.) Mr. Eiler believes that "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 vehicle has been

[37] 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".

decontaminated in accordance with the procedures given in Section 1420.107. Mr. Eiler said that the cost would increase 100% if a long-haul vehicle were required to haul PIMW to one destination and then return with an empty vehicle. (Tr2. at 796, 805.)

NSWMA concurred with the use of dedicated PIMW vehicles and cited Ohio and Texas regulations that do not allow use of medical waste vehicles until decontamination has occurred. Mr. Eiler agreed, stating that decontamination should be done prior to backhauling any hardgoods. (Tr2. at 781; 795-6.) The Agency expressed concern about enforcing decontamination standards in an interstate setting. The possible use of "certificates of decontamination" was discussed, as was the use of enforcement against a hauler when present in Illinois. (Tr2. at 798-814.) Mr. Eastep stated that treatment conducted outside Illinois could also not be enforced by Illinois; however, he further stated that there are performance standards for treatment. (Tr2. at 810, 813.)

The Board is sympathetic with the concerns expressed by Mr. Eiler. While we do not today propose language changes allowing for such backhauling, the Board solicits specific draft language that might accomplish this end. Specifically, the Board solicits language that allows "backhauling" of "hardgoods" by "long-haul vehicles" after decontamination has occurred, and that provides definitions of those terms. Justification for all proposed provisions is also sought. Comment is also requested as to why this exception should only apply to vehicles delivering interstate.

The Board has questioned the provision of Section 1430.141(i) that allows equipment and supplies intended for waste management to be transported in a vehicle transporting PIMW and sought clarification on the types of materials allowable. (Tr2. at 349-50.) This question was reiterated to the Agency at the August hearing and the Agency provided a list of "acceptable" waste management supplies (Exh. 75, attachment 1). These are incorporated into the rule as examples at subsection (i).

Mr. Eiler also offered an addition to the proposed rules that would allow for multi-stop manifesting. The Agency objected to this testimony because it pertains to manifesting. The Board overrules the objection for the same reasons as stated earlier regarding Mr. Frank's testimony. Mr. Eiler stated at hearing that he would attempt to discuss these matters with the Agency. The concerned participants are requested to comment if they believe that some additional clarification is needed in the proposed rules as opposed to the manifest form prescribed by the Agency.

The remainder of the Subpart E provisions are offered in the same form as presented by the Agency.

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.

General Provisions (Subpart A)

This short subpart contains a single section that 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[38].

Storage/Transfer Operations (Subpart B)

Subpart B consists of two sections that apply to the owner or operator of any PIMW storage operation[39]. The subpart is proposed 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.

[38] 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).

[39] 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 proposal 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 basically 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.)

It is to be noted that the standards and criteria of both 1422.111(a) and (b) constitute requirements for the granting of a permit for a storage operation. As a general matter, for any permit to be issued the applicant must prove to the Agency, pursuant to Section 39(a) of the Act, that it will not cause a violation of the Act or regulations promulgated thereunder. Accordingly, failure to supply proof of meeting any of the Section 1422.111 requirements could be grounds for permit denial.

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).

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. As noted above in reference to Section 1422.110, these provisions constitute requirements for the granting of a permit.

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. Subsection (b)(2) allows the unit to be operated under an adjusted standard granted by the Board. Subsection (b)(1) allows the unit to be operated if the unit uses thermal, chemical, or irradiation treatment ((b)(1)(A)), and the unit "is mechanically identical to one previously permitted in Illinois for the treatment of PIMW" ((b)(1)(B)), and is operated under basically identical operating conditions as the permitted unit.

Allowing an "identical" unit to operate under the same conditions as a permitted facility or unit seems as though it would save the "identical" unit operator (and the Agency) the time and expense necessary to obtain its own permit or an adjusted standard. However, this type of arrangement raises many questions pertaining to operation and possible enforcement, since the unit would not be operated under its own permit. Some of the questions were addressed by the Agency at hearing and in responses filed subsequent to hearing (Tr2. at 1053-9; Exh. 75).

The Board continues to be disturbed by the implications of such an arrangement. The question was raised concerning the subsequent modification of the permitted unit and issuance to that unit of a new, modified permit. The Agency responded that the unpermitted but identical facility may still operate under the terms of the original permit. (Exh. 75 at 9.) However, the unpermitted facility would no longer be identical, and hence, may fall out of the terms of rule. An argument can be made that the unpermitted unit is identical to "one previously permitted" ((b)(1)(B) emphasis added). This raises other questions regarding possible difficulty with tracking older permits. Also, the permit-exempt facility operator would not have the same appeal rights as a permit holder, since the permit-exempt facility operator was not issued any permit. Since the permit-exempt facility operator has chosen to operate under conditions of another's permit, it may be unlikely that the permit-exempt facility operator would ever seek appeal. (See Exh. 75 at 9.) It is the permit-exempt operator who would determine whether he or she is operating a mechanically identical unit. This has raised questions of whether the rule allows for an unlawful delegation of the Agency's authority to issue permits. Since the facility would be permit exempt, and no permit is actually issued, it can be argued that there is no delegation problem. The bottom line is that there are uncertainties and possible greater exposure to enforcement by such an approach. We decline today to propose specific amendments and seek further comment from interested persons on the matter.

One solution is that Section 1422.123(b)(1)(B) be omitted. Case law has held that having a permit does not insulate the permittee, and by extension, any person similarly operating in reliance on that permit, from an enforcement action for allegedly violating the Act or Board regulations. The permittee is simply protected from charges of operating without a required permit; if the permit is required, it is an authorization to operate, not an insulation against enforcement. (Landfill, Inc. v. IPCB (1978), 74 Ill.2d. 541, 387 N.E.2d 258; see also Illinois Power Company v. IPCB (5th Dist. 1983), 122 Ill.App.3d 457, 445 N.E.2d 820.) For example, the Act gives any person the right to enforce if later periodic verification tests show that one of the units, whether or not it is that of the permittee, is not continuing to perform as required in the Board regulations.

In so saying, we wish to emphasize that the Agency's detailed review under the permitting system is considered a vital component in the State's environmental regulatory scheme. We note, though, that where a permit is not required, operators in other areas also face a similar dilemma to that occurring here. This was discussed in relation to on-site landfills in In the Matter of: Development, Operating and Reporting Requirements for

Non-Hazardous Waste Landfills (June 7, 1990), R88-7 at 6, 112 PCB 84).

We note that the proposed regulatory standards give quite detailed directions to those who are not required to have a permit. We also note that there is nothing preventing an unpermitted facility from complying with the additional requirements in Section 1422.122(c) for those needing a treatment facility permit. We suggest that the use of the Board's adjusted standard procedure may provide a remedy for many of the concerns expressed above. For example, if a commercial treatment process, including an innovative one, is granted an adjusted standard by the Board after a demonstration has been made justifying the treatment process in relation to the regulatory standards, the adjusted standard can contain conditions such as requiring notification to the users of the process certifying that the adjusted standard has been granted. Similarly, if an adjusted standard has been granted for a modification, then a similar certification can take place.

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.)

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.

The Board has made one minor change worth noting. The text of the Agency's proposal at 1422.125(a)(3) was moved to (a)(4). The text of subsection (a)(3) covers alternatives that are defined and discussed mainly in (a)(4). The subsection was then renumbered to accommodate this change.

The Board solicits comments, especially from the treatment industry, as to the workability and clarity of the methods set out in Sections 1422.124 and 125 and 1422.Appendix A and B. The Board also solicits comment on what procedures the Agency will use for approval of alternative periodic verification tests discussed at renumbered Section 1422.125(a)(3).

In addition, the Board notes that there are a number of issues in the treatment Sections 1422.124 and 1422.125 for which additional clarification of intent is desirous. Accordingly, the Board requests that interested persons, and the Agency in particular, address the following questions and provide suggestions for clarifying language where appropriate:

1) Section 1422.124(e)(2) requires that test or indicator microorganisms be cultured and enumerated according to "applicable manufacturer's" recommendations; this language is repeated in Section 1422.125(b)(4). Is this "manufacturer" intended to be the manufacturer of the treatment unit, the microorganism test unit, or some other?

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

3) Section 1422.125(a)(2) requires that the log kill (L) from the Initial Efficacy Test be correlated to an equivalent log kill (T) calculated pursuant to Section 1422.Appendix B. However, three equivalent log kill (T) calculations are made pursuant to Section 1422.Appendix B (TA, TB, and TC). Which of these equivalent log kills (T) is the appropriate standard to be used in Periodic Verification Testing by the treatment facility?

4) Section 1422.Appendix B (a) requires that a "certified microbiological indicator assay containing the test microorganisms and indicator microorganism spores" be used. How is this certification obtained and is an assay containing both the proposed test and indicator microorganisms widely available?

5) Section 1422.Appendix B (b) requires that the test microorganisms and indicator microorganism spores be placed in a sealed container that remains intact during treatment for the Periodic Verification Test. In the method for the Initial Efficacy Test (Appendix A), two types of testing are allowed, one for treatment technologies that can maintain the integrity of the test container and one for those in which integrity cannot be maintained. How does the Periodic Verification Test differ from the Initial Efficacy Test in this regard?

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[40]. Residues from a treatment unit with an experimental permit may or may not be considered PIMW, depending on the experimental permit conditions.

Discussion of the principal questions regarding the treatment provisions of the instant proposal has been presented above (see "General Considerations"). One matter which remains is the recommendation that tap water be allowed as a substitute for a chemical disinfectant in the portion of the Initial Efficacy Test that determines the appropriate microbial challenge for the actual test (Phase 1). Winfield (PC #8) requested that dechlorinated water be allowed in substitute for the disinfectant. The Agency has proposed the use of sterile saline solution (0.9%, volume/volume) or phosphate buffer solution in place of the chemical disinfectant(s). The Agency's concern is the osmotic nature of tap water versus that of a physiological-like solution. The purpose of the Phase I method is to determine how many microorganisms are destroyed by the mechanical process without any application of treatment. If an inappropriate (non-isosmotic) solution is used in this part, more microorganisms may be destroyed by the hyposmotic nature of the tap or dechlorinate water and the Phase I measurement may be inaccurate relative to Phase II testing (Tr2. at 229). Dr. Cole argues that the use of physiological buffers like saline or phosphate buffer would impose an immense burden on those operating chemical treatment systems. The Board notes that this requirement is present only in the Initial Efficacy Test which is required of manufacturers, not operators (unless the operator is the manufacturer), and is required to be made once per model, not per unit. A once per model burden to more accurately document efficacy does not appear unduly burdensome to this Board. However, we solicit further comment on the appropriate liquid.

Dr. Cohen suggests that the six test microorganisms may be run through the Initial Efficacy Test together rather than separately as proposed by the Agency in Section 1422.Appendix A (Exh. 46 at 15). After questioning regarding appropriate methods to simultaneously identify and quantify multiple species of microorganisms from a single inoculum, Dr. Cohen submitted a proposed method as Exhibit 70. The Board solicits comment about which method is the most appropriate and effective.

[40] In the Agency Proposal the word "Part" was used within Section 1422.127(a) to denote the scope of possible experimental permits. This reading would allow experimental permits to be issued for both storage operations and treatment facilities. Today the Board replaces the word "Part" with "subpart", to limit experimental permits to treatment matters, as is the seeming intention.

ORDER

The Board hereby proposes for first notice the following amendments to 35 Ill. Adm. Code 1420 and the following new Parts 35 Ill. Adm. Code 1421 and 1422. The Clerk of the Board is directed to file these proposed rules with the Secretary of State.

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

PART 1420
GENERAL PROVISIONS

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

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

SOURCE: Adopted in R91-19, at 16 Ill. Reg. 2594, effective February 3, 1992; amended in R91-20 at _____ Ill. Reg. _____, effective _____.

NOTE: Capitalization denotes statutory language.

1420.101 Scope and Applicability

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

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

~~BOARD NOTE: Section 56.2(d) requires the Board to repeal pre-existing rules for handling medical wastes by January 1, 1992. Section 56.2(e) requires the Board~~

~~to adopt by January 1, 1992 a list of Class 4 etiologic agents, which lends operative meaning to "isolation waste," as that term is used in the statutory definition of potentially infectious medical waste at Section 3.81. Section 56.2(a) and (c) require the Board to adopt standards for the transportation, packaging, segregation, labelling, and marking of potentially infectious medical waste by January 1, 1993. Section 56.2(f) authorizes additional rules to promote the purposes of Title XV of the Environmental Protection Act (Ill. Rev. Stat. 1989 ch. 111½, par. 1001 et seq., as amended by P.A. 87-752, effective January 1, 1992).~~

Section 1420.102 Definitions

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

"Act" means the Environmental Protection Act (Ill. Rev. Stat. 198991, ch. 111 1/2, par. 1001 et seq., as amended by P.A. 87-1097, effective January 1, 1993 ~~752 and P.A. 87-650, both effective January 1, 1992~~).

"Agency" means the Illinois Environmental Protection Agency.

"ATCC" means American Type Culture Collection.

"Board" means the Illinois Pollution Control Board.

"CFU" means colony forming unit.

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

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

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

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

Herpesvirus simiae (Monkey B virus)

Lassa virus

Marburg virus

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

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

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

BOARD NOTE: A Class 4 Agent helps define an "isolation waste" for the purposes of Section 3.8~~1~~4(a)(6) of the Act and this Subtitle. This listing derives from the CDC document, "Classification of Etiologic Agents on the Basis of Hazard," and is supplemented from the CDC/NIH document "Biosafety in Microbiological and Biomedical Laboratories."

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

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

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

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

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

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

"HIGHLY COMMUNICABLE DISEASE" MEANS THOSE DISEASES IDENTIFIED AS CLASS 4 ETIOLOGIC AGENTS under this Part. (Section 3.81~~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.Appendix 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.

"Low-level disinfection" means a process that causes the death of most bacteria except Mycobacterium tuberculosis and M. bovis, lipid-enveloped and medium-sized viruses (e.g., herpes simplex virus, cytomegalovirus, respiratory syncytial virus, hepatitis B virus, and human immunodeficiency virus), and fungi (e.g., Trichophyton sp., Cryptococcus sp., and Candida sp.).

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

"Registered land surveyor" means a person registered under the Illinois Land Surveyors Act (Ill. Rev. Stat. 1989, ch. 111, pars. 3201 et seq.).

"Registered professional engineer" means a person registered under the Illinois Professional Engineering Act (Ill. Rev. Stat. 1989, ch. 111, par. 5101 et seq.).

"Package" means a receptacle that contains PIMW.

"PFU" means plaque forming unit.

"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:

~~CULTURES AND STOCKS;~~

~~HUMAN PATHOLOGICAL WASTES;~~

~~HUMAN BLOOD AND BLOOD PRODUCTS~~

~~USED SHARPS;~~

~~ANIMAL WASTE;~~

~~ISOLATION WASTE; AND~~

~~UNUSED 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~~+~~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.

"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, non-absorbent, and smooth; and designed and constructed so as to easily permit cleaning and disinfection in accordance with Section 1420.107 of this Subtitle. A reusable container is not a single-use container or is not made of cardboard.

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

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

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

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

"SITE" MEANS ANY LOCATION, PLACE, TRACT OF LAND, AND FACILITIES, INCLUDING BUT NOT LIMITED TO BUILDINGS, AND IMPROVEMENTS USED FOR PURPOSES SUBJECT TO REGULATION OR CONTROL BY THIS ACT OR REGULATIONS THEREUNDER. (Section 3.43 of the Act). For the purpose of this

Subtitle, each campus of an educational institution is considered to be a single site.

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

"STORAGE" MEANS THE CONTAINMENT OF WASTE, EITHER ON A TEMPORARY BASIS OR FOR A PERIOD OF YEARS, IN SUCH A MANNER AS NOT TO CONSTITUTE DISPOSAL. (Section 3.46 of the Act)

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

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

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

"TRANSFER STATION" MEANS A SITE OR FACILITY THAT ACCEPTS WASTE FOR TEMPORARY STORAGE OR CONSOLIDATION AND FURTHER TRANSFER TO A WASTE DISPOSAL, TREATMENT OR STORAGE FACILITY. "TRANSFER STATION" INCLUDES A SITE WHERE WASTE IS TRANSFERRED FROM (1) A RAIL CARRIER TO A MOTOR VEHICLE OR WATER CARRIER; (2) A WATER CARRIER TO A RAIL CARRIER OR MOTOR VEHICLE; (3) A MOTOR VEHICLE TO A RAIL CARRIER, WATER CARRIER OR MOTOR VEHICLE; (4) A RAIL CARRIER TO A RAIL CARRIER, IF THE WASTE IS REMOVED FROM A RAIL CAR; OR (5) A WATER CARRIER TO A WATER CARRIER, IF THE WASTE IS REMOVED FROM A VESSEL. (Section 3.83 of the Act)

"TREATMENT" MEANS ANY METHOD, TECHNIQUE OR PROCESS, INCLUDING NEUTRALIZATION, DESIGNED TO CHANGE THE PHYSICAL, CHEMICAL, OR BIOLOGICAL CHARACTER OR COMPOSITION OF ANY WASTE SO AS TO NEUTRALIZE IT OR RENDER IT NONHAZARDOUS, SAFER FOR TRANSPORT, AMENABLE FOR RECOVERY, AMENABLE FOR STORAGE, OR REDUCED IN VOLUME. SUCH TERM INCLUDES ANY ACTIVITY OR PROCESSING DESIGNED TO CHANGE THE PHYSICAL FORM OR CHEMICAL COMPOSITION OF HAZARDOUS WASTE SO AS TO RENDER IT NONHAZARDOUS. (Section 3.49 of the Act)

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

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

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

Section 1420.103 Incorporations by Reference

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

Standard Methods for the Examination of Water and Wastewater, American Public Health Association et al. (1015 Fifteenth Street, N.W., Washington, D.C. 20005) (17th Edition, 1989).

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

Section 1420.104 Prohibitions

NO PERSON SHALL

a) CAUSE OR ALLOW THE DISPOSAL OF ANY PIMW. SHARPS MAY BE DISPOSED IN ANY LANDFILL PERMITTED BY THE AGENCY UNDER SECTION 21 OF the ACT TO ACCEPT MUNICIPAL WASTE FOR DISPOSAL, IF BOTH:

1) THE INFECTIOUS POTENTIAL HAS BEEN ELIMINATED FROM THE SHARPS BY TREATMENT; AND

2) THE SHARPS ARE PACKAGED IN ACCORDANCE WITH Part 1421, Subpart C of this Subtitle.

b) CAUSE OR ALLOW THE DELIVERY OF ANY PIMW FOR TRANSPORT, STORAGE, TREATMENT OR TRANSFER EXCEPT IN ACCORDANCE WITH Part 1421,Subpart C of this Subtitle.

c) BEGINNING JULY 1, 1992, CAUSE OR ALLOW THE DELIVERY OF ANY PIMW TO A PERSON OR FACILITY FOR STORAGE, TREATMENT, OR TRANSFER THAT DOES NOT HAVE A PERMIT

ISSUED BY THE AGENCY TO RECEIVE PIMW pursuant to Section 39 of the Act, UNLESS NO PERMIT IS REQUIRED pursuant to subsection 1420.105(b) 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(a) 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(c) 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(a) 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(b) 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(c) 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 are informed that local ordinances may also cover discharges to sewer systems.

Section 1420.105 Permit and Manifest Requirements and Exceptions

a) 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).

b) 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.

c) In a permit application, the engineering features of plans, specifications, and reports must be certified by a registered professional engineer and must bear the registered professional engineer's seal and signature along with the signature or seal of any registered land surveyor who has supplied data contained in the submittal. References are to be included when such data are obtained from published sources.

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

1) PIMW BEING TRANSPORTED BY GENERATORS WHO GENERATED THE WASTE BY THEIR OWN ACTIVITIES, WHEN THE PIMW IS TRANSPORTED WITHIN OR BETWEEN SITES OR FACILITIES OWNED, CONTROLLED, OR OPERATED BY THAT PERSON; OR

2) LESS THAN 50 POUNDS OF PIMW AT ANY ONE TIME FORE A NONCOMMERCIAL TRANSPORTATION ACTIVITY; OR

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

Section 1420.106 Penalty Factor

IN MAKING ITS ORDERS AND DETERMINATIONS RELATIVE TO PENALTIES, IF ANY, TO BE IMPOSED FOR VIOLATING SECTION 56.1(a) OF the ACT, THE BOARD, IN ADDITION TO THE FACTORS IN SECTIONS 33(c) AND 42(h) OF the ACT, OR THE COURT SHALL TAKE INTO CONSIDERATION WHETHER THE OWNER OR OPERATOR OF THE LANDFILL REASONABLY RELIED ON WRITTEN STATEMENTS FROM THE PERSON GENERATING OR TREATING THE WASTE THAT THE WASTE IS NOT POTENTIALLY INFECTIOUS MEDICAL WASTE. (Section 56.1(k) of the Act)

Section 1420.107 Cleaning and Disinfection

a) Cleaning and disinfection comprises:

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

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

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

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

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

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

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

Section 1420.120 Severability

If any Section, subsection, sentence or clause of this Subtitle is adjudged unconstitutional, invalid or otherwise not effective for any reason, such adjudication does not affect the validity of this Subtitle as a whole or of any Section, subsection, sentence or clause thereof not adjudged unconstitutional, invalid or otherwise not effective for any reason.

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

PART 1421
ACTIVITY STANDARDS

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SUBPART D: LABELING AND MARKING

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SUBPART E: TRANSPORTATION

Section
1421.140 Scope and Applicability
1421.141 Standards and Criteria

1421.Appendix A International Biohazard Symbol

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

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 and operators of PIMW storage sites, transfer stations and treatment facilities.

Section 1421.111 Standards and Criteria

a) Generators shall segregate PIMW as follows:

1) Sharps,

2) Oversized PIMW, and

3) All other.

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

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

SUBPART C: PACKAGING

Section 1421.120 Scope and Applicability

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

Section 1421.121 Standards and Criteria

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

1) RIGID;

2) LEAK-RESISTANT;

3) IMPERVIOUS TO MOISTURE;

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

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

b) Sharps must be packaged in a container, or a combination of containers, that is puncture-resistant and meets the requirements of subsection (a) of this Section.

c) Oversized PIMW must be covered or packaged in a manner so as to avoid 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 are informed that local ordinances may also cover discharges to sewer systems.

## SUBPART D: LABELING AND MARKING

### Section 1421.130 Scope and Applicability

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

### Section 1421.131 Standards and Criteria

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

1) The generator shall:

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

i) The International Biohazard Symbol as shown in Section 1421.Appendix A of this Part and the word "Biohazard"; and

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

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

i) The generator's name,

ii) The generator's address, and

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

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

A) The transporter's name,

B) The transporter's permit number,

C) The transporter's address,

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

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

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

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

1) The International Biohazard Symbol as shown in Section 1421.Appendix A of this Part and the word "biohazard"; and

2) The word "sharps".

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

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

1) The generator shall:

A) Mark on one side of the outer package in lettering that is readable at a minimum distance of five (5) feet the International Biohazard Symbol as shown in Section 1421.Appendix A of this Part and the word "biohazard".

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

i) The generator's name,

ii) The generator's address, and

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

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

A) The transporter's name,

B) The transporter's permit number,

C) The transporter's address,

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

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

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

SUBPART E: TRANSPORTATION

Section 1421.140 Scope and Applicability

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

Section 1421.141 Standards and Criteria

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

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

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

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

2) In good repair when transporting PIMW.

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

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

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

BOARD NOTE: Interested persons are informed that local ordinances may also cover discharges to sewer systems.

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.Appendix A: International Biohazard Symbol

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

PART 1422
DESIGN AND OPERATION OF FACILITIES

SUBPART A: GENERAL PROVISIONS

Section
1422.101 Compliance Dates

SUBPART B: STORAGE OR TRANSFER OPERATIONS

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

SUBPART C: TREATMENT FACILITIES

Section

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

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

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

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).

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 are informed that local ordinances may also cover discharges to sewer systems.

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.)

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

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

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

5) Adequate aisle space, as specified in the permit, must be maintained between packages to allow inspection of at least one (1) side of each package. Packages must be stacked so that labels

are readable. A vehicle containing PIMW is exempt from the above aisle space requirement:

A) When loading or unloading a vehicle; or

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

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

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

7) Signs identifying the storage operation must be prominently displayed at the points of access to the secured storage area. Signs must be marked in lettering that is readable at a minimum distance of five (5) feet. At a minimum, the signs must display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421.Appendix 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 and 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. 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. Proof that the infectious potential is eliminated must be demonstrated by the Initial Efficacy Test and Periodic Verification Test(s), pursuant to Sections 1422.124 and 1422.125 of this Part. Mechanical treatment may only be conducted as an integral step of the treatment process;

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

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 are informed that local ordinances may also cover discharges to sewer systems.

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

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

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

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

c) In addition to the requirements listed in subsections (a) and (b) of this Section, owners and 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.).

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.Appendix A and the word "biohazard".

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

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

brief description of the emergency procedures must be posted at the treatment facility.

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

A) Quantities and disposition of PIMW treated;

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

C) Date and time the PIMW was treated;

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

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

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

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

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

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

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

Section 1422.123 Treatment Units

a) A treatment unit must be:

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

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

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

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

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

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

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

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

B) The treatment unit is mechanically identical to one previously permitted in Illinois for the treatment of PIMW, is operated under the same operating conditions and feed rate, and

uses the same Periodic Verification Test method and frequency.

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

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 model number:

3) Have the same capacity; and

4) Have no significant mechanical changes.

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

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

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

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

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

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

c) Composition of Challenge Loads

1) For treatment units designed to treat all types of PIMW, all three (3) types of challenge loads must be used in conducting the Initial Efficacy Test. The three (3) types of challenge loads represent PIMW with a high moisture content, low moisture

content, and high organic content. The quantity of each challenge load must equal 100% of the maximum capacity of the treatment unit. Each challenge load must include, at a minimum, 5% of each of the following categories: blood/broth cultures, fibers, metals, sharps, plastics, pathological waste, glass, non-woven fibers, and bottles of liquids. Table C of Appendix A of this Part contains the moisture and organic content requirements that must be met in each type of challenge load.

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

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

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

1) Each container of test microorganisms and/or indicator microorganism spores is placed in the load to simulate the worse case scenario (i.e., that part of the load that is the most difficult to treat). For example, the worst case scenario for an autoclave would be to place the container of test microorganisms and/or indicator microorganism spores within a sharp container 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 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) A Document of Initial Efficacy Demonstration 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. The Document of Initial Efficacy Demonstration must include, at a minimum:

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

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

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

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

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

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

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

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

Section 1422.125 Periodic Verification Test(s)

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

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

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

3) Submitting and obtaining written approval by the Agency for a procedure that is equivalent to subsection (a)(2) of this Section. Examples of alternatives include, but are not limited to, use of another indicator microorganism or measurement of disinfectant concentrations in the treated residue. For incinerators only, an example of an alternative is visually inspecting the ash from each load of treated PIMW to insure that all PIMW within the load is completely combusted. The approval of an alternative by the Agency may require more frequent testing and/or monitoring of the treatment unit.

b) For the Correlating Periodic Verification Test, which provides the correlation of log kill (L) of the test

microorganisms with the equivalent log kill (T) of the indicator microorganisms, the following procedures apply:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3) Test protocols;

4) Evaluation of test results; and

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

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

Section 1422.126 Sharps

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

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

b) Have been:

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

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

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

Section 1422.127 Experimental Permits

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

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

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

d) Application for renewal of an experimental permit must be submitted to the Agency at least ninety (90) days

prior to the expiration of the existing permit. To the extent the information to be supplied for renewal is identical with that contained in the prior permit application, the applicant shall so note on the renewal application, and the Agency shall not require the resubmittal of data and information previously supplied to it.

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

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

2) A discussion of how the equipment performed;

3) A discussion of how residuals were managed; and

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

Section 1422.APPENDIX A INITIAL EFFICACY TEST PROCEDURES

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

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

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

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

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

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

d) The container of test microorganisms and challenge loads must be processed together without the physical and/or chemical agents designed to kill the test microorganisms. For example, in treatment units that use chemical disinfectant(s) an equal volume of sterile saline solution (0.9%, volume/volume) or phosphate buffer solution 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 3rd day of December, 1992, by a vote of 7-0.

Dorothy M. Gunn

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board

TITLE 35: ENVIRONMENTAL PROTECTION

SUBTITLE G: WASTE DISPOSAL

CHAPTER I: POLLUTION CONTROL BOARD

SUBCHAPTER i: SOLID WASTE AND SPECIAL WASTE HAULING

# PART 812
# INFORMATION TO BE SUBMITTED IN A PERMIT APPLICATION

## SUBPART A: GENERAL INFORMATION REQUIRED FOR ALL LANDFILLS



## SUBPART B: ADDITIONAL INFORMATION REQUIRED FOR INERT WASTE LANDFILLS



## SUBPART C: ADDITIONAL INFORMATION REQUIRED FOR PUTRESCIBLE AND CHEMICAL WASTE LANDFILLS



AUTHORITY: Implementing Sections 5, 21, 21.1, 22, 22.17 and 28.1, and authorized by Section 27 of the Environmental Protection Act (Ill. Rev. Stat. 1989, ch. 111 1/2, pars. 1005, 1021, 1021.1, 1022, 1022.17, 1028.1 and 1027).

SOURCE: Adopted in R88-7 at 14 Ill. Reg. 15785, effective September 18, 1990.

NOTE: Capitalization indicates statutory language.

## SUBPART A: GENERAL INFORMATION REQUIRED FOR ALL LANDFILLS

### Section 812.101 Scope and Applicability

a) All persons, except those specifically exempted by Section 21(d) of the Environmental Protection Act (Act) (Ill. Rev. Stat. 1989, ch. 111 1/2, par. 1021(d)), shall submit to the Agency an application for a permit to develop and operate a landfill. The application must contain the information required by this Subpart and by Section 39(a) of the Act.

b) Subpart A contains general standards applicable to all landfills. Subpart B contains additional standards applicable to landfills which accept only inert waste. Subpart C contains additional standards applicable to landfills which accept chemical and putrescible waste.

c) All general provisions of 35 Ill. Adm. Code 810 apply to this Part.

### Section 812.102 Certification by Professional Engineer

All designs shall 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.

### Section 812.103 Application Fees

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

### Section 812.104 Required Signatures

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

b) All permit applications shall be signed by a duly authorized agent of the operator and the property owner, shall be accompanied by an oath or affidavit attesting to the agent's authority to sign the application and shall 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.

### Section 812.105 Approval by Unit of Local Government

The applicant shall 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 shall identify the unit of local government with jurisdiction. The application shall contain any approval issued by that unit of local government. If no approval has been granted, the application shall describe the status of the approval request.

**Section 812.106 Site Location Map**

All permit applications shall contain a site location map on the most recent United States Geological Survey (USGS) quadrangle of the area from the 7 1/2 minute series (topographic), or on such other map whose scale clearly shows the following information:

a) The permit area and all adjacent property, extending at least 1000 meters (3300 feet) beyond the boundary of the facility;

b) All surface waters;

c) The prevailing wind direction;

d) All rivers designated for protection under the Wild and Scenic Rivers Act (16 U.S.C. 1271 et seq.);

e) The limits of all 100-year floodplains;

f) All natural areas designated as a Dedicated Illinois Nature Preserve pursuant to the Illinois Natural Areas Preservation Act (Ill. Rev. Stat. 1989, ch. 105, par. 701 et seq.);

g) All historic and archaeological sites designated by the National Historic Preservation Act (16 U.S.C. 470 et seq.) and the Illinois Historic Preservation Act (Ill. Rev. Stat. 1989 ch. 127, par. 133d1 et seq.);

h) All areas identified as critical habitat pursuant to the Endangered Species Act (16 U.S.C. 1531 et seq.) and the Illinois Endangered Species Protection Act (Ill. Rev. Stat. 1989, ch. 8, par. 331 et seq.); and

i) All main service corridors, transportation routes, and access roads to the facility.

**Section 812.107 Site Plan Map**

The application shall contain maps, including cross sectional maps of the site boundaries, showing the location of the facility on a scale no smaller than one inch equals 200 feet containing a two-foot contour interval. The following information shall be shown:

a) The entire permit area;

b) The boundaries, both above and below ground level, of the facility and all units included in the facility;

c) Location of borrow areas;

d) Boundaries of all areas to be disturbed;

e) The proposed phasing of the facility, including a delineation of the approximate area to be disturbed each year and areas expected to be closed each year in compliance with 35 Ill. Adm. Code 811.107(a);

f) All roads in and around the facility;

g) Devices for controlling access to the facility;

h) Devices for controlling litter;

i) Fire protection facilities; and

j) Utilities.

**Section 812.108 Narrative Description of the Facility**

The permit application shall contain a written description of the facility with supporting documentation describing the procedures and plans that will be used at the facility to comply with the requirements of 35 Ill. Adm. Code 811 and any other applicable Parts of 35 Ill. Adm. Code: Chapter I. Such descriptions shall include, but not be limited to the following information:

a) The type of waste disposal units and the types of wastes expected in each unit;

b) An estimate of the maximum capacity of each unit and the rate at which waste is to be placed;

c) The manner in which waste will be placed and compacted to comply with 35 Ill. Adm. Code 811.105;

d) The estimated unit weight of the waste;

e) The length of time each unit will receive waste;

f) The design period to be used for each unit;

g) Size of the open face area, including all information showing that slopes steeper than two to one will be stable and in compliance with 35 Ill. Adm. Code 811.107(b);

h) A description of how units will be developed to allow contemporaneous closure and stabilization pursuant to 35 Ill. Adm. Code 811.110, 811.111, 811.204, 811.205 or 811.322;

i) A description of all equipment to be used at the facility for complying with 35 Ill. Adm. Code 807.304;

j) A litter control plan for complying with 35 Ill. Adm. Code 811.107(k);

k) A salvaging plan including a description of all salvage facilities and a plan for complying with 35 Ill. Adm. Code 811.108;

l) A description of all utilities for operation in compliance with 35 Ill. Adm. Code 811.107(d);

m) A boundary control plan describing how the operator will comply the requirements of 35 Ill. Adm. Code 811.109;

n) A maintenance plan describing how the operator will comply with 35 Ill. Adm. Code 811.107(c) and (e);

o) An air quality plan describing the methods to be used to comply with the open burning requirements of 35 Ill. Adm. Code 811.107(f) and for controlling dust in compliance with 35 Ill. Adm. Code 811.107(g);

p) A noise control plan describing how the operator will control noise in compliance with 35 Ill. Adm. Code 811.107(h);

q) An odor control plan;

r) A vector control plan to comply with 35 Ill. Adm. Code 811.107(i);

s) A firefighting and fire safety plan; and

l) A transportation plan that includes all existing and planned roads in the facility that will be used during the operation of the landfill facility; the size and type of such roads and the frequency with which they will be used.

**Section 812.109 Location Standards**

The permit application shall contain:

a) Documentation that the facility will operate in compliance with 35 Ill. Adm. Code 811.102(a).

b) A floodplain determination containing:

1) Documentation that the facility is not located within the floodplain of the 100-year flood event; or

2) Documentation that the facility meets the requirements of 35 Ill. Adm. Code 811.102(b).

c) Documentation from the State Historic Preservation Officer that the facility will be in compliance with 35 Ill. Adm. Code 811.102(c).

d) Documentation from the Illinois Nature Preserves Commission that the facility will be in compliance with 811.102(c) as it relates to Dedicated Illinois Nature preserves.

e) Documentation that the facility will be in compliance with 35 Ill. Adm. Code 811.102(d).

f) Documentation that a facility located within a wetland is in compliance with Section 404 of the Clean Water Act (35 U.S.C. 1344).

g) Documentation that the facility is in compliance with 35 Ill. Adm. Code 811.102(f).

**Section 812.110 Surface Water Control**

The permit application shall contain a plan for controlling surface water which demonstrates compliance with 35 Ill. Adm. Code 811.103, and which shall include at least the following:

a) A copy of the approved National Pollutant Discharge Elimination System (NPDES) permit issued pursuant to 35 Ill. Adm. Code 309 or, if a permit is pending, a copy of the NPDES permit application to discharge runoff from all disturbed areas;

b) A map showing the location of all structures affected by the surface water runoff from disturbed areas on the facility;

c) Detailed designs of all structures to be constructed during development of the facility and during the first five year operating period; and

d) Estimated construction dates of all structures to be constructed beyond the first five year operating period.

**Section 812.111 Daily Cover**

The application shall contain a description of the material to be used as daily cover:

a) A description of the soil to be used, including its classification and approximate hydraulic conductivity; or

b) Documentation that any proposed alternative materials or procedures to substitute for daily cover meet the minimum requirements of 35 Ill. Adm. Code 811.106(b).

**Section 812.112 Legal Description**

The permit application shall contain a legal description of the facility boundary and the boundaries of all units included in the facility. This legal description shall identify the nature and location of all stakes and monuments required by Section 811.104 and shall be prepared by or under the supervision of a professional surveyor, who shall affix a professional seal to the work.

**Section 812.113 Proof of Property Ownership and Certification**

The permit application shall contain a certificate of ownership of the permit area or a copy of the lease. The lease shall clearly specify that the owner authorizes the construction of a waste disposal facility on the leased premises, and the duration of the lease will be at least as long as the design period of the landfill. Any prior conduct certifications issued to the owner or operator shall be included in the permit application. The owner and operator shall certify that the Agency will be notified within seven days of any changes in ownership or conditions in the lease affecting the permit area.

**Section 812.114 Closure Plans**

The permit application shall contain a written closure plan which contains, at a minimum, the following:

a) A map showing the configuration of the facility after closure of all units, with the following:

1) A contour map showing the proposed final topography (after placement of the final cover) of all disturbed areas on a 1" = 200' scale and a contour interval of two feet; and

2) The location of all facility-related structures to remain as permanent features after closure.

b) Steps necessary for the premature final closure of the site at the assumed closure date, as defined in 35 Ill. Adm. Code 811.700(e);

c) Steps necessary for the final closure of the site at the end of its intended operating life;

d) Steps necessary to prevent damage to the environment during temporary suspension of waste acceptance if the operator wants a permit which would allow temporary suspension of waste acceptance at the site without initiating final closure;

e) A description of the steps necessary to decontaminate equipment during closure;

f) An estimate of the expected year of closure;

g) Schedules for the premature and final closure, which shall include, at a minimum:

1) Total time required to close the site; and

2) Time required for closure activities which will allow tracking of the progress of closure; and

h) A description of methods for compliance with all closure requirements of 35 Ill. Adm. Code 811.

**Section 812.115 Postclosure Care Plans**

The application shall contain a postclosure care plan which includes a written description of the measures to be taken during