ILLINOIS POLLUTION CONTROL BOARD
May 7, 2026

IN THE MATTER OF:	)	
	)	
POTENTIALLY INFECTIOUS MEDICAL WASTE (PIMW): PROPOSED AMENDMENT OF 35 ILL. ADM. CODE 1422 APPENDIX A, TABLE B – INDICATOR MICROORGANISMS	)	R 25-24 (Rulemaking – Land)

Proposed Rule. First Notice.

OPINION AND ORDER OF THE BOARD (by J.A. Van Wie):

On March 20, 2025, BioSAFE Engineering (BioSAFE) filed a rulemaking proposal (Prop.), which included its Statement of Reasons (SR) and proposed revision to Part 1422 of the Board's potentially infectious medical waste (PIMW) rules. BioSAFE proposes adding an indicator microorganism, *Bacillus Atrophaeus*, for validation testing requirements for low-pressure treatment systems.

After conducting two public hearings and considering the entire record, the Board proposes BioSAFE's amendments, with the changes noted below, for first-notice publication in the *Illinois Register*. The proposed rules appear in the addendum to this opinion and order. Publishing the proposed rules in the *Illinois Register* begins a public comment period of at least 45 days. The Board provides information on submitting public comments at page 9 of this opinion.

PROCEDURAL HISTORY

On March 20, 2025, BioSAFE filed a proposal to amend Part 1422 of the Board's PIMW rules. BioSAFE's filing included a Statement of Reasons, the proposed amendments, and a Motion for Waiver of Signature Requirement. On April 3, 2025, the Board accepted the proposal for hearing and granted the motion to waive the signature requirement. On May 15, 2025, the hearing officer issued an order scheduling two hearings, each to be held via videoconference between the Board's Springfield office and the Michael A. Bilandic Building in Chicago.

In a letter dated May 15, 2025, the Board requested that the Department of Commerce and Economic Opportunity (DCEO) conduct an economic impact study for BioSAFE's rulemaking proposal as required by Section 27(b) of the Act. 415 ILCS 5/27(b) (2024). The Board asked that DCEO determine by July 14, 2025 whether it would conduct such a study. The Board received no response from DCEO.

On May 22, 2025, BioSAFE pre-filed the testimony of Brandon Ross and Daniel Nelsen for the first hearing. On June 12, 2025, IEPA filed pre-filed questions for the first hearing. Also

on June 12, 2025, the hearing officer issued written questions from the Board directed to BioSAFE. On June 25, 2025, BioSAFE filed responses to both IEPA's and the Board's pre-filed questions.

The first hearing took place on June 26, 2025, and the Board received the transcript (Tr. 1) on July 14, 2025. During the hearing, the hearing officer admitted into the record four exhibits: IEPA's pre-filed questions (Hrg. 1, Exh. 1); the Board's pre-filed questions (Hrg. 1, Exh. 2); the pre-filed testimony of Brandon Ross and Daniel Nelsen on behalf of BioSAFE (Hrg. 1, Exh. 3); and BioSAFE's responses to the pre-filed questions (Hrg. 1, Exh. 4).

On July 31, 2025, IEPA pre-filed the testimony of Joshua Rhoades for the second hearing. On August 13, 2025, BioSAFE filed pre-filed questions for the second hearing. On August 18, 2025, the hearing officer issued written questions directed to IEPA. On August 20, 2025, IEPA filed responses to both BioSAFE's and the Board's pre-filed questions.

The second hearing took place on August 21, 2025, and the Board received the transcript (Tr. 2) on September 5, 2025. During the hearing, the hearing officer admitted into the record four exhibits: the pre-filed testimony of Joshua Rhoades on behalf of IEPA (Hrg. 2, Exh. 1); the pre-filed questions of BioSAFE (Hrg. 2, Exh. 2); the Board's pre-filed questions (Hrg. 2, Exh. 3); and IEPA's responses to the pre-filed questions (Hrg. 2, Exh. 4).

BioSAFE's RULEMAKING PROPOSAL

Section 1422.TABLE B Indicator Microorganisms

On March 20, 2025, BioSAFE filed a proposal to amend Part 1422 by adding *Bacillus Atrophaeus* to Table B. The amendment would allow operators of treatment systems to use *Bacillus Atrophaeus* as an indicator organism for efficacy testing of low-pressure systems.

BioSAFE TESTIMONY

Testimony of Brandon Ross

Brandon Ross is an Engineering Manager at BioSAFE. Hrg. 1, Exh. 3 at 1. Mr. Ross states that the current approved indicator organisms in 35 Ill. Adm. Code Part 1422, Appendix A, Table B are "primarily geared toward high-temperature, high-pressure autoclave systems." *Id*. at 2. Mr. Ross reports that not all treatment systems operate under those same conditions, including low-pressure steam systems. *Id*.

Mr. Ross contends that indicator organisms like *Geobacillus Stearothermophilus* often overestimate the required treatment intensity for low-pressure systems. Hrg. 1, Exh. 3 at 2. As a result, its use can create false negatives in validation testing leading to unnecessary modifications to systems and potential rejection of safe, effective technologies. *Id*. Mr. Ross also argues that other states with comparable environmental and health standards have adopted *Bacillus Atrophaeus* as a valid alternative with success. *Id*.

Mr. Ross also contends that the State and Territorial Association on Alternative Treatment Technologies (STAATT) for Medical Waste developed guidelines, STAATT II and STAATT III, recognize *Bacillus Atrophaeus* as an appropriate indicator. Hrg. 1, Exh. 3 at 2. Mr. Ross asserts that the STAATT II and III guidelines are "widely cited by regulators and have served as a benchmark for many state-level approvals." *Id*. Mr. Ross concludes that the guidelines' inclusion of *Bacillus Atrophaeus* as an appropriate indicator organism supports its validity and use as an indicator in evaluating low-pressure steam systems. *Id*. at 2-3.

Mr. Ross states that if the Board approves the use of *Bacillus Atrophaeus* as an indicator organism, it will align with best practices used elsewhere in the country. Hrg. 1, Exh. 3 at 3. Mr. Ross provides the following list of states that have approved use of *Bacillus Atrophaeus*:

- California: Recognized for validating low-pressure steam sterilization processes;
- Florida: Accepted for alternative treatment technologies under state biomedical waste regulations;
- Texas: Approved for use in demonstrating efficacy of medical waste treatment systems; and
- Washington: Permitted as a biological indicator for certain sterilization methods. *Id*.

Mr. Ross states the U.S. Department of Defense also lists *Bacillus Atrophaeus* as a standard biological indicator organism in sterilization processes. *Id*., *citing* Military Specification A-A-50879.

Mr. Ross contends that adding *Bacillus Atrophaeus* as an additional indicator organism would improve accuracy for low-pressure, low-temperature inactivation without compromising the public's health or safety. Hrg. 1, Exh. 3 at 3. Mr. Ross adds that the proposed change would merely add an additional organism and not replace or remove any existing organism in the table. *Id*.

Testimony of Daniel Nelsen

Daniel Nelsen is the Chief Commercial Officer of BioSAFE. Hrg. 1, Exh. 3 at 1. Mr. Nelsen is responsible for leading the company's commercial strategy and efforts to expand new environmentally sound medical waste treatment technologies. *Id*. at 2.

Mr. Nelsen states that BioSAFE operates both high- and low-pressure alkaline hydrolysis tissue digesters (TDs). Hrg. 1, Exh. 3 at 2. Mr. Nelsen argues that low-pressure alkaline hydrolysis systems have advantages over high-pressure systems due to space, safety, or environmental considerations. *Id*. Because the lower-pressure systems operate also at lower temperatures, they avoid the production of hazardous byproducts, like those from incineration. *Id*. at 2-3. The low-pressure systems also avoid the airborne release of heavy metals or flue gas. *Id*. at 3.

Mr. Nelsen contends that *Bacillus Atrophaeus* is recognized across many jurisdictions as a suitable indicator organism for validating low-pressure systems. Hrg. 1, Exh. 3 at 3. Mr.

Nelsen argues *Bacillus Atrophaeus* offers a reliable resistance profile and aligns with low-pressure system parameters, unlike *Geobacillus Stearothermophilus*, a listed indicator organism that may be unnecessarily restrictive in low-pressure scenarios. *Id*.

Mr. Nelsen lists several environmental benefits low-pressure TDs offer, including that they:

- Eliminate dioxin formation by avoiding combustion;
- Reduce greenhouse gas emissions relative to both incineration and high-temperature steam autoclaves;
- Avoid the need for flue gas scrubbing and ash handling;
- Minimize water and energy consumption per unit of tissue processed;
- Enable on-site treatment, reducing emissions and risk associated with transporting untreated waste; and
- Produce an effluent that is biologically sterile and contains no viable pathogens, suitable for further treatment or safe discharge depending on jurisdiction. Hrg. 1, Exh. 3 at 3.

Mr. Nelsen argues that high-pressure alkaline hydrolysis has its place in industry, but that low-pressure systems allow facilities to achieve comparable inactivation with lower energy and environmental overhead. *Id*. at 3-4.

BioSAFE's Response to Pre-Filed Questions

Response to IEPA Questions. In its written response to IEPA questions, BioSAFE acknowledges their proposed change to allow *Bacillus Atrophaeus* would be limited to use in low pressure/low temperature destruction methods. Hrg. 1, Exh. 4 at 1. Additionally, BioSAFE adds that it is in favor of IEPA's historical approach of allowing equipment manufacturers to suggest the appropriate indicator organism for each type of system. *Id*.

BioSAFE defines a "low pressure/low temperature" system as a system that operates at pressures below 15 pounds per square inch gauge (psig) and temperatures below 212°F. Hrg. 1, Exh. 4 at 1.

BioSAFE argues that *Bacillus Atrophaeus*, due to its "hierarchy of susceptibility", would provide adequate levels of decontamination indication in both low- and high-pressure applications. Hrg. 1, Exh. 4 at 1-2. BioSAFE notes there are other treatment modes beyond low- and high-pressure, but they would have to be analyzed individually. *Id*. at 2. However, BioSAFE clarifies they are only proposing the use of *Bacillus Atrophaeus* in low-pressure/low-temperature systems. *Id*.

Response to Board Questions. BioSAFE points to hospitals, clinics, and doctor's offices that have adopted the use of low-pressure systems. Hrg. 1, Exh. 4 at 2. BioSAFE argues that a shift to more numerous, smaller outpatient facilities over legacy hospitals is the trend in the United States currently. *Id*. BioSAFE adds that biotechnology/biopharmaceutical production sites and third-party haulers are increasingly using low-pressure systems for treating PIMW. *Id*.

Next, BioSAFE argues that its TD and STI Series 2000 systems should be considered as "Option 3" treatment units under Part 1422 that use thermal treatment while maintaining the integrity of the container of indicator microorganism spores. Hrg. 1, Exh. 4 at 3; SR at 5; *see also* 35 Ill. Adm. Code 1422.124(b)(3). BioSAFE continues, stating that Option 3 validation under Section 1422.Appendix A (c)(1) through (c)(4) is appropriate for low-pressure systems, except for indicator microorganisms listed in Section 1422.Appendix A, Table B. Hrg. 1, Exh. 4 at 3.

The Board asked whether references to *Bacillus Stearothermophilus* in Section 1422.Appendix A, Table B should be replaced with *Geobacillus Stearothermophilus*, considering BioSAFE's statement of reasons refers to *Geobacillus Stearothermphilus* instead of *Bacillus Stearothermophilus* following a 2001 study showing that *Bacillus Stearothermophilus* formed a distinct clade of bacteria, which lead to the creation of the new genus *Geobacillus Stearothermophilus*. Hrg. 1, Exh. 2 at 2; *see also* SR at 5. BioSAFE agreed that references to *Bacillus Stearothermophilus* should be replaced with references to *Geobacillus Stearothermophilus*. Hrg. 1, Exh. 4 at 3. Additionally, BioSAFE provides an example of an expert claiming *Geobacillus Stearothermophilus* is not appropriate for low-pressure technology. *Id*. at 3-5, *see also* Attachment A. BioSAFE confirms that "[s]imilar approved technologies" refers to Petition of BioMedical Technology Solutions Inc. for an Adjusted Standard from 35 Ill. Adm. Code 1422 (AS 2008-006) in Illinois, as well as other states that have approved BioSAFE's technology. *Id*. at 5.

BioSAFE states that for this proposal they are only considering low-pressure/low-temperature TD systems with optimal operating temperature of ~100°C, based on operating elevation above sea level. Hrg. 1, Exh. 4 at 5. BioSAFE believes this amendment would be beneficial to any generator of PIMW in Illinois. *Id*. BioSAFE continues, arguing that increasing in-state non-incineration treatment technologies results in more capacity and lower costs for hospitals, clinics, and other generators. *Id*. at 5-6.

The Board asked BioSAFE whether *Bacillus Subtilis* and *Bacillus Pumilus* should be removed from Table B because they are not commercially available. Hrg. 1 Exh. 2 at 3. BioSAFE does not believe they should be removed and argues they are more likely to become commercially available if they remain on the list. Hrg. 1, Exh. 4 at 6.

In response to Board questions directed to Brandon Ross, BioSAFE provided typical operating ranges of temperature and pressure for various types of commercially available treatment systems. Hrg. 1, Exh. 4 at 6-7.

High-pressure/high-temperature:

- Treatment systems: autoclave, high pressure TD
- Typical operating range: 121°C, 30 PSI

High-temperature/low-pressure:

- Treatment systems: incinerator
- Typical operating range: 900°C-1200°C, 14 PSI

Low-temperature/low-pressure:

- Treatment systems: STI, low-pressure TD
- Typical operating range: 100°C, 14 PSI

Low-temperature/high-pressure:

- Treatment systems: other alternative treatment technologies
- Typical operating range: varies. *Id*.

BioSAFE states that *Geobacillus Stearothermophilus* can be used as an indicator organism to test high-temperature/high-pressure treatment systems. Hrg. 1, Exh. 4 at 7. BioSAFE also states that *Bacillus Atrophaeus* can be used as an indicator organism for low-temperature/low-pressure treatment systems. *Id*. Again, BioSAFE agrees with IEPA's historical approach of allowing equipment manufacturers to suggest appropriate indicator organisms for each treatment system. *Id*.

IEPA Pre-Filed Testimony

Joshua Rhoades is the Section Manager of the permit section within IEPA's Bureau of Land. Hrg. 2, Exh. 1 at 2. Mr. Rhoades' duties include administering the hazardous and non-hazardous waste programs through the Bureau of Land's Division of Pollution Control, Permit Section, as well as assessing designs and remedial actions for facilities regulated under those programs. *Id*.

In response to a Board pre-filed question, Mr. Rhoades reports that IEPA prefers the flexibility under the existing rules that allows equipment manufacturers to suggest and IEPA to review and permit which indicator organism should be used for different types of PIMW treatment systems. Hrg. 2, Exh. 1 at 3. Mr. Rhoades assures the Board that IEPA will ensure an improper identifier organism is not used for a specific treatment system. *Id*.

Mr. Rhoades argues the suggested amendments are necessary because of outdated information and to make clarifications regarding specific systems. Hrg. 2, Exh. 1 at 3. Mr. Rhoades suggested changes to Sections 1422.105(a)(4)(F), 1422.122(a)(4)(E), 1422.123(a)(3), 1422.123(c)(1), and 1422.127(e)(1) that would add reference to operation parameters including temperature and pressure. *Id*. at 3-4, *see also* Exh. A. In Section 1422.106(e), Mr. Rhoades suggests removing the word "regional" because "regional pollution control facility" is no longer a utilized term. *Id*. at 4, *see also* Exh. A. At the August 21, 2025 hearing, BioSAFE acknowledged it had no objections to IEPA's above suggested changes. Tr. 2 at 11.

IEPA Response to Board Pre-Filed Questions

IEPA states its intention is to clarify the operating parameters most relevant to autoclaves and other thermal units. Hrg. 2, Exh. 4 at 2. IEPA does not object to expanding the list of operating parameters, beyond temperature and pressure, in Section 1422.105(a)(4)(F), as long as it remains illustrative and not exhaustive. *Id*. Further, IEPA does not object to the Board adding similar clarifying language to improve consistency in Part 1422. *Id*. at 3. IEPA argues it did not

propose those revisions because the existing provisions already instruct applicants to identify and document operating parameters sufficient for IEPA review. *Id*.

IEPA is not opposed to adding a definition for "operating parameters" under Section 1420.102 if the Board determines one is necessary for consistency. Hrg. 2, Exh. 4 at 3-4. IEPA requests the definition make clear the list of "operating parameters" is not exhaustive. *Id*. IEPA proposes the following definition:

> "Operating parameters" means treatment parameters including, but not limited to, temperature, pressure, residence time, chemical concentration, and irradiation dose." *Id*. at 4.

IEPA Response to BioSAFE Pre-Filed Questions

IEPA states it does not have any objection to BioSAFE's proposal. Hrg. 2, Exh. 4 at 4. IEPA continues, stating its focus is ensuring "the rules remain clear and sufficiently flexible so that appropriate biological indicators can be reviewed and approved through the permitting process." *Id*. IEPA also states it defers to the Board on whether to adopt BioSAFE's amendments regarding biological indicators. *Id*.

Additionally, IEPA does not object to replacing references to *Bacillus Stearothermophilus* with references to *Geobacillus Stearothermophilus*. Hrg. 2, Exh. 4 at 4. IEPA states that the change reflects current nomenclature and eliminates outdated terminology. *Id*. IEPA also notes that Section 1422.125(a)(1) also uses *Bacillus Stearothermophilus* and should be changed to *Geobacillus Stearothermophilus* for consistency. Tr. 1 at 13-14.

Additional Amendments

Based on the Board's review of IEPA's suggested language in its pre-filed testimony, the Board does have additional proposed revisions. The Board suggests adding "All" at the beginning of Section 1422.105(a)(4)(F) to cover any operating parameters not covered in the list. The Board also adds "residence time, chemical concentration and irradiation dose" to Section 1422.105(a)(4)(F) be consistent with other sections of the rules. Furthermore, the Board adds the same parameter example list to Sections 1422.125(c)(2) and 1422.Appendix A(a)(2)(A).

In Section 1422.123(a)(3) the Board proposes adding "for all operating parameters" before the list of parameters to add clarification and consistency. Similarly, the Board adds "all" to Section 1422.127(e)(1).

In addition, the Board has made minor non-substantive changes to the rule language, including replacing outdated language and other non-substantive clarifications.

TECHNICAL FEASIBILITY AND ECONOMIC REASONABLENESS

Economic Impact Study

As required by Section 27(b) of the Act (415 ILCS 5/27(b) (2024)), the Board requested in a letter dated May 15, 2025 that DCEO determine by July 14, 2025 whether it would conduct such a study. The Board has not received any response from DCEO to this request. During each hearing, the hearing officer afforded those participants present an opportunity to address the Board's request for a study and DCEO's lack of a response. Tr. 1 at 5; Tr. 2 at 6. No participant offered testimony or comment on the request or lack of response. *Id*.

Technical Feasibility

BioSAFE states that it "thoroughly vetted the technical feasibility of using *Bacillus Atrophaeus* as an indicator microorganism for efficacy testing of its low-pressure systems." SR at 9. Additionally, BioSAFE states the Board already approved *Bacillus Atrophaeus* as an indicator microorganism for another company. *Id*., *citing* PCB AS 2008-006 (Apr. 3, 2008).

Economic Reasonableness

BioSAFE states that *Bacillus Atrophaeus* "is commercially available as a self-contained biological indicator" and does "not require equipment or specialized training to be utilized effectively". SR at 10.

BOARD DISCUSSION

The Board finds that BioSAFE's proposal to add *Bacillus Atrophaeus* to Part 1422 Table B is supported by the record in this proceeding. Additionally, the parties have come to agreement on further revisions in Part 1422 to promote clarity and consistency. The Board incorporates these changes, along with some of its own, in its first-notice proposal.

The Board has reviewed the record in this proceeding on the issues of technical feasibility and economic reasonableness. The Board finds that BioSAFE's proposal is technically feasible and economically reasonable. As discussed above, the addition of *Bacillus Atrophaeus* as an indicator microorganism for low-pressure systems increases PIMW treatment options and could increase in-state, non-incineration treatment technologies, resulting in more capacity and potentially lower costs for PIMW treatment.

Conclusion

The Board proposes for first-notice amendments to Part 1422 of the Board's regulations governing PIMW. The Board will allow a comment period of at least 45 days following publication in the *Illinois Register*, during which anyone may file public comments with the Board.

FILING COMMENTS ON THE BOARD'S FIRST-NOTICE PROPOSAL

First-notice publication of the Board's proposal in the *Illinois Register* will start a period of at least 45 days during which any person may file a public comment with the Board, regardless of whether the person has already filed a public comment. 5 ILCS 100/5-40(b) (2024). The Board encourages the filing of public comments on the proposed amendments. The docket number for this rulemaking, R25-24, should be referenced on the public comment. Public comments may be filed with the Clerk of the Board at the following address:

Illinois Pollution Control Board
Don A. Brown, Clerk
60 E. Van Buren St., Suite 630
Chicago, IL 60605

Public comments may also be filed electronically through the Clerk's Office On-Line (COOL) on the Board's website, www.pcb.illinois.gov. Questions about electronic filing should be directed to the Clerk's Office at (312) 814-3461. Public comments and all other filings with the Clerk must be served on the hearing officer and on those persons on the Service List for this rulemaking. The current version of the Service List for R25-24 is available on COOL.

ORDER

The Board directs the Clerk to cause first-notice publication of the following proposed amendment to Part 1422 of the Board's potentially infectious medical waste regulations in the *Illinois Register*. Proposed additions to Part 1422 are underlined and proposed deletions appear stricken.

IT IS SO ORDERED.

I, Don A. Brown, Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above order on April 16, 2026, by a vote of 4-0.

Don A. Brown

Don A. Brown, Clerk
Illinois Pollution Control Board

POLLUTION CONTROL BOARD

NOTICE OF PROPOSED AMENDMENTS

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

SUBPART B: STORAGE OR TRANSFER OPERATIONS

SUBPART C: TREATMENT FACILITIES

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

SOURCE: Adopted in R91-20, at 17 Ill. Reg. 9911, effective June 21, 1993; amended in R18-29 at 43 Ill. Reg. 10072, effective August 30, 2019; amended in R25-24 at 50 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL PROVISIONS

Section 1422.105 PIMW Permit Application Contents

a) A permit application for a PIMW treatment, storage, or transfer operation must contain:

1) Legal description of the facility's location.

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

3) Process flow diagrams or schematic drawings showing the flow of waste through the facility. The diagrams or drawings must show the locations of residuals, recycled streams, sample points, equipment, and process monitoring devices. Equipment must be labeled on the process flow diagram to correspond to an equipment number.

4) Written description of the facility or facility operations with supporting documentation describing the procedures and plans that will be used at the facility to comply with the requirements of 35 Ill. Adm. Code Subtitle M and any other applicable Board rules. The description must include:

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

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

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

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

E) The days and hours of operation;

F) All~~The~~ operating parameters for the treatment units, including temperature, pressure, residence time, chemical concentration and irradiation dose;

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

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

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

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

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

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

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

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

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

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

b) If the applicant believes that any of the documentation or information listed in subsection (a) is not applicable for reasons such as irrelevancy, the application must include the reasons in support of that belief.

(Source: Amended at 50 Ill. Reg. _____, effective _____)

Section 1422.106 PIMW Permit Application Certifications

A permit application for PIMW treatment, storage, or transfer operation must contain the certifications specified in this Section.

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

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

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

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

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

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

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

e) The applicant must state whether the facility is a new ~~regional~~ pollution control facility, as defined in Section 3.330 of the Act, that is subject to the site location suitability approval requirements of Sections 39(c) and 39.2 of the Act. If approval by a unit of local government is required, the application must identify the unit of local government with jurisdiction. The application must contain any approval issued by that unit of local government. If no approval has been granted, the application must describe the status of the approval request.

(Source: Amended at 50 Ill. Reg. _____, effective _____)

SUBPART C: TREATMENT FACILITIES

Section 1422.122 Design and Operating Standards

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

1) *Eliminates the infectious potential of the waste.* A treatment process eliminates the infectious potential of PIMW if the owner or operator of a treatment unit demonstrates that an Initial Efficacy Test and Periodic Verification Test have been completed successfully.

A) Demonstrate successful completion of an Initial Efficacy Test by a 6-log kill of test microorganisms. For a thermal unit that maintains the integrity of the container, a 6-log kill

of indicator microorganism spores may be used as an alternative test. These demonstrations must comply with Section 1422.124.

B) Successful completion of a Periodic Verification Test must comply with Section 1422.125, and may be demonstrated by:

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

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

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

2) *Prevents compaction and rupture of containers during handling operations,* except when compaction or rupture is an integral part of the treatment process and the treatment process is conducted without discharge of PIMW to the environment;

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

4) *Provides for quality assurance programs* that must include a written plan that:

A) Designates responsibility to personnel;

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

C) Identifies monitoring devices;

D) Ensures monitoring devices are operating properly;

E) Establishes appropriate ranges for all operating parameters (e.g., temperature, pressure, residence time, chemical concentration, irradiation dose);

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

G) Identifies the person or persons who must evaluate any discrepancies or problems;

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

I) Identifies the person or persons who must assess actions taken and document improvement;

5) *Provides for periodic testing using biological testing, where appropriate, that demonstrate proper treatment of the waste*;

6) *Provides for assurances that clearly demonstrate that* PIMW *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) through (7) of the Act)

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

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

BOARD NOTE: Interested persons should note that local government units can regulate discharges to sewer systems.

2) Manage ash resulting from the incineration of PIMW as a special waste in compliance with 35 Ill. Adm. Code 807 and 809 because it is an industrial process waste, as defined in Section 3.235 of the Act.

3) Retain copies of PIMW manifests required by 35 Ill. Adm. Code 1420.105 at the treatment facility for three years and make them available at the treatment facility during normal business hours for inspection and photocopying by the Agency. The retention period for PIMW manifests is extended automatically during any unresolved enforcement action regarding the treatment facility or as requested in writing by the Agency.

4) *Each treatment facility for which a permit is required* by 35 Ill. Adm. Code 1420.105 shall annually file the report required by this subsection (b)(4). Additionally, *each facility not required to have a permit* under 35 Ill. Adm. Code 1420.105 *that treats more than 50 pounds per month of* PIMW *shall file the report.* The report must~~shall~~ be filed *with the Agency specifying the quantities and disposition of* PIMW *treated during the previous calendar year. These reports shall be on forms prescribed and provided by the Agency.* (Section 56.3 of the Act)

5) Upon closure of a treatment facility, clean the area, equipment, and structures in compliance with 35 Ill. Adm. Code 1420.107.

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

1) Weigh amounts of PIMW received in pounds with a device for which certification has been obtained under the Weights and Measures Act.

2) Prominently display signs identifying that the facility treats PIMW at the points of access to the treatment area. The signs must:

A) Display the International Biohazard Symbol as shown in 35 Ill. Adm. Code 1421.Illustration A and the word "Biohazard"; and

B) Be marked in lettering that is readable from ~~at~~ a ~~minimum~~ distance of at least five feet.

3) Provide personnel training to all staff annually, and prior to the handling of PIMW, that includes a thorough explanation of the operating procedures to be implemented~~taken~~ during normal and emergency situations. The owner or operator must keep records verifying training of personnel.

4) Have a written contingency plan and implement the applicable sections of that plan if there is equipment failure, injury, or a discharge of PIMW.

A) The contingency plan must:

i) Describe the actions to be taken by personnel in response to emergency situations such as injury, discharges of PIMW, and equipment failure; and

ii) Include a list of all emergency equipment at the treatment facility, an up-to-date list of names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinator, procedures for cleanup, protection of personnel, disposal of spill residue, and alternative arrangements for PIMW treatment; and

B) The treatment facility must keep a copy of the contingency plan and must post emergency phone numbers and a brief description of the emergency procedures.

5) Keep a written operating record that includes the following information:

A) Quantities and disposition of PIMW treated;

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

C) Date and time PIMW was treated;

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

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

F) Generator names, location or locations, and, if applicable, the generator identification numbers issued by the Agency for each PIMW load received at the treatment facility;

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

H) A separate log, with the date, time, nature, and extent of all discharges and injuries, and with the date, time, nature, and result of any responses taken.

6) Retain the following records:

A) The records required by subsections (c)(3) and (c)(5) must be:

i) Kept at the treatment facility until closure of the treatment facility; and

ii) Made available at the treatment facility during normal business hours for inspection and photocopying by the Agency.

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

7) For a planned closure:

A) Notify the Agency of the planned closure at least 60 days prior to closing a treatment facility; and

B) Certify to the Agency that final closure has been completed in compliance with the permit, the Act, and all applicable regulations promulgated under the Act within 90 days after the date the final load of PIMW is received at the storage operation.

(Source: Amended at 50 Ill. Reg. _____, effective _____)

Section 1422.123 Treatment Units

a) A treatment unit must be:

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

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

3) Operated under the same conditions for all operating parameters (e.g., temperature, pressure, residence time, chemical concentration, irradiation dose) that have been used to demonstrate that the infectious potential was eliminated in compliance with this Part;

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

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

b) A treatment unit may be used by the owner or operator of a treatment facility not required to have a permit by 35 Ill. Adm. Code 1420.105 if:

1) The treatment unit meets the standards of subsection (a) and:

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

B) The owner or operator maintains a copy of the Initial Efficacy Test results for the treatment unit and conducts Periodic Verification Tests compliant with the manufacturer's instructions and the requirements of Section 1422.125. Test results must be kept and made available for inspection as required by Section 1422.125(d) and (g); and

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

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

c) For treatment facilities required to have a permit by 35 Ill. Adm. Code 1420.105, the permit application must include the following information regarding the treatment unit:

1) An operating plan that includes a description of the treatment facility's operating procedures and parameters (e.g., temperature, pressure, residence time, chemical concentration, irradiation dose); and

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

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

(Source: Amended at 50 Ill. Reg. _____, effective _____)

Section 1422.125 Periodic Verification Tests

a) The effectiveness of the treatment unit is verified by the Periodic Verification Tests. The manufacturer, owner, or operator of a treatment

unit must perform Periodic Verification Tests that satisfy at least one of the following:

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

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

3) Submitting and obtaining written approval by the Agency for a procedure that is equivalent to subsection (a)(2).

   A) Examples of alternatives include use of another indicator microorganism or measurement of disinfectant concentrations in the treated residue.

   B) For incinerators only, an example of an alternative is visually inspecting the ash from each load of treated PIMW to ensure that all PIMW within the load is completely combusted.

C) The approval of an alternative by the Agency may require more frequent testing and monitoring of the treatment unit.

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

1) Use an initial population of 1,000,000 indicator microorganism spores per gram of waste solids in each challenge load;

2) Use the fraction of surviving indicator microorganisms that correlates to a log kill of six for each test microorganism in future Periodic Verification Tests.

A) For example, if a log kill of four for the indicator microorganism spores per gram of waste solids is achieved during this demonstration, then a population of 10,000 of the indicator microorganism must be used in all future Periodic Verification Tests.

B) For future Periodic Verification Tests, the three challenge loads described in Appendix A, Table C do not need to be used.

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

3) The minimum threshold death rate is an equivalent log kill of three for the indicator microorganism spores to ensure that all test microorganisms are destroyed;

4) Test microorganisms or indicator microorganisms must be cultured and enumerated compliant with instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater (see 35 Ill. Adm. Code 1420.103); and

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

c) If a load of PIMW fails a Periodic Verification Test, the Periodic Verification Test must be repeated.

1) The operator must implement the quality assurance program (see Section 1422.122(a)(4)) and contact the manufacturer, if applicable, to identify and correct the problem or problems until the unit can eliminate the infectious potential of the PIMW.

2) If the operating parameters (e.g., temperature, pressure, residence time, chemical concentration, irradiation dose) are altered, another Initial Efficacy Test must be performed to demonstrate the effectiveness of the unit and, if applicable, another Periodic Verification Test correlation, under subsection (a), must also be repeated.

3) Loads of PIMW that were first processed prior to receiving results showing a failure of the Periodic Verification Tests are considered treated.

4) A second Periodic Verification Test must be run immediately after the first Periodic Verification Test indicates a failure. The second Periodic Verification Test is to determine whether the treatment unit is eliminating the infectious potential of the waste.

5) After the second Periodic Verification Test shows a failure of the treatment unit, the processed waste is considered PIMW and must be managed in compliance with this Subtitle.

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

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

f) A Document of Correlating Periodic Verification Demonstration must be prepared by and kept 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:

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

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

3) A description of quality assurance and quality control procedures and practices for the culture, storage, and preparation of test or indicator microorganisms (including organism history, source, stock culture maintenance, and enumeration procedures). The purity of the test microorganisms 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 liquid samples);

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

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

7) The name, date, signature, title, and qualifications of the person or persons conducting the Periodic Verification Test; and

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

g) Records of Periodic Verification Tests must be prepared by and kept 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:

1) The dates the Periodic Verification Tests were performed;

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

3) Test protocols;

4) Evaluation of test results; and

5) The names, date, signature, title, and qualifications of the person or persons conducting the Periodic Verification Tests.

h) Periodic Verification Tests must be conducted under the same operating conditions 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. This feed rate must never be exceeded during the operation of the treatment unit.

(Source: Amended at 50 Ill. Reg. _____, effective _____)

Section 1422.127 Experimental Permits

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

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

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

d) Application for renewal of an experimental permit must be submitted to the Agency at least 90 days prior to the expiration of the existing permit. The applicant must note in its renewal application whether the information to be supplied for renewal is identical with that contained in the prior permit application. The Agency may not require the resubmittal of data and information previously supplied to it.

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

1) A summary of operating data, including all operating parameters (e.g., temperature, pressure, residence time, chemical concentration, irradiation dose) and results of the Initial Efficacy Tests or Periodic Verification Tests;

2) A discussion of how the equipment performed;

3) A discussion of how residuals were managed; and

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

(Source: Amended at 50 Ill. Reg. _____, effective _____)

Section 1422.APPENDIX A Initial Efficacy Test Procedures

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

a) 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).

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

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

B) Process each test microorganism in separate runs through the treatment unit. Prior to each run, the number of viable test microorganisms in each container must be determined using applicable manufacturer's recommendations and Standard Methods for the Examination of Water and Wastewater (see 35 Ill. Adm. Code 1420.103).

C) Process the PIMW within 30 minutes after introducing the container of test microorganisms into the treatment unit.

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

E) Take a minimum of five representative grab samples from the processed residue of each challenge load in compliance with Test Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846) (see 35 Ill. Adm. Code 1420.103). Determine the number of viable test microorganisms in each grab sample using applicable manufacturer's recommendations and Standard Methods for the Examination of Water and Wastewater (see 35 Ill. Adm. Code 1420.103).

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

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

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

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

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

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

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

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

A) Using the inoculum size (NoA) determined in Phase 1 above, repeat Phase 1 steps (A) through (E) under the same operating parameters (e.g., temperature, pressure, residence time, chemical concentration, irradiation dose), except that

the physical and 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 the steps in subsections (a)(2)(A) and (B) in Phase 2 for challenge loads Types B and C identified in Appendix A, Table C to determine the effectiveness of the treatment unit (LB and LC, respectively).

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

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

2) Place the container of test microorganisms within a Type A challenge load as identified in Appendix A, Table C.

3) 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.

4) Repeat steps (b)(1) through (3) in this option for challenge loads Types B and C identified in Appendix A, Table C to determine the effectiveness of the treatment unit (LB and LC, respectively).

c) 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).

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

2) Place the container of indicator microorganisms within a Type A challenge load as identified in Appendix A, Table C.

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

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

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

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

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

4) Repeat steps (c)(1) through (3) in this option for challenge loads Types B and C identified in Appendix A, Table C to determine the effectiveness of the treatment unit (LB and LC, respectively).

(Source: Amended at 50 Ill. Reg. _____, effective _____)

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

1. Bacillus subtilis (ATCC 19659)
2. Geobacillus stearothermophilus ~~Bacillus stearothermophilus~~ (ATCC 7953)
3. Bacillus pumilus (ATCC 27142)
4. Bacillus atrophaeus (ATCC 9372)

(Source: Amended at 50 Ill. Reg. _____, effective _____)