ILLINOIS POLLUTION CONTROL BOARD
June 12, 2025

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

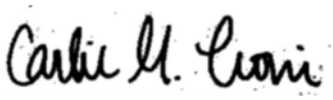
HEARING OFFICER ORDER

On March 20, 2025, BioSAFE Engineering (BioSAFE) proposed that the Board amend Part 1422 of its rules for potentially infectious medical waste (PIMW). On April 3, 2025, the Board accepted the proposal for hearing and has scheduled the first hearing for June 26, 2025, with a prefiling deadline of June 12, 2025, for written questions.

The Board and its Staff have reviewed the pre-filed testimony filed by BioSAFE in this matter, and submit with this order their questions to those witnesses, included as Attachment A. Anyone may file a comment, and anyone may respond to the attached questions, as well as any other pre-filed questions on the record.

All filings in this proceeding will be available on the Board's website at https://pcb.illinois.gov in the rulemaking docket R25-24. Unless the Board, hearing officer, Clerk, or procedural rules provide otherwise, all documents in this proceeding must be filed electronically through the Clerk's Office On-Line. 35 Ill. Adm. Code 101.302(h), 101.1000(c), 101.Subpart J.

IT IS SO ORDERED.



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ATTACHMENT A

R25-24
Potentially Infectious Medical Waste (PIMW) Regulations: Proposed Amendment of 35 Ill. Adm. Code 1422.Appendix A, Table B – Indicator Microorganisms

Questions on Statement of Reasons (SOR)

1. On page 1, BioSAFE states, "Low-pressure systems are being adopted for use by a broader range of users, such as front-line healthcare providers."

    a. Please clarify whether front-line providers using low-pressure systems for treating PIMW include hospitals, clinics and doctor's offices.

    b. Provide examples of users other than front-line providers who are adopting the use of low-pressure systems for treating PIMW.

2. On page 4, the SOR states that the validation process under Part 1422 is not appropriate for or achievable by low-pressure systems like BioSAFE's tissue digesters (TD) and STI Series 2000 systems (STI). Specifically, the three indicator microorganisms for efficacy testing [*Bacillus Subtilis* (ATCC (American Type Culture Collection) 19659), *Bacillus Stearothermophilus* (ATCC 7953) and *Bacillus Pumilus* (ATCC 27142)] in Section 1422.Appendix A, Table B are not suitable for low-pressure technologies, making it impossible to validate these technologies in Illinois as required. SOR at 8-9.

    a. Please clarify whether the low-pressure systems like STI and TD can be considered as Option 3 treatment units that use thermal treatment and maintain the integrity of the container of indicator microorganism spores.

    b. If so, comment on whether the existing Option 3 validation procedures under Section 1422.Appendix A (c)(1) through (c)(4) are appropriate for low-pressure systems except for the indicator microorganisms listed in Section 1422.Appendix A, Table B.

    c. If not, should there be a separate Option 4 for low pressure systems?

3. The SOR refers to *Geobacillus Stearothermophilus* instead of *Bacillus Stearothermophilus* (listed in Section 1422.Appendix A, Table B) because a 2001 study showed that *Bacillus Stearothermophilus* formed a distinct clade, which lead to the creation of the new genus *Geobacillus Stearothermophilus*. SOR at 5. Please comment on whether *Bacillus stearothermophilus* (ATCC 7953) listed in Section 1422.Appendix A, Table B should be replaced with *Geobacillus Stearothermophilus* (ATCC 7953).

4. BioSAFE states, "other industry experts have determined: that *Geobacillus Stearothermophilus* was not appropriate for low pressure technology. Similar approved treatment technologies have also struggled to pass this requirement for efficacy testing due to the narrow range of treatment technologies (specifically high-pressure autoclaves) this requirement was designed for." SOR at 5.

    a. Please provide additional details about the "industry experts" who have determined that *Geobacillus Stearothermophilus* is not appropriate for low-pressure technology, with names and citations to any technical papers or reports.

    b. Please clarify whether "[s]imilar approved technologies" refers to technologies approved by Illinois Environmental Protection Agency for use in Illinois or technologies approved for use in other states by those states.

5. The SOR also states that low treatment temperature technologies cannot pass efficacy testing using G*eobacillus Stearothermophilus*. SOR at 9.

    a. Please clarify whether BioSAFE's TD and STI technologies are considered as low-pressure as well as low-temperature treatment systems.

    b. What would be the optimal operating temperature range for TD and STI systems?

6. On page 9, BioSAFE states that the proposed amendment to Part 1422 adding *Bacillus Atrophaeus* as an indicator microorganism could apply to any facility located in Illinois.

    a. Does BioSAFE know how many companies in Illinois would be affected by the proposed amendment to Part 1422, including those having problems with lower treatment temperature/pressure technologies using G*eobacillus Stearothermophilus,* or the commercial unavailability of *Bacillus Subtilis* and *Bacillus Pumilus*?

    b. Please comment on whether the addition of *Bacillus Atrophaeus* is expected to have a positive economic impact on affected Illinois companies.

    c. If so, would it be possible to quantify the positive economic impact?

7. The SOR states that *Bacillus Subtilis* and *Bacillus Pumilus,* which are listed in Section 1422.Appendix A, Table B, are not currently commercially available as a self-contained biological indicator. SOR at 9. Given that Table B microorganisms are to be used for Initial Efficacy Testing of a treatment unit that uses thermal treatment and maintains the integrity of the container of indicator microorganism, please comment on whether *Bacillus Subtilis* and *Bacillus Pumilus* should be removed from Table B.

Questions Directed to Brandon Ross

8. On page 2, you state that the indicator organisms listed Section 1422.Appendix A, Table B are primarily geared toward high-temperature, high-pressure autoclave systems, and they are inappropriate for low-pressure steam systems. Please provide the typical operating ranges of temperature and pressure for various types of commercially available treatment systems that could be tested under Section 1422.Appendix A(c), including any high-temperature, high-pressure; high-temperature, low-pressure; low-temperature, low-pressure; and low-temperature, high-pressure treatment systems.

9. Considering two (*Bacillus Subtilis* and *Bacillus Pumilus*) of the three indicator microorganisms in Table B are not commercially available and the possible addition of *Bacillus atrophaeus*:

    a. Please clarify as to what type of treatment systems can be tested by using *Geobacillus stearothermophilus* as an indicator organism: high-temperature, high-pressure; high-temperature, low-pressure; low-temperature, low-pressure; and low-temperature, high-pressure treatment systems.

    b. Please clarify as to what type of treatment systems can be tested by using *Bacillus atrophaeus* as an indicator organism: high-temperature, high-pressure; high-temperature, low-pressure; low-temperature, low-pressure; and low temperature, high-pressure treatment systems.

    c. Comment on whether Section 1422.Appendix A, Table B should specify for each indicator microorganism the type of treatment system that the organism may be used for efficacy testing. For example, Table B could specify *Geobacillus stearothermophilus* as an indicator microorganism for testing autoclaves and incinerators.