BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

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

NOTICE OF FILING

TO: Mr. Don A. Brown
Clerk of the Board
Illinois Pollution Control Board
60 E. Van Buren Street, Suite 630
Chicago, Illinois 60605
don.brown@illinois.gov

Carlie Leoni
Hearing Officer
Illinois Pollution Control Board
60 E. Van Buren Street, Suite 630
Chicago, Illinois 60605
Carlie.Leoni@Illinois.gov

VIA ELECTRONIC MAIL

(SEE PERSONS ON ATTACHED SERVICE LIST)

PLEASE TAKE NOTICE that I have today filed with the Office of the Clerk of the Illinois Pollution Control Board **PRE-FILED TESTIMONY OF BRANDON ROSS ON BEHALF OF BIOSAFE ENGINEERING** and **PRE-FILED TESTIMONY OF DANIEL NELSEN ON BEHALF OF BIOSAFE ENGINEERING**, copies of which are hereby served upon you.

Respectfully submitted,
BioSAFE Engineering,

Dated: May 22, 2025

By: /s/ *Alec Messina* ___
One of Its Attorneys

Alec Messina
Melissa S. Brown
HEPLERBROOM, LLC
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Springfield, Illinois 62711
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CERTIFICATE OF SERVICE

I, the undersigned, on oath state the following: **PRE-FILED TESTIMONY OF BRANDON ROSS ON BEHALF OF BIOSAFE ENGINEERING** and **PRE-FILED TESTIMONY OF DANIEL NELSEN ON BEHALF OF BIOSAFE ENGINEERING,** that I have served the attached upon:

Don Brown Clerk of the Board Illinois Pollution Board 60 E Van Buren Street, Suite 630 Chicago, Illinois 60605 don.brown@illinois.gov	Carlie Leoni Hearing Officer Illinois Pollution Control Board 60 E. Van Buren Street, Suite 630 Chicago, Illinois 60605 Carlie.Leoni@Illinois.gov
Nick M. San Diego Deputy General Counsel Illinois Environmental Protection Agency 2520 W Iles Avenue PO Box 19276 Springfield, Illinois 62794 nick.m.sandiego@illinois.gov	Trevor D. Dell'Aquila Assistant Counsel Illinois Environmental Protection Agency 115 S. LaSalle Street, Suite 2203 Chicago, Illinois 60603 trevor.dellaquila@illinois.gov
Renee Snow General Counsel Illinois Department of Natural Resources One Natural Resource Way Springfield, Illinois 62702 renee.snow@illinois.gov	Office of the Attorney General Division of Legal Counsel 69 West Washington Street, Suite 1800 Chicago, Illinois 60602 enviro@ilag.gov

That my email address is Alec.Messina@heplerbroom.com

That the number of pages in the email transmission is 10.

That I have sent the email transmission on May 22, 2025.

Date: May 22, 2025

/s/ *Alec Messina*
Alec Messina

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PRE-FILED TESTIMONY OF BRANDON ROSS
ON BEHALF OF BIOSAFE ENGINEERING

BioSAFE Engineering, LLC ("BioSAFE"), by and through its attorneys, HEPLERBROOM, LLC, and pursuant to 35 Ill. Adm. Code 102.306 and the Notice of Hearings and Hearing Officer Order dated May 15, 2025, hereby submits the following Pre-Filed Testimony of Brandon Ross for presentation at the June 26, 2025 hearing scheduled in this matter.

I. EDUCATION

My name is Brandon Ross. I am the Engineering Manager at BioSAFE Engineering, LLC, based in Indianapolis, Indiana. I hold a Bachelor of Science degree in Industrial Engineering Technology from Iowa State University.

For nearly two decades, I've been involved in the design, development, and technical validation of waste treatment technologies at BioSAFE. My work has focused on advancing system reliability, user safety, and treatment efficacy—especially in facilities dealing with high-risk biological materials.

II. ROLE AND RESPONSBILITIES AT BIOSAFE

As Engineering Manager, I lead BioSAFE's efforts in product development, system performance validation, and regulatory support. I work closely with our manufacturing, QA/QC, and field support teams to ensure our systems consistently meet or exceed the biological inactivation standards required by law.

A key part of my role involves validation testing, where we demonstrate a system's ability to reliably inactivate pathogenic microorganisms under defined operating conditions. This includes working directly with indicator organisms to verify system effectiveness and ensure compliance with both state and federal standards.

III. LIMITATIONS OF EXISTING INDICATOR ORGANISMS

In Illinois, the approved indicator organisms listed in 35 Ill. Adm. Code Part 1422, Appendix A, Table B are primarily geared toward high-temperature, high-pressure autoclave systems. In practice, however, not all treatment systems—especially low-pressure steam systems—operate under those same conditions.

Geobacillus stearothermophilus, one of the currently approved organisms, often overestimates the required treatment intensity for low-pressure systems. This mismatch can create false negatives in validation testing, leading to unnecessary system design changes or rejection of safe, effective technologies.

Other states—including those with comparable environmental and health standards—have adopted Bacillus atrophaeus as a scientifically valid alternative for low-pressure steam validation. Our experience in those jurisdictions has been positive. Bacillus atrophaeus provides a reliable, appropriately resistant benchmark organism and allows for more accurate assessments of system performance.

In addition, the STAATT II and STAATT III guidelines—developed by the State and Territorial Association on Alternative Treatment Technologies for Medical Waste—explicitly recognize Bacillus atrophaeus as an appropriate indicator organism. These guidelines are widely cited by regulators and have served as a benchmark for many state-level approvals. Their inclusion of B. atrophaeus supports its validity and reinforces its use in evaluating low-pressure steam

systems where traditional thermophilic organisms may not be representative of actual performance conditions.

IV. BROADER CONTEXT AND CONSISTENCY

By approving Bacillus atrophaeus as an additional indicator organism, the Illinois Pollution Control Board would align with best practices used elsewhere in the country. Bacillus atrophaeus is already approved for use in several jurisdictions, including, for example:

- 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.

Additionally, the U.S. Department of Defense has specified Bacillus atrophaeus as a standard biological indicator organism for validating sterilization processes, as outlined in military specification A-A-50879.

Approval of Bacillus atrophaeus as an additional indicator organism would also improve validation accuracy for technologies like ours that are specifically designed for lower-pressure, lower-temperature inactivation—without compromising the health or safety of the public. This change would not replace the existing organisms in Table B; it would simply expand the list to include a tool that matches the reality of modern treatment technologies.

V. CONCLUSION

Based on both engineering principles and direct field experience, I support BioSAFE's petition to add Bacillus atrophaeus to the list of approved indicator microorganisms. This

amendment is scientifically justified, operationally sound, and consistent with current best practices across the industry.

Thank you for the opportunity to provide this testimony. I would be pleased to answer any questions at the hearing.

Respectfully submitted,

BIOSAFE ENGINEERING,

Dated: May 22, 2025

By: /s/ Alec Messina
One of Its Attorneys

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PRE-FILED TESTIMONY OF DANIEL NELSEN
ON BEHALF OF BIOSAFE ENGINEERING

BioSAFE Engineering, LLC ("BioSAFE"), by and through its attorneys, HEPLERBROOM, LLC, and pursuant to 35 Ill. Adm. Code 102.306 and the Notice of Hearings and Hearing Officer Order dated May 15, 2025, hereby submits the following Pre-Filed Testimony of Daniel Nelsen for presentation at the June 26, 2025 hearing scheduled in this matter.

I. EDUCATION

My name is Daniel Nelsen and I serve as the Chief Commercial Officer of BioSAFE Engineering, LLC, headquartered in Indianapolis, Indiana. I hold a Master's degree in Civil and Environmental Engineering and a Bachelor's in Management Science and Engineering with a minor in Biology, both from Stanford University.

My academic training focused on sustainable infrastructure, environmental systems analysis, and lifecycle impact modeling. Professionally, I've applied those foundations in roles at the intersection of technology, finance, and regulatory policy. Prior to joining BioSAFE, I worked in investment due diligence at Albourne Partners, where I was responsible for evaluating energy and infrastructure projects on behalf of institutional clients. My work included site visits to major oil basins during the peak of the fracking boom, inspections of drilling rigs and midstream assets, and analysis of liquefied natural gas export terminals and power generation facilities. I also assessed these assets for alignment with emerging ESG frameworks and sustainability disclosure

requirements relevant to large endowments, pension funds, and insurers. That experience provided me with a broad framework and deep practical understanding of environmental impacts, regulatory drivers, and the complex relationship between operational design and sustainable development.

II. POSITION AND RESPONSIBILITIES AT BIOSAFE

In my current role at BioSAFE, I oversee the company's commercial strategy and lead efforts to expand access to innovative, environmentally sound medical waste treatment technologies. I work closely with regulators, healthcare clients, and facility operators to ensure our systems meet both operational needs and regulatory requirements.

BioSAFE engineers, manufactures, installs, and services advanced sterilization systems for treating regulated medical waste, including high-containment materials. Our technology is deployed across the U.S. and internationally, often in settings requiring high confidence in pathogen inactivation and consistent system validation.

III. BIOSAFE'S SYSTEMS AND THE IMPORTANCE OF BACILLUS ATROPHAEUS

At BioSAFE, we design and deploy a range of systems for the treatment of regulated medical and biological waste, including both high- and low-pressure alkaline hydrolysis tissue digesters. While both systems are validated for complete tissue destruction and pathogen inactivation, low-pressure units offer unique advantages in settings where space, safety, or environmental considerations are paramount. Our approach is to provide the right tool for the application—not a one-size-fits-all solution.

Low-pressure alkaline hydrolysis systems operate at lower temperatures and pressures compared to high-pressure units or traditional technologies like incinerators and autoclaves. These conditions are sufficient to achieve complete tissue breakdown and microbial inactivation, while avoiding the production of hazardous byproducts. For example, unlike incineration, alkaline

hydrolysis produces no dioxins—a class of persistent organic pollutants and known carcinogens. It also avoids the airborne release of heavy metals and does not generate flue gas, dramatically reducing the risk of exposure for both operators and surrounding communities.

Across many jurisdictions, Bacillus atrophaeus is recognized as a suitable indicator organism for validating low-pressure systems. It offers a reliable resistance profile and aligns with the physical parameters under which these systems operate—parameters where organisms like Geobacillus stearothermophilus may be unnecessarily restrictive. By adding B. atrophaeus to the list of approved indicators in Table B of Appendix A, Illinois would join a growing number of states and federal bodies that allow for more context-appropriate validation without compromising safety.

IV. ENVIRONMENTAL BENEFITS OF LOW-PRESSURE SYSTEMS

The environmental advantages of low-pressure tissue digesters are substantial. These systems:

- 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.

While high-pressure alkaline hydrolysis digesters remain important for high-throughput or specific institutional settings, low-pressure systems allow facilities—particularly hospitals, universities, and research labs—to achieve comparable inactivation with lower energy and

environmental overhead. That alignment with emission reduction and sustainability goals makes them especially relevant to Illinois' environmental and substantiality mission.

V. CONCLUSION

We respectfully request that the Illinois Pollution Control Board adopt the proposed amendment to add Bacillus atrophaeus as a permitted indicator microorganism. This change would support the broader adoption of next-generation, environmentally preferable treatment systems—advancing both safety and sustainability in the management of infectious medical waste.

Thank you for the opportunity to provide this testimony. I am happy to answer any questions at the hearing.

Respectfully submitted,

BIOSAFE ENGINEERING,

Dated: May 22, 2025

By: /s/ Alec Messina
One of Its Attorneys

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