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
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Chicago, Illinois 60605
don.brown@illinois.gov

Carlie Leoni
Hearing Officer
Illinois Pollution Control Board
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Chicago, Illinois 60605
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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 **BIOSAFE'S RESPONSES TO PRE-FILED QUESTIONS**, copies of which are hereby served upon you.

Respectfully submitted,
BioSAFE Engineering,

Dated: June 25, 2025

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

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CERTIFICATE OF SERVICE

I, the undersigned, on oath state the following: **BIOSAFE'S RESPONSES TO PRE-FILED QUESTIONS,** 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
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That my email address is Alec.Messina@heplerbroom.com

That the number of pages in the email transmission is 15.

That I have sent the email transmission on June 25, 2025.

Date: June 25, 2025

/s/ *Alec Messina*
Alec Messina

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BIOSAFE'S RESPONSES TO PRE-FILED QUESTIONS

BioSAFE Engineering, LLC ("BioSAFE"), by and through its attorneys, HEPLERBROOM, LLC, hereby submits its responses to pre-filed questions submitted by the Illinois Pollution Control Board ("Board") and the Illinois Environmental Protection Agency ("Illinois EPA") for presentation at the June 26, 2025 hearing scheduled in this matter.

A. RESPONSES TO ILLINOIS EPA'S PRE-FILED QUESTIONS

1. Would the Proponent be willing to clarify that the use of *Bacillus atrophaeus* be limited specifically to low pressure/low temperature destruction method?

Our proposed change allowing the use of *Bacillus atrophaeus* ("BA") would be limited specifically to low pressure/low temperature destruction methods. High pressure/high temperature destruction methods would continue to use *Geobacillus stearothermophilus* ("GBS"). As for adding a similar clarification to the rule language itself, we believe the Illinois EPA's historical approach of having equipment manufacturers suggest the appropriate indicator organism for each type of treatment system is most appropriate.

2. Please also clarify the specific conditions that qualify as low pressure/low temperature destruction.

Low pressure/low temperature destruction systems are those that operate at pressures below 15 psig (pounds per square inch gauge) and temperatures below 212°F.

3. If *Geobacillus stearothermophilus* overestimates the required treatment intensity for low pressure systems, thereby creating false negatives in validation testing, can the opposite be realized where the use of this microorganism, for systems that are not low pressure/temperature, allow for false positives?

In this first situation, target pathogens have been decontaminated, but GBS has not been inactivated, so indicators would show a failure to decontaminate. This would be defined as a false negative. The opposite situation would be where GBS has been inactivated, so indicators would show a successful decontamination, but target pathogens have not been decontaminated.

This would be defined as a false positive. Because GBS is generally much more resistant to treatment than target pathogens, this would be a very unlikely situation to occur without both a BI failure (manufacturing/storage defect, incubation failure) and a system failure (no heat/improper heating etc). To mitigate this risk, most testing protocols call for multiple BI runs or have the test repeated at regular intervals (weekly, monthly, etc). So while a false positive in a non-low pressure/low-temperature system testing with GBS is possible, it is unlikely and unlikely to persist over multiple rounds of testing.

Both GBS and BA are spore forming bacteria but belong to different genera (family) and have distinct characteristics. GBS has a higher heat resistance to moist heat whereas BA has a higher resistance to dry heat. However, both organisms sit at the top of the "hierarchy of susceptibility" which indicates that all other organisms below are more susceptible to the same decontamination conditions.

While GBS is not be appropriate for low pressure applications, BA would still provide sufficient levels of decontamination indication in both low and high pressure applications, due to its position on the "hierarchy of susceptibility", to not allow for an increased rate of false positives. There are a variety of other treatment modes beyond high pressure and low pressure, which we would have to consider individually as relates to the efficacy of using BA as an indicator organism on. We are only proposing the use of this organism in low pressure/low temperature systems.

B. RESPONSES TO THE BOARD'S PRE-FILED QUESTIONS

Questions on Statement of Reasons

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.**

Yes, these include hospitals, clinics, and doctor's offices. The prevailing trend in the U.S. is a shift towards outpatient facilities that are smaller and more numerous than legacy hospitals.

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

Biotechnology/biopharmaceutical production sites are increasingly seeking to treat waste generated onsite using low-pressure treatment systems. Additionally, third-party haulers and treaters 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.

Yes, low-pressure STI and TD systems should be considered as Option 3 treatment units as they 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.

Yes, the 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?

No, we believe the Option 3 validation procedures are appropriate.

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).**

Our understanding of the current state of the field suggests that yes, references to *Bacillus Stearothermophilus* should be replaced with references to *Geobacillus Stearothermophilus*.

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.**

Disinfection, Sterilization, and Preservation, edited by Seymour S. Block. Page 700, chapter 36: Sterilization by Heat discusses the appropriateness of different indicators at different temperatures. Using standard D/Z value math, we can also see why this would not be appropriate:

Given:

- **D-value at 121°C (D_{121}):** 1.6 minutes
- **z-value:** 8°C
- **Target temperature:** 100°C
- **Target log reduction:** 6 logs

Step 1: Calculate D-value at 100°C

$$\log D_{100} = \log D_{121} + \frac{121 - 100}{z}$$

$$\log D_{100} = \log(1.6) + \frac{21}{8} = 0.2041 + 2.625 = 2.8291$$

$$D_{100} = 10^{2.8291} \approx 675.9 \text{ minutes}$$

Step 2: Calculate total time for 6-log reduction

$$\text{Time} = 6 \times D_{100} = 6 \times 675.9 = 4,055.4 \text{ minutes}$$

As shown, time to kill for GBS begins increasing exponentially as temperature approaches 100°C from 121°C. This supports the conclusion that as treatment temperature approaches 100°C, indicators other than GBS are more appropriate.

Additionally, Mesa Labs, a core provider of BIs in the U.S., states that *Geobacillus Stearothermophilus* is not appropriate for lower temperature treatment methods:

> **Low-Temperature Steam**
>
> ***
>
> **Porous or Hard Goods**
>
> As with heat-sensitive liquids, G. stearothermophilus may be too resistant for cycles utilizing sterilization temperatures less than 121°C for heat-sensitive porous or hard goods and Bacillus subtilis 5230 (ATCC 35021) may need to be used.(3) For this application, Mesa recommends our Bacillus subtilis 5230 MesaStrip or the Mesa UniQ microstrip if a regular-sized strip is too large for the location.

"How to Choose a Biological Indicator?" Nicole Robichaud, Spore News: Life Sciences Expert Resource, MesaLabs, attached hereto as Attachment A.[1]

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.

Both. We are referring to the Petition of BioMedical Technology Solutions Inc. for an Adjusted Standard from 35 Ill. Adm. Code 1422 (AS 2008-006) in Illinois, and our own technologies approved in other states.

5. The SOR also states that low treatment temperature technologies cannot pass efficacy testing using *Geobacillus 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.

BioSAFE's STI technology is both low-pressure and low-temperature. BioSAFE manufactures two types of TD technologies: low-pressure/low-temperature and high-pressure/high-temperature. For the purposes of this proposal, we are only considering low-pressure/low-temperature TD systems.

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

For low-pressure/low-temperature TD systems, and STI systems, optimal operating temperature is ~100°C, based on operating elevation above sea level.

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 *Geobacillus Stearothermophilus,* or the commercial unavailability of *Bacillus Subtilis* and *Bacillus Pumilus*?

We believe that any generator of PIMW would be positively affected by this change. This proposed amendment would increase the availability of competing treatment technologies, resulting in greater total in-state non-incineration based treatment capacity and lowering prices for hospitals, clinics, and other generators.

[1] The whitepaper is also available on MesaLabs' website, upon registration, at https://mesalabs.com/spore-news-resources/selecting-biological-indicators.

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

Yes, this would be expected to increase the availability of lower cost of treatment options, which should reduce the cost paid to treat waste by Illinois companies and therefore have a positive economic impact.

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

Yes, to quantify it I would take the volume processed in *Bacillus Atrophaeus* approved technologies (i.e. 1,000,000 lbs/yr), and multiply it by the cost savings associated with these technologies (i.e., 10c/lb) to get an annual positive economic impact of $100,000/yr. Additional positive economic impacts could be calculated by deriving the reduction in truck miles driven due to increased in-state treatment capacity and increased densification of treated waste, and calculating the public health savings associated with this.

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.

While these organisms are not currently commercially available, we see no reason to remove them from the list, and in fact inclusion on the list probably makes them more likely to become commercially available in the future.

<u>Questions Directed to Brandon Ross</u>

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.

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

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.

High-temperature/high-pressure treatment systems can be tested by using *Geobacillus stearothermophilus* as an indicator organism.

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.

Low-temperature/low-pressure treatment systems can be tested by using *Bacillus atrophaeus* as an indicator organism.

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.

We believe the Illinois EPA's historical approach of having equipment manufacturers suggest the appropriate indicator organism for each type of treatment system is most appropriate.

Respectfully submitted,

BIOSAFE ENGINEERING,

Dated: June 25, 2025

By: /s/ Alec Messina
One of Its Attorneys

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ATTACHMENT A

Spore News: Life Sciences Expert Resources

Knowledge Center

How to Choose a Biological Indicator?

By Nicole Robichaud

With the many types of biological indicators (BIs) available - spore strips, self-contained biological indicators (SCBIs), glass ampoule liquid submersible BIs, stainless steel BIs, and Mesa UniQ Industrial Use BIs such as threads, microstrips, and paper discs - the process of selecting the appropriate BI to monitor a sterilization process may seem like a daunting task. However, with a quick evaluation of the load type and/or the sterilization parameters, the selection can be easily narrowed down. This Spore News will provide information on beginning the process of BI selection, enabling end-users to more accurately determine which type of BI is appropriate for monitoring their sterilization cycle.

Steam

Porous or Hard Goods

If the load consists of porous or hard goods, Mesa Labs recommends using MesaStrip, Spore Strips, EZTest® SCBI, or Smart-Read™ EZTest SCBI. Porous and hard goods are sterilized by direct contact with the steam generated by the autoclave.[1] The steam generated by the autoclave surrounds or penetrates the items and directly contacts the bioburden thus inactivating it. This is also true with the BIs used in autoclave loads containing porous or hard goods, steam surrounds and penetrates the BI and directly contacts the spores on the BI carrier material.

Strips and SCBIs function in essentially the same manner during a sterilization cycle; however, post sterilization, strips need to be aseptically cultured into growth media and if not handled properly can result in contamination of the spore strip or culture media which will cause a false positive result. Using an SCBI provides an alternative option for customers who do not have the capability to perform aseptic culturing as the system is 'self-contained' and this eliminates the chance of post-process contamination. Customers sterilizing items in dental offices, small clinics, or body art studios may choose to use a service such as Mesa Labs Mail-In Spore Testing where after sterilization, the BI is sent to Mesa for testing.

If the BI must be placed into a small area, such as tubing or a medical device, then a regular-sized spore strip or SCBI may be too large and instead, a Mesa UniQ™ BI for Industrial Use such as a microstrip, paper disc, thread or ProLine Tubing Process Challenge Device can be used.

Containers of Aqueous Liquids

If the load consists of containers of aqueous liquid, Mesa recommends one of our glass ampoule, liquid submersible BIs, ProSpore®, MagnaAmp®, or SterilAmp® II. Liquids are not sterilized by direct contact with the autoclave steam because the steam cannot reach the liquid inside the container.[2] In simple terms, the steam from the autoclave heats the container, which in turn heats the liquid contents and inactivates the bioburden. Likewise, the spores in the glass ampoule BI will never be contacted by the steam from the autoclave. The glass ampoule will be heated, which in turn heats the liquid media, inactivating the spores in the media. The volume of liquid inside the containers being sterilized will determine which liquid submersible BI is best to use.

For volumes of liquid greater than 150 mL, Mesa recommends the use of ProSpore or MagnaAmp. Volumes of liquid greater than 150 mL will experience a lag time to temperature in the geometric center of the liquid making this the most difficult to sterilize area and the ideal location to suspend the BI. ProSpore and MagnaAmp have a "neck" around which a fine gauge wire can be easily attached to suspend the ampoule in the liquid where it can monitor this most difficult to sterilize location.

For volumes of liquid less than or equal to 150 mL, Mesa recommends the use of SterilAmp II. Volumes of 150 mL or less will heat consistently throughout with minimal to no lag time for the geometric center of the liquid to heat to sterilization temperature. SterilAmp II is a small (26 x 6.5 mm or 18 x 6.5 mm) glass ampoule that will float on top of the liquid but

since there is a minimal lag time for the geometric center of these small volumes to heat to temperature, SterilAmp II will adequately monitor the conditions that are experienced by the liquid.

In some instances, the liquid BI may not need to be placed into the liquid but rather can be placed at various locations in the autoclave next to the containers of liquid. Generally, ProSpore or MagnaAmp are used in this manner when sterilizing vials of product that are approximately the same volume as ProSpore (~ 4 mL) or MagnaAmp (~ 1 mL). In this way, the BI will function as a surrogate vial and will experience similar conditions as the product vials.

Waste

If the load consists of bags or containers of biohazardous waste, Mesa recommends the use of one of our glass ampoule, liquid submersible BIs MagnaAmp or ProSpore. Fluids inside of the bags or containers will coat and damage a spore strip or SCBI leaving the possibility of a false positive result, but a glass ampoule BI will not be affected by waste fluids. Near the bottom of the waste container will typically be the most difficult to sterilize area and so a fine gauge wire can be attached to the neck of the MagnaAmp or ProSpore for ease of placement into the waste and ease of retrieval of the BI after completion of the cycle.

Low-Temperature Steam

Liquids

The organism of choice for steam sterilization cycles at temperatures of 121 °C or greater is *Geobacillus stearothermophilus* (ATCC 7953). For sterilization temperatures of less than 121°C which are typically used for the sterilization of heat-sensitive aqueous liquid products, *G. stearothermophilus* may be too resistant and *Bacillus subtilis* 5230 (ATCC 35021) may need to be used.[2] For this purpose, Mesa recommends SterilAmp II 5230 which utilizes the same ampoule as SterilAmp II but contains *Bacillus subtilis* 5230.

Porous or Hard Goods

As with heat-sensitive liquids, *G. stearothermophilus* may be too resistant for cycles utilizing sterilization temperatures less than 121°C for heat-sensitive porous or hard goods and *Bacillus subtilis* 5230 (ATCC 35021) may need to be used.[3] For this application, Mesa recommends our *Bacillus subtilis* 5230 MesaStrip or the Mesa UniQ microstrip if a regular-sized strip is too large for the location.

Ethylene Oxide

Ethylene Oxide (EO) sterilization is generally used for items that would be damaged by heat or radiation.[4] BI selection for this process can be less complicated than Steam BI selection simply because EO is not used to sterilize liquids. For EO sterilization Mesa recommends the use of MesaStrip, Spore Strips, Releasat Biological Indicator Culturing Kit, or EZTest SCBI, each inoculated with *Bacillus atrophaeus* (9372).

Strips and SCBIs function in essentially the same manner during a sterilization cycle; however, post sterilization, strips need to be aseptically cultured into growth media and if not handled properly, this can result in contamination of the spore strip or culture media which will cause a false positive result. Using an SCBI provides an alternative option for customers who do not have the capability to perform aseptic culturing as the system is 'self-contained' and this eliminates the chance of post-process contamination.

If the BI must be placed into a small area of a device, then a regular-sized spore strip or an SCBI may be too large and instead, a Mesa UniQ BI for Industrial Use such as MicroStrips, Paper Discs, or Threads can be used.

When sterilizing large loads, it's time-consuming and costly to place and retrieve BIs that are embedded in the load. However, after performing the appropriate validation activities with BIs embedded in the load, the user may be able to switch to one of Mesa's Process Challenge Devices (PCD) for routine monitoring. A PCD is selected that provides an equal or greater challenge to the cycle as compared to the embedded BIs.[5] The PCDs are then placed on the outside of the load, making placement and removal an easy task.

Dry Heat

Dry heat is used to sterilize items that will not be damaged by heat (such as glass or stainless steel) or items that cannot be sterilized by steam (such as non-aqueous liquids or powders).[6] The main consideration for dry heat BI selection is the temperature of the cycle.

For cycles operating at 180°C or less, Mesa recommends Mesa Strips, Spore Strips, or Releasat Biological Indicator Culturing Kit, each inoculated with *Bacillus atrophaeus* (9372). The strips are packaged in a protective glassine envelope which can withstand the lower dry heat temperatures; however, at temperatures above 180 °C, the glue that holds the glassine envelope together can separate, leaving the strip susceptible to post-process contamination.

For cycles operating above 180 °C, Mesa recommends DriAmp® which consists of silica material, inoculated with *Bacillus atrophaeus* (9372), and sealed in a glass ampoule. DriAmp can withstand temperatures in excess of 350°C, and so it can even be used when it is necessary for a user to monitor sterilization with a BI in a dry heat depyrogenation cycle.

For dry heat sterilization of non-aqueous products such as oils, Mesa recommends the use of DriAmp. Just like aqueous liquids, the conditions of the product inside of the container must be monitored. Since DriAmp is a sealed glass ampoule, it's ideal for placement in the product where a spore strip would be compromised.

Vaporized Hydrogen Peroxide (VH_2O_2)

Sterilization

ISO recommends the use of *Geobacillus stearothermophilus* on a non-cellulosic carrier to demonstrate the microbiocidal effectiveness of VH_2O_2 sterilization cycles used by process developers, sterilization equipment manufacturers, medical device manufacturers and end users of VH_2O_2 sterilizers and medical devices sterilized by VH_2O_2[(7)]. For these processes, Mesa recommends one of our *Geobacillus stearothermophilus*, non-cellulosic carrier SCBIs, ExpoSure®, or EZTest. Exposure is ideal for US Healthcare settings and EZTest is ideal for all other settings.

Decontamination

When performing VH_2O_2 decontamination at ambient temperature and pressure, the USP recommends, *Selection of the appropriate biological indicator (BI) and resistance should be based on experimentation within the user's system.*[(8)] With the numerous different types of VH_2O_2 systems and the infinite number of different cycles, Mesa's line of Apex® VH_2O_2 BIs offers a wide variety of choices to suit any need. The Apex line consists of three types of BIs (stainless-steel discs packaged in Tyvek®, unpackaged stainless-steel ribbons, and the Apex EZTest SCBI), three different organisms (*G. stearothermophilus* 12980 or 7953, and *B. atrophaeus*) and a variety of populations.

Radiation

Biological indicators may not be necessary for all radiation sterilization processes but may be required when sterilizing biological products such as tissues or cell preparations or other products that may provide spore protection.[(9)] When a BI is necessary, Mesa recommends the use of MesaStrip for radiation.

Alternative Sterilization Methods

Today there are a variety of alternative vapors and gases being used for decontamination and sterilization; however, BI resistance and population requirements for these processes are not specified in standards. Mesa offers MesaStrips for Chlorine Dioxide and Ozone but for other alternative modalities reach out to one of our experts for help in selecting a BI that will meet your needs.

Additional Services

During cycle development, the Contract Studies team at Mesa can assist in performing studies to determine if a BI from our extensive portfolio will be appropriate for your cycle validation and if not, they can assist with a custom solution that will be appropriate for your unique situation. For an outline of services offered by the Contract Studies Laboratory, see our white paper Spore News – *Contract Studies*.

While identifying the correct type of BI for a specific process is the initial step, there are other important variables to consider. What spore population do you require? For steam sterilization, United States Healthcare is required to use a BI with a spore population of at least 10^5 and generally speaking, outside of US Healthcare, a BI with a spore population of 10^6 is used. Do you need a BI with FDA 510(k) clearance? United States Healthcare must use a BI with FDA 510(k) clearance when reprocessing items for patient use. If you are unsure about requirements you must follow, it's best to contact your regulatory agency for guidance.

Reference

1. United States Pharmacopeia 2022, General Information, Chapter <1229.1> Steam Sterilization by Direct Contact
2. United States Pharmacopeia 2022, General Information, Chapter <1229.2> Moist Heat Sterilization of Aqueous Liquids
3. ANSI/AAMI/ISO 11138-3:2017 Sterilization of health care products-Biological indicators-Part 3: Biological indicators for moist heat sterilization processes
4. United States Pharmacopeia 2022, General Information, Chapter <1229.7> Gaseous Sterilization
5. ANSI/AMMI/ISO 11135:2014 Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
6. United States Pharmacopeia 2022, General Information, Chapter <1229.8> Dry Heat Sterilization
7. ISO 22441:2022 Sterilization of health care products – Low temperature vaporized hydrogen peroxide – Requirements for development, validation and routine control of a sterilization process for medical devices
8. United States Pharmacopeia 2022, General Information, Chapter <1229.11> Vapor Phase Sterilization
9. European Pharmacopoeia 10 – 5.1.2 Biological indicators and related microbial preparations

SN062-V1

Topics: General Biological Indicator Information, Product Profiles

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