

ILLINOIS POLLUTION CONTROL BOARD

June 26, 2025

IN THE MATTER OF)
POTENTIALLY INFECTIOUS MEDICAL)
WASTE (PIMW) PROPOSED AMENDMENT) R 25-24
OF 35 ILL. ADM CODE 1442.) (Rulemaking - Land)
APPENDIX A, TABLE B - INDICATOR)
MICROORGANISMS)

Record of proceedings before POLLUTION
CONTROL BOARD, commencing at 10:00 a.m. on the 26th day
of June, A.D. 2025 upon the hearing of the above-entitled
case.

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P R E S E N T:
ATTENDING BOARD MEMBERS:
Jennifer A. Van Wie
Angela Tin
Michael Mankowski

BOARD STAFF
Carlie Leoni - Hearing Officer
BOARD ATTORNEY ADVISORS
Timothy Fox
Daniel Pauley
Nick San Diego
IPEA Attorney

Melissa Brown
Alec Messina
BioSafe

Joshua Rhoades
Trevor Dell'Aquila
IEPA

Ananda Rao,
Chief Environmental Scientist
Essence Brown,
Environmental Scientist

REPORTED BY:
CAROL CONNOLLY, CSR, CRR
CSR License No. 84-3113

1 HEARING OFFICER LEONI: Good morning, and welcome to
2 this Illinois Pollution Control Board Hearing. My name
3 is Carlie Leoni. I'm the hearing officer for this
4 rule-making proceeding entitled Potentially Infectious
5 Medical Waste, or PIMW, Proposed Amendment of 35 Illinois
6 Administrative Code 1422.Appendix A, Table B Indicator
7 Microorganisms. The Board docket number for this rule
8 making is R25-24.

9 Also present today from the Board is Board
10 Member Jenner Van Wie, Board Member Michael Mankowski,
11 and Board Member Angela Tin.

12 Board Staff in Chicago via video are the
13 Board's technical unit, Chief Environmental Scientist
14 Anand Rao, Environmental Scientist is Essence Brown, also
15 Board Senior Attorney Tim Fox, and Board Staff Attorney
16 Daniel Pauley.

17 Participants of the rule making here in
18 Springfield today are Melissa Brown and Alex Messina for
19 the rule proponent BioSafe Engineering, Nick San Diego,
20 and Joshua Rhoades for the Illinois Environmental
21 Protection Agency.

22 And in Chicago, there's Trevor Della'Aquila for
23 the Illinois Environmental Protection Agency.

24 Witnesses today in Springfield are Brandon Ross

1 and Daniel Nelsen.

2 This hearing is governed by the Board's
3 procedural rules. All information that is relevant and
4 that is not repetitious or privileged will be admitted
5 into the record. Please bear in mind that any questions
6 posed today by the Board and its staff are intended
7 solely to help develop a clear and complete record for
8 the Board's decision and do not reflect any decision on
9 the proposal testimony or other questions.

10 For the sake of our court reporter, please
11 speak clearly and avoid speaking at the same time as
12 another person so that we can help produce a clear
13 transcript.

14 For background on this proceeding, on
15 March 20th, 2025, BioSafe filed a rule making that
16 proposed the Board amend Part 1422 of its potentially
17 Infectious Medical Waste rules. BioSafe requests that
18 the Board add an indicator microorganisms Bacillus
19 Atrophaeus to Part 1422 to be used for validation of
20 low-pressure steam-based treatment systems for
21 potentially infectious medical waste.

22 On April 3rd, 2025 the Board accepted the
23 proposal and directed the hearing officer to proceed to
24 hearing. Today we will hold the first hearing. This

1 hearing will be focused on the proponent witnesses and
2 their testimonies. Notice for this hearing was posted in
3 the State Journal Register and the Chicago Sun-Times.
4 These publications occurred in the State Journal Register
5 on May 18th, and in the Chicago Sun-Times on May 19th.

6 On May 15th, 2025 the Board requested pursuant
7 to Section 27(b) of the Illinois Environmental Protection
8 Act that the Department of Commerce and Economic
9 Opportunity conduct a study on the economic impact of the
10 proposed rule amendment. The letter requested that DCEO
11 provide their response by July 14th, 2025. As of today,
12 DCEO has not responded to the request. BioSafe filed the
13 written testimony of two total witnesses on May 22nd.
14 The Board and the Agency filed written questions on
15 June 12th. BioSafe filed written responses to those
16 questions on June 25th.

17 I just have one note on BioSafe's responses
18 which were filed with the Board right about at the
19 24-hour mark before today's hearing. I'm going to
20 propose to enter these responses into the record as I've
21 read today, but if anyone objects to that, please raise
22 your objection and state your reason at that time.

23 Please also keep in mind that this is the first
24 of two hearings and there will be plenty of time to

1 review the responses and prepare any additional follow-up
2 questions ahead of our second hearing in August, if
3 needed.

4 So as to the order of today's proceedings,
5 today BioSafe will put forth its two witnesses to answer
6 any follow-up questions the participants and the Board
7 might have regarding their testimony and written
8 responses.

9 We have Brandon Ross and Daniel Nelsen
10 available for testimony today. The court reporter will
11 swear in the witnesses when they begin. Typically we
12 enter pre-filed testimony as an exhibit as if read, and
13 counsel are allowed to give a short opening statement, if
14 they choose. Witnesses are also allowed a short opening
15 summary of their testimony if they choose. Following
16 this hearing, I will issue an exhibit list.

17 Ms. Court Reporter, please feel free to stop me
18 or anyone at any point if we're going too fast, talking
19 too softly, or if you need something repeated. For any
20 participants asking questions today, please start your
21 question by stating your name and the organization that
22 you are representing.

23 Since we began at 10:00 a.m., I anticipate
24 going until around 10:55 and then breaking for the

1 11:00 a.m. Board meeting scheduled today. If needed, we
2 will resume after the Board meeting ends at about
3 11:30 a.m. If we are still going at 12:30 p.m., we'll
4 break for an hour lunch and resume at 1:30. Any witness
5 -- after witness testimony, we will open it up to any
6 public comments and end today, at the latest, at around
7 3:00 p.m.

8 If we get to the end of the hearing today and
9 still have questions or remaining testimony, we will
10 address it at that time. We do have a sign-up sheet in
11 Springfield to sign up for public comment. So if there
12 are any members of the public here in person today,
13 please go ahead and write your name on the list. We will
14 address public comments after witness testimony today.
15 And anyone can submit written public comments on the
16 Board's clerk's office online system or as we call it
17 QUO. Please note that the Board weighs oral and written
18 public comments equally.

19 Before we proceed to testimony, we have
20 pre-filed questions for the witnesses that we will now
21 enter into the record.

22 First, we have the pre-filed questions of the
23 Illinois Environmental Protection Agency, which we will
24 enter as if read as Exhibit 1.

1 Next, we have the Board's pre-filed questions
2 that we will enter as if read as Exhibit 2.

3 Okay. Are there any questions about the order
4 of today's proceedings? If not, we will move on to
5 swearing in today's witnesses for BioSafe, Brandon Ross
6 and Daniel Nelsen.

7 (Witnesses duly sworn)

8 HEARING OFFICER LEONI: As mentioned earlier, the
9 pre-filed testimony is entered into the record as if
10 read.

11 Would BioSafe like to enter the pre-filed
12 testimony of his witnesses as if read?

13 MR. MESSINA: Yes, thank you.

14 HEARING OFFICER LEONI: All right. Do the witnesses
15 or -- I'm sorry. That will be entered as if read as
16 Exhibit 3.

17 Do the witnesses or their counsel wish to offer
18 a brief introduction and summary?

19 MR. MESSINA: Good morning, and thank you. Yes, I
20 would, very brief. My name is Alex Messina representing
21 BioSafe Engineering. Thank you for the opportunity to be
22 here today. Again, as the hearing officer noted, the
23 testimony and the response to the initial questions have
24 now been entered into the record. We would have liked to

1 gotten those answers submitted a little sooner so that
2 the Agency and the Board would have had some additional
3 time to review that material, but we are certainly happy
4 to address those questions today or any follow up that
5 you may have as a result of the answers that you've seen.
6 We just want to make sure that all of the parties here
7 have ample opportunity to ask questions of our two
8 witnesses today. And that's all that we have.

9 HEARING OFFICER LEONI: Okay.

10 MR. MESSINA: Thank you.

11 HEARING OFFICER LEONI: Thank you. If the witnesses
12 are ready, we will proceed to those questions. Since the
13 questions for the witnesses have been entered as if read,
14 would BioSafe like to enter the responses of the
15 witnesses as if read as well?

16 MR. MESSINA: Yes, we would like to enter those as
17 read.

18 HEARING OFFICER LEONI: Thank you. Are there any
19 objections to entering the responses of BioSafe's
20 witnesses into the record as if read?

21 Hearing none, BioSafe's responses to the
22 pre-filed questions will be entered as if read as
23 Exhibit 4.

24 All right. Now, on to follow-up questions for

1 the witnesses. Are there any follow-up questions for
2 BioSafe's witnesses?

3 MR. DELL'AQUILA: My name is Trevor Della'Aquila on
4 behalf of the Illinois Environmental Protection Agency.
5 I have just a few questions to follow up on the
6 responses.

7 In your response to the Illinois EPA's question
8 number 3, you mention -- this is directed towards either
9 of you. You mention that GBS, which is Geobacillus
10 Stearothermophilus, has a higher heat resistance to moist
11 here, whereas Bacillus Atrophaeus, BA, has a higher
12 resistance to dry heat, and that in the following
13 paragraph -- this is the final paragraph in the
14 response -- that BA would still provide sufficient levels
15 of decontamination in both low- and high-pressure
16 applications due to its position on the hierarchy of
17 susceptibility to not allow for an increased rate of
18 false positives.

19 I do know that your proposal is directed
20 towards exclusively using BA in low-pressure,
21 low-temperature systems, but it does appear based off of
22 this response that BA is also applicable in my pressure
23 situations -- or systems. Is that correct?

24 MR. NELSEN: From our kind of experience and

1 industry knowledge, what -- you could make the argument
2 that Bacillus Atrophaeus is an appropriate indicator
3 organism for high-pressure systems. There does not
4 exist, to our knowledge, from the body of scientific
5 literature and consensus to fully support that. Neither
6 of us are currently microbiologists, so we're not trying
7 to make that claim. We're taking kind of the information
8 we gleaned from other industry experts, experts in
9 microbiology, experts in sterilization, and applying kind
10 of those findings and those best practices to our
11 recommendations to the Board.

12 So while from a technical perspective, you
13 know, one could make the argument that Bacillus
14 Atrophaeus is appropriate for high-pressure systems,
15 we're not seeking to make that argument today.

16 MR. DELL'AQUILA: Okay. Additionally in response to
17 the Board's question number 2 -- I guess more to question
18 2A -- the response to question 2A, in that response, it
19 is stated that low pressure STI and TD systems should be
20 considered as Option 3 treatment units as they use
21 thermal treatment and maintain the integrity of the
22 container of indicator microorganism spores. According
23 to BioSafe engineering's website, STI's systems utilize
24 an integrated shredder that waste is pushed through prior

1 to treatment under low-pressure steam.

2 So my follow-up question there is if these STI
3 systems utilize an integrated shredder, how can they
4 maintain the integrity of the container of microorganism
5 spores.

6 MR. NELSEN: That's a great question. So for
7 validation testing on the STI system, we introduced the
8 spore carrier with the biological indicator below the
9 shredding system so that the indicator does not pass
10 through the shredder.

11 MR. DELL'AQUILA: So they are able to maintain under
12 Option 3 systems because the container never passes
13 through the shredder?

14 MR. NELSEN: Correct.

15 MR. RAO: May I can ask a follow-up? You just
16 mentioned that you introduced the spores after the
17 shredder. Just wanted to clarify if the -- you know,
18 once you introduce the spores, is it still under low
19 pressure and temperature within the system, or is there a
20 change in that pressure after it goes -- the waste goes
21 through the shredder?

22 MR. NELSEN: The entire system is nonpressurized so
23 it's open to atmospheric pressure so there's no pressure
24 difference between going in before the shredder versus

1 after the shredder. If anything, that's going to create
2 a more challenging environment for the biological
3 indicator. As the heat has to penetrate through the kind
4 of glass ampule that the biological indicator is
5 contained within whereas other waste being treated with
6 the system will be shredded to increase the surface area
7 and break up any containers or pockets before as it
8 enters the heat treatment auger, so in this situation the
9 biological indicator, you know, as a -- is more
10 challenging to decontaminator treat than the shredded
11 waste passing through the shredder would be.

12 MR. RAO: Thank you.

13 MR. DELL'AQUILA: Okay. My final one I have is in
14 response to the Board's question number 3. It's stated
15 that Bacillus Stearothermophilus should be replaced with
16 references to Geo Stearothermophilus. This is less of a
17 question and more of just bringing this to attention of
18 all parties involved.

19 If the suggestion is to replace the Table B
20 indicator for Bacillus Stearothermophilus with
21 Geobacillus Stearothermophilus, it should be noted that a
22 reference to Bacillus Thermophilous is also is found in
23 part 1422.125(a)(1). There would -- it would also have
24 to be replaced there in order to maintain the consistency

1 of Part 1422.

2 So that's less of a question, more of just
3 bringing it to the attention of everyone. So we know in
4 the future if that is going to be amended, and if you're
5 suggesting that is amended, it has to be amended both in
6 that section and in the table.

7 MR. MESSINA: I appreciate that. I would just note
8 that as the Board oftentimes makes changes to initial
9 proposals as they're reviewing the testimony and the
10 record that we simply wanted to make that information --
11 wanted to make the board aware of that information.

12 MR. DELL'AQUILA: Nothing further at this moment.

13 HEARING OFFICER LEONI: Okay. Thank you. Are there
14 any other follow-up questions for the witnesses here or
15 in Chicago?

16 Member Tin?

17 BOARD MEMBER TIN: Yes. Do you operate the
18 high-temperature systems also, or do you do only the low?

19 MR. NELSEN: So we -- within our range of tissue
20 digesters we have both low-pressure systems and
21 high-pressure systems. Those are two separate lines
22 within our tissue type --

23 BOARD MEMBER TIN: For the high-pressure systems,
24 would you be using the Geobacillus then?

1 MR. NELSEN: Yes.

2 BOARD MEMBER TIN: Thank you.

3 HEARING OFFICER LEONI: Okay. Thank you. Are there
4 any other follow-up questions in Springfield or Chicago?

5 All right. Hearing none, then we have
6 concluded the testimony and questions of Mr. Ross and
7 Mr. Nelsen. Thank you, Mr. Ross and Mr. Nelsen.

8 That concludes our testimony and questions
9 today.

10 For the record, is there anyone present here
11 today who did not pre-file testimony for this hearing but
12 does wish to offer testimony?

13 Hearing none, we will move on to comments.

14 Here in Springfield we do not have anyone who
15 has signed up to offer public comments. So I do not
16 believe that needs to be addressed at this time. And it
17 looks like we have addressed everything that's on my
18 agenda for the hearing.

19 Are there any other matters that the
20 participants would like to address at this time?

21 MR. MESSINA: I'll just quickly add that, again, we
22 submitted these pre-filed answers just yesterday so if
23 there happens to be additional information that either
24 the Board or the Agency would like us to address in

1 advance of the second hearing, certainly we're open to
2 that and happy to further the record however -- however
3 anyone would ask of us.

4 HEARING OFFICER LEONI: Thank you.

5 MR. RAO: Carlie? Just have a question, if Agency
6 will have someone at the second hearing to answer
7 questions? I just had one question based on what BioSafe
8 had responded to one of our questions. Otherwise, I can
9 put it on the record and they can get back to us on it?

10 HEARING OFFICER LEONI: That would be great, if the
11 agency agrees with that.

12 MR. SAN DIEGO: That would be fine.

13 HEARING OFFICER LEONI: Go ahead.

14 MR. RAO: It relates to BioSafe's answer to Board
15 question number 9, 9B -- 9C, where BioSafe states that
16 they believe that Illinois EPA's historical approach of
17 having equipment manufacturers suggest appropriate
18 indicator organisms for each type of treatment system is
19 more appropriate than the Board specifying in the rules
20 itself as to what microorganism should be used for what
21 kind of system. So I just wanted to ask the Agency
22 whether the Agency is comfortable with its historical
23 approach, or would it be clear if the Board specifies,
24 you know, which microorganism should be used depending on

1 the type of treatment system.

2 That's all I have. Thank you.

3 HEARING OFFICER LEONI: Okay. Thank you. If there
4 are not any other matters that the participants would
5 like to address at this time, that concludes our hearing.
6 I would like to thank everyone for participating today,
7 and we're now off the record. Thank you.

8 (Off the record at 10:21 a.m.)

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1 STATE OF ILLINOIS)
) SS:
2 COUNTY OF C O O K)
3

4 CAROL CONNOLLY, being first duly sworn, deposes
5 and says that she is a Certified Shorthand Reporter in
6 Cook County, Illinois, and reporting proceedings in the
7 Courts in said County;

8 That she reported in shorthand and thereafter
9 transcribed the foregoing proceedings;

10 That the within and foregoing transcript is
11 true, accurate and complete and contains all the evidence
12 which was received and the proceedings had upon the
13 within cause.

14 
15

16 CAROL CONNOLLY, CSR, CRR
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19
20 Subscribed and sworn to before me this
21
22 14th day of July, A.D., 2025.
23
24 _____

[084-003113 - asking]

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