Microbiology Expert Committee (MEC)
Meeting Summary

December 13, 2022

1. Roll Call:

   Cody, Chair, called the meeting to order at 1:30pm Eastern on December 13, 2022, by teleconference. Attendance is recorded in Attachment A – there were 11 members present. Associates present: David Lo, Joe Guzman, Nigel Allison, Chandra Thekkekalathil, and Alma McCammond (joined 2:30pm).

   The November meeting minutes were distributed for review. The Committee cannot vote on the minutes due to a balance issue with the removal of Lily Giles membership today. Cody is reaching out to find additional membership to bring the Committee back into balance. Robin knows someone who will be applying as an Other. When the application comes in, Ilona will distribute it to the group for review and comment prior to an email vote.

   (Addition: The vote on the Response to Comments Summary table was re-done by email on 2/14/23. See February 14, 2023 Minutes.)

2. Winter Meeting – San Antonio, TX

   Planning to attend: Robin, Elisa, Cody, Jody – put in request, and Chandra

   Cody shared what was discussed at the last public microbiology meeting to help come up with ideas regarding this January's meeting.

   Agenda:
   DRAFT Standard
   Training Series
   SIRs
   Open floor to Discussion

   The meeting will be on Tuesday, January 10, 2023 at 3:30-5pm Eastern.

   Slide Presentation –
   Ilona will look at action items for the slides – accomplishments and goals.

   Jody commented that there are some committees looking for lab members – Standard Methods in ASTM 9223, 9020 – low to no lab representation. The committee meets 1 hour every other month.

   Weblinks:
   https://www.astm.org/get-involved/technical-committees/committee-d19

https://www.standardmethods.org/joinsmcommittee

3. SIRs

Lynn Bradley shared SIR 443, though it was not accepted as an SIR. It is for informational purposes, so the Committee is aware of questions being asked.

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.1.a).i
Describe the problem: Can a negative control culture (V1M5 1.7.3.6.i) be used as a check of sterility?	

SIR 423 was returned. This SIR has been getting discussed since December 2021. A copy of the information sent by Lynn and commented on by Robin (green text) can be found in Attachment D.

Robin commented that Lynn provided information and the NELAP AC's comments. Robin would rather have labs do it, but there is history as to why it is set up as it is. Today's 2016 Standard is what it is and you cannot add something to the Standard. Our response is inconsistent with the definition of a quality control sample. If we want it to be a QC standard or a QC sample, we have to write that section very differently because it's not the way that it was written.

Robin reviewed the information she provided in Attachment D.

After thorough discussion, Cody offered to try to draft up some language based on what was talked about today and the points that Robin made and see if we can get something through that does not add a requirement to the existing 2016 standard but still explains why we don't feel it falls under QC testing and then how the 1.7.3.1.8 does not umbrella over 1.7.3.1.6.

4. Continue work on DRAFT Standard Comments

We were about halfway through voting when it came to light that Lily was no longer on the committee, and we now have a dominance of lab stakeholders. The Committee will handle this conservatively. The vote will be redone after membership is back in balance.

5. New Business

Cody and Ilona finalized the dates for the Understanding Microbiology Series. The first class will be on May 25th and every fourth Thursday after that for the remaining four parts.

6. Next Meeting and Close

The next meeting will be in person in San Antonio, TX at the winter conference – Tuesday, January 10, 2023 at 3:30pm Central.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Cody adjourned the meeting at 2:58pm Eastern.

Attachment A

Participants

Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information
Cody Danielson (Chair) (2025) **Present**	Oklahoma	Lab	Cody.Danielson@deq.ok.gov
Matt Graves (2025*) **Present – Joined 2pm**	ERA	Other	Matt_graves@waters.com
~~Lily Giles (2025)~~ ~~**Absent**~~	~~Louisiana~~	~~AB~~	~~Lily.Giles@LA.GOV~~
Amy Hackman (2025*) **Present**	Indiana	AB	mrobinson@isdh.IN.gov
Robin Cook (Vice Chair) (2024*) **Present**	City of Daytona Beach, EML	Lab	cookr@codb.us
Ashley Larssen (2024*) **Present – Joined 2:09pm**	KC Water	Lab	ashley.larssen@kcmo.org
Jody Frymire (2025) **Present**	IDEXX	Other	Jody-Frymire@idexx.com
Jessica Hoch (2025) **Present**	TCEQ	Other	Jessica.hoch@tceq.texas.gov
Elisa Snyder (2023*) **Present**	City of Austin – Austin Water Division	Lab	elisa.snyder@austintexas.gov
Hunter Adams (2023*) **Absent**	City of Wichita Falls – Water Purification	Lab	hunter.adams@wichitafallstx.gov
Enoma Omoregie (2024) **Present**	NYC DOHMH	Lab	eomoregie@health.nyc.gov
Christabel Monteiro (2024) **Present**	Pace National, Analytical	Lab	christabel.monteiro@pacelabs.com
Robert Royce (2025*) **Present**	New Jersey	AB	Robert.royce@dep.nj.gov
Maria Friedman (2025*) **Absent**	California	AB	qamfriedman@gmail.com
Ilona Taunton (Program Administrator) **Present**	The NELAC Institute	n/a	Ilona.taunton@nelac-institute.org

Attachment B
Action Items – MEC

	Action Item	Who	Expected Completion	Actual Completion
104	Implementation Guidance for Equilibrium.	Committee	TBD	See note in 5/11/21 minutes.
105	Discuss definition of Lot with Chair of CSDP EC.	Kasey Paul Junio	2/11/21	Started, but ongoing. 7/13/21: Remove
112	Develop Understanding Microbiology Course	Cody Committee	TBD	7/12/22: Ready for first class in VA.
113	Complete Response to Draft Comments Process	All	Ongoing	5/10/22: Voted on Comments: 2, 3, 7, 8, 9 and 10 6/14/22: Voted on Comments 5 and 6.
114	Email vote for Comments 1, 4 and 11	All	11/30/22	Complete 11/17/22 *(Addition: New vote on 2/14/23 by email – passed.)*

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter (if needed) every 5 years.	n/a	Ongoing
2	Review Method codes and send comments to Robin for Dan Hickman.		Moved to back-burner on 6/9/20.
3	Provide an update on what has been done with the method codes and database after Jennifer's review and internal EPA meetings.		This was moved from the Action Items table. Notes: 6/9/20: Ask Jennifer for a follow-up. 11/9/20 – Not available for a follow-up.

Attachment D – Information Regarding SIR 423 – Robin's Response – Green

SIR 423

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.6.d

Describe the problem:
In a recently published SIR of V1M5: 1.7.3.b.i, the interpretation allows the media performance testing language of "at a minimum with first use" to be applied by the laboratory as "before first use, or with the first used". V1M5: 1.7.3.6.d states that each batch of ready-to-use lot of medium and each batch of medium prepared in the laboratory shall be tested with at least one or more known negative and positive culture control 'prior to first use of the medium".

These sections do not specify that the culture controls must be performed "by the laboratory" (as stated in V1M5: 1.7.3.1.a for sterility checks), nor do they specify "the laboratory shall perform" the culture controls on media (as stated in V1M5: 1.7.3.1.a.i for sterility checks). V1M5: 1.7.3.6.d states that the media must be tested with known positive and negative culture controls prior to first use, but not why whom.

Are positive and negative culture controls that have been performed by the media manufacturer for pre-prepared, ready-to-use medium or medium prepared in the laboratory, or both acceptable to meet this TNI requirement?

Committee Comment:

Response: The language in V1M5 1.7.3.6.d of the 2016 TNI Standard does not prohibit the use of positive and negative culture controls performed by the manufacturer, however the laboratory must prove that the testing meets the requirements of Section 1.7.3.6.d.i.b and 1.7.3.6.d.ii.b . These Sections of the Standard do explicitly state that lab-prepared media shall be analyzed with control cultures.

AC comments:
This response is inconsistent with the definition of a quality control sample given in the standard. The media performance check is not the same as a QC sample. It is solely intended to show that the media reacts in the expected way. There are other checks that are intended to check the technique, and environment of the lab. As much as I am loathe the compare Micro to Chemistry, the media check is really not very different than say a reference standard made at 100 ppm of XXXX. That material is made by weight (recipe) then shipped out to be used as a calibration standard with a COA and we NEVER BAT AN EYE. Media is made the same way.
We feel mandating the lab to perform this would be adding a requirement to the standard. Agreed, while it is probably a good idea and in the next revision, to do so now goes against our process.
The analyst technique and the lab environment are universally understood to impact growth and recovery media, and so these checks must be performed in the lab to be meaningful. Response correctly asserts that lab-prepared media must be checked by lab, though the wording could be more clear. The checking of pre-prepared media must also be done by the lab once per lot. While I agree with the sentiment of this comment, it is not the intent of the media check. Again, they are attaching something to the purpose of this check that is simply not there.

QC and sterility checks are meant to show that the lab knows what they are doing and that their system is in control. This is a slippery slope. If this were ever allowed, then labs could say that they could just use the sterility check from the manufacturer for bottles; or pipettes; or the quanti-tray, etc. This will not happen as it is strictly prohibited in the examples that the commenter is referencing. Again, I agree with

the general direction of the comment, it is clear that they are thinking about this media check in a way that is not appropriate.

Even if it wasn't the manufacturer's QC check and the lab hired a 3rd party to come in and do all their QC checks that would not show that the laboratory staff has the appropriate micro techniques to successfully run micro samples. This SIR response, as written, is hazy to me on whether the situation proposed in the last sentence of the request would be allowed or not. When I read the response and the citations given I do not interpret it as saying that the lab has to check their media. It would be better to also include citations to V1M2 3.1 QC definition and V1M5 1.7.3.1.a or just spell out how all these are interconnected. Again, while I agree with the general sense of the comment, this is not the purpose of the media check. I will say again, the sole purpose of ***THIS*** check is to verify that the media grows what it is supposed to and doesn't grow what it's not.

AC suggested language: Volume 1 of the 2016 TNI Standard is titled "Management and Technical Requirements for Laboratories Performing Environmental Analysis" and lays out the requirements for a laboratory to be accredited. Positive and negative culture controls performed external to the laboratory do not meet the definition of Quality Control (V1M2 3.0), i.e., a sample used to assess the performance of all or a portion of the measurement system that demonstrates that a measurement system or activity is in control. The measurement system being evaluated is the measurement system of the accredited laboratory. Quality control testing done by another facility or by a manufacturer does not provide appropriate defensibility or demonstration of the competence and capability for an accredited laboratory and its staff. Phrases in 1.7.3.1.a under 'sterility' provide additional clarity to that specific section regarding the need for a laboratory to perform sterility testing and do not negate the requirements for quality control procedures laid out in the remainder of the module to apply to the laboratory being accredited under the Standard.

If the AC is going the write a response because they don't like ours, why bother to send it to the expert committee. In my opinion it negates the entire consensus process. While I don't have issue with the content of the suggestion, I think it misses the mark on the point of consensus and the rationale for purpose of this, and only this,