

**Microbiology Expert Committee (MEC)
Meeting Summary**

September 12, 2023

1. Roll Call:

Cody, Chair, called the meeting to order at 1:30pm Eastern on September 12, 2023, by teleconference. Attendance is recorded in Attachment A – there were 10 members present. Associates present: Nigel Allison, Tina Buttermore, Tiffany Carey, Stacey Chmura, Bryan Disch, Sviatlana Haubner, Carl Kircher (by phone only), Elizabeth Lesold, Brian Mercer, and Chandra Thekkekalathil. Paul Junio attended in the absence of Ilona Taunton as the scribe for minutes.

2. Previous Meeting Minutes

A quorum was present to approve minutes, but the minutes were not available. When they are available, voting will be accomplished via email.

3. Recap of August Conference in Minneapolis

The Conference featured a discussion on the Response to Comments document of the Draft Standard, an update on the 5 Part Training Series, discussion on Temperature Distribution Guidance, and an Open Forum.

The final session of the Training is scheduled for August 24. Once all 5 parts have had their recordings processed, the entire series will be available on the TNI website.

4. Status Updates

- a) The Response to Comments document has been sent for posting but has not yet been posted. *[Editor's Note – It was posted on September 16, 2023.]*
- b) The Understanding Micro Training Series has concluded. All sessions have been presented and recorded. *[Editor's Note – this series was released on the website on September 24, 2023.]*

5. SIR 423 Response Discussion and Voting

There has been back and forth on this SIR between the Committee and the AC. The decision can't be seen as adding a requirement where one doesn't currently exist. The comments from the AC and MEC were each read. No other comments were received. The response as written below was moved by Robin and seconded by Jody for approval. 9 votes were received in favor (note that Jessica Hoch was in attendance at the meeting but had audio issues which prevented her from communicating with the committee).

Response: While the language in VIM5 1.7.3.6.d of the 2016 TNI Standard does not strictly prohibit the use of positive and negative culture controls performed by the manufacturer, 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 as well as the appropriate sections of VIM2 3.0. The definition of Quality Control Sample states that it is “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.” As such the checks are to be performed by the laboratory to be meaningful.

6. Implementation Guidance regarding Temperature Distribution Study

Cody opened with a discussion of the background of equilibrium, and following suggestions from Jody, the following language was suggested:

Equilibrium implementation:

The equilibrium requirement is stated in the 2016 TNI Standard, Volume 1, Module 5 Quality Systems for Microbiology Testing, section 1.7.3.7.b.v.a.

This section states:

“The laboratory shall establish the uniformity of temperature distribution and equilibrium conditions in incubators and water baths prior to first use after installation or service. The equilibrium check shall include time required after test sample addition to re-establish equilibrium conditions under full capacity load appropriate for the intended use.”

Checking the incubator and/or water bath two times (2X) a day, at least four (4) hours apart when testing demonstrates that the incubator and/or water bath is performing as expected.

It is up to the laboratory to define a full capacity load for the laboratory’s incubator and/or water bath.

Some analytical test methods have been validated using samples at compliance temperature (for example, cold temperatures), and the time for the sample to increase to the incubation temperature is part of the method, meaning no extra incubation time is required.

Robin didn’t disagree with Jody’s suggestion. The reason it is on the Committee’s To-Do list is due to confusion regarding what you do with the information that you gather from this process. Laboratories should prove that the incubator holds temperature so that cultures grow as they are supposed to. [Jody had to leave the meeting at 14:16 Eastern]. The Standard (1.7.3.7 b v a) asks what the equilibrium conditions are. We could ask questions in search of information: it could be the most samples you could/have put in this incubator. The decision would be dependent on the temperature of samples when they went into the incubator. Samples in the middle will take longer to come to temperature. What if samples are put in cold?

Maybe we define what a full capacity load IS NOT.

Although some media do not require prewarming, method requirements must be followed.

Standard Methods 24th edition page 1165: to ensure samples at proper temp for incubation time, labs SHOULD prewarm samples. Also language in 23rd edition of 9223B for SHOULD prewarm. Some ABs are taking the above should and applying it to all media used in 9223B.

From the Small lab handbook: Full load is addressed, temp maintenance addressed, day of use addressed, traceability addressed. Perhaps we recycle language from that.

Additional Discussions: Robin: Perhaps we approach this as we approached the autoclave maintenance. We say that as long as you are checking your seals, the $PV = nRT$ formula can be used to determine there are no leaks.

Paul's Input: Implementation guidance is written by LASEC, we can propose it per SOP 3-114

Paul says to write up how the lab can comply with this since it is a current requirement and they need help.

Guidance has all kinds of requirements as found in the SOPs. Instead, the Committee can say that 'this is what we mean', and 'this is how you can comply'. It does not mean this is the only way to comply, but is meant as help. SOP 1-105 can help us instead of SOP 3-114

7. Implementation Guidance regarding Equilibrium Testing

Cody said this discussion had left people pretty happy. The request at the Conference was what do you do about the data gathered by data loggers. How do you handle those weird excursions. No comments were received. *[Editor's note: The DoD/DOE Quality Systems Manual Draft 6.0 attempts to address this. Paul provided that language to Cody with these minutes]*. Cody will draft something using the Small Lab Handbook and the Temperature Distribution work already done.

8. Next Meeting and Close

The next meeting will be on October 10, 2023 at 1:00 PM Eastern by teleconference.

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

Cody adjourned the meeting at 2:30 pm Eastern.

Attachment A

**Participants
Microbiology Expert Committee (MEC)**

Members	Affiliation	Balance	Contact Information
Hunter Adams 2023* Absent	City of Wichita Falls	Lab	hunter.adams@wichitafallstx.gov
Robin Cook (Vice Chair) 2024* Present	City of Daytona Beach	Lab	cookr@codb.us
Cody Danielson (Chair) 2025 Present	Oklahoma DEQ	Lab	Cody.Danielson@deq.ok.gov
Maria Fayard 2026* Absent	ORELAP	AB	maria.j.fayard@oha.oregon.gov
Maria Friedman 2025* Absent	California ELAP	AB	qamfriedman@gmail.com
Jody Frymire 2025 Present	IDEXX Laboratories	Other	Jody-Frymire@idexx.com
Matt Graves 2025* Present	ERA	Other	matt_graves@waters.com
Jessica Hoch 2025 Present	Texas Comm. on Env. Quality	Other	jessica.hoch@tceq.texas.gov
Silky Labie 2026* Present	ELCAT, LLC	Other	elcatllc@centurylink.net
Ashley Larssen 2024* Present	KC Water	Lab	ashley.larssen@kcmo.org
Christabel Monteiro 2024 Absent	Pace Laboratories	Lab	christabel.monteiro@pacelabs.com
Enoma Omoregie 2024 Present	NYC DOHMH	Lab	eomoregie@health.nyc.gov
Robert Royce 2025* Present	New Jersey DEP	AB	Robert.Royce@dep.nj.gov
Elisa Snyder 2023* Present	City of Austin - Austin Water	Lab	elisa.snyder@austintexas.gov
Ilona Taunton Program Administrator Absent – Paul Junio standing in.	The NELAC Institute	NA	ilona.taunton@nelac-institute.org

* - eligible to serve another term

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				

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.