

Microbiology Expert Committee (MEC) Meeting Summary

June 13, 2023

1. Roll Call:

Cody, Chair, called the meeting to order at 1:30pm Eastern on June 13, 2023, by teleconference. Attendance is recorded in Attachment A – there were 10 voting members present. Associates present: Carl Kircher, Tiffany Carey, Debbie Bond, Joe Guzman, Alma McCammond, Regina and Thekkekalathil Chandrasekhar.

2. Status of Understanding Micro Training Series

The first Webinar in the series was presented May 25, 2023. Slides were added from what was done during the live training in Crystal City. There were lots of good questions during the training, so people are getting information from the trainings.

3. Summer Meeting in Minneapolis, MN

Status on people attending Tuesday at the summer meeting in Minneapolis: Jody will know in the next week, Cody and Elisa will be there, Silky should be there, and Matt put in a request and should know this week. Joe Guzman will be there.

Cody asked for ideas for the meeting agenda:

- Let people know about the Understanding Microbiology Series
- Update on DRAFT Standard
- Equilibrium Implementation Guidance
- Discussion/Comments

4. Implementation Guidance on Temperature Distribution

Jodi and Patsy Root offered some comments on the Guidance to be reviewed today (see Attachment D). Cody pulled the document on screen and Jodi reviewed the comments/suggestions.

Question 1

- Change “establish the uniformity” to “assess the uniformity”.
- There was a question on whether the concern is adjusting the temperature versus changing the set point. Maybe it checked at each set point? Does the Committee need to go back to the DRAFT Standard about first use at different temperatures?

Delete it as a bullet and add a paragraph instead: Incubators are sometimes used at different temperatures over time; therefore, temperature distribution testing should be

done at each of the setpoint temperature. For example, at 35.0 +/- 0.5°C and at 41.0 +/- 0.5°C.

- Delete bullet 5, because bullet 6 covers it.

Question 2:

- First two sentences don't answer the question. Put them somewhere else. Preamble?
- It is "circulate air", not "circulate R".
- Keep examples. Makes it clear there isn't only one way.
- Label the picture.
- Intro – these are examples in no specific order and if another approach is used ... the lab must show meets the requirement.

Question 3:

- Jodi added a few bullet points
- When Joe did his study, he found the probe in the center was always in range, but when closer to the walls of the incubator, they were out of range. They marked where all the readings were in the range for the entire time while doing the check. They then wouldn't use the area that was out of range.
- David Lo shared the following:
I found this blog regarding the number of sensors depending on the chamber size that mention 9 sensors for 2 cubic meters and 15 sensors for up to 20 cubic meters. Probably either the ISPE or the USP references. <https://www.lives-international.com/blog/306-how-many-sensors-should-i-use-in-a-thermal-mapping-study>.
- Should it state if repairs or adjustments are made, the incubator needs to be revalidated? This is already required, so leave out.

Cody will recirculate the DRAFT to the Committee with the changes made today. A clean copy will be included in the July 2023 minutes.

Cody noted: When we were talking about temperature distribution, we split off just a few things to save for equilibrium, so I'm going to read these real quick and then we can decide if we want to get into the appropriate amount of time to be treated similar to that of an MDL study for chemistry equipment and that you do it upon install and if equipment is moved.

- Labs need to determine appropriate amount of time to come to temp and what to do with data
- Can be treated similar to that of an MDL study for chemistry equipment in that you do it upon install, if equipment moved.
- Also take into considerations mobile labs because they are on the road and subjected to bumps, etc. Any time out on location, they would do an equilibrium study while onsite.

If you do a study to determine how many racks you can use, what do you do with this information?

- If you put four racks in, but it takes 45 minutes for the incubator to come back to temperature, does that mean you extend your incubation period for 45 minutes?

- The IDEXX insert talks about the time to come to temperature is part of the process. So, you don't extend it for 45 minutes.
- You need to experiment to figure out how many samples you can put in (equilibrium or load study) and then that goes into your SOP.

5. New Business

None.

6. Next Meeting and Close

The next meeting will be on July 11, 2023 in by teleconference.

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

Cody adjourned the meeting at 2:22 pm 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	ERA	Other	Matt_graves@waters.com
Maria Fayard (2025*) Present	Oregon	AB	maria.j.fayard@oha.oregon.gov
Robin Cook (Vice Chair) (2024*) Present	City of Daytona Beach, EML	Lab	cookr@codb.us
Ashley Larssen (2024*) Absent	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*) Absent	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
Silky Labie (2025*) Present	ELCAT LLC	Other	elcatllc@centurylink.net
Ilona Taunton (Program Administrator) Absent - Recording	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 Temperature Distribution and Equilibrium.	Committee	TBD	See note in 5/11/21 minutes. 4/11/23: Working on Temperature Equilibrium
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. 5/9/23: Webinar Series has started. 5 Parts.
113	Complete Response to Draft Comments Process	All	Voting is complete.	5/10/22: Voted on Comments: 2, 3, 7, 8, 9 and 10 6/14/22: Voted on Comments 5 and 6. 2/14/23: Final vote on 1, 4 and 11. 4/11/23: Need to post the document.
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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.