

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

**July 9, 2024**

### **I Welcome and Roll Call:**

Cody the meeting to order at 1:35pm Eastern on June 11, 2024, by teleconference. Attendance is recorded in Attachment A – there were 11 members present. Associates present Nigel Allison, Jennifer Best, Debbie Bond, Tiffany Carey, Antoine Chamsi, Thekkekalathil Chandrasekhar, Bryan Disch, Jody Frymire, Joe Guzman, Morgan Lawrence, David Lo, and Christabel Monteiro. Paul Junio attended in the absence of Ilona Taunton as the scribe for minutes.

### **II Approval of Agenda**

Cody asked for approval of the Agenda. Hearing no objections, she declared the agenda approved.

### **III Approval of May Meeting minutes**

The Meeting minutes from the June 11, 2024 were emailed to all members in advance of the announcement for this meeting. Following a motion by Patsy and a second by Liz, an email vote was taken. Voting to approve were: Cody Danielson, Maria Fayard, Silky Labie, Liz Lesold, Brian Mercer, Patsy Root, Tina Shidel, and Elisa Snyder. Matt Graves abstained.

### **IV Discussion on the Draft Standard**

NOTE – much of these discussions relate to emails among the committee members. A summary of those discussions was maintained in a spreadsheet that was used as a guide for what follows:  
Cold or Hot spots?

What direction do we want to give if they exist? Patsy suggested that we annotate such as in other spots with ‘appropriate steps will be taken if out of tolerance’. This would require addressing any deviation. Cody said it would be similar to the wording in 7.3.3. Liz suggested adding the steps need to be taken to ensure samples comply with the method and regulatory requirements. Cody thinks this is what we want, but we want to make sure we catch the correction aspect. Paul likes Patsy’s suggestion. Robin suggested when such specifications are identified, appropriate corrective action must be implemented. David asked if the requirement is to check for hot or cold areas? Do we need to specify that this must be done at the appropriate temperature? Tina asked if there is better language. Bryan suggested ‘areas of temperature non-conformance’. There was general agreement on the language.

7.3.6 b) v. a) - The laboratory must establish the uniformity of temperature distribution conditions in incubators and water baths prior to first use after installation or service to check for areas of temperature nonconformance. When such areas are identified, the laboratory must implement and document appropriate corrective actions.

Silky commented that we’re directed to change shall to must and to update the Revision History. Liz asked what limits would apply to the requirements for accuracy in 5.1? Patsy said that the Agency develops acceptance limits for reference methods which should include what percent difference is acceptable. Robin said that this is over and above the method requirement. Patsy

said that there's a big difference between method validation and method verification. Robin said that this is the minimum. The Primacy Agency can accept (or not) the modification.

Liz had the same comment for section 5.3, but agreed that it was acceptable as is given the discussion on 5.1

Liz asked about 7.3.1 a regarding forceps. They should be covered by aseptic technique and not be sterilization. There was agreement that the language was ok as written

7.3.1.b.ii.a – email discussions led to agreement on the following language:

Reference cultures used as positive and negative controls must be obtained from a recognized national collection, organization, or manufacturer recognized by the accreditation body to ensure identity and traceability. Microorganisms may be single-use preparations or cultures maintained for their intended use by documented procedures that demonstrate the continued purity and viability of the organism

7.3.1.b.ii.b.i – email discussions led to agreement on the following language:

Reference cultures, once prepared, may be sub-cultured once to provide reference stocks. The reference stocks must be preserved by a technique that maintains the characteristics of the strains. Reference stocks must be used to prepare working stocks for routine work. If reference stocks have been thawed, they must not be refrozen and re-used

Robin commented that a single use product is not a maintained culture. Liz said that she has seen single use products used as cultures. Patsy thought that they may be created the same and thus used for cultures. Tina pointed out that Quick Sticks and Bioballs are called single use. Robin asked if it would be a problem doing this? Liz had concern over the actual viability. There is data on the subject, but she wasn't sure if it showed the 'answer' to the question. Tina thought that a laboratory ought to be able to use a Quick Stick more than once.

Comment – the numbering in this section is amiss. Paul will correct it and formatting.

Liz commented that 7.3.1.b.ii and b.iii seemed to contain informational items regarding Negative Culture Controls. Robin said this was intentional based on previous comments/concerns. Patsy thought that the language was more clear in the 2016 version than in the Draft. Cody thought that the first two sentences should be in definitions.

Negative Culture Controls: demonstrate that the medium does not support the growth of non-target organisms or does not exhibit the typical positive reaction of the target organism(s).

Positive Culture Controls: demonstrate that the medium can support the growth of the target organism(s), and that the medium produces the specified or expected reaction to the target organism (s).

7.3.1 f it should be clarified that the laboratory must verify the pH. There was a question regarding document or verify, and document was selected to affirm that the laboratory must do this, and not verify that it had been done elsewhere.

As mentioned in Section 1.2, documentation for media and reagents must meet the requirements of Volume 1, Module 2, Section 5.4.6.2. prepared in the laboratory must include date of preparation, preparer's initials, type, manufacturer, lot number, final pH, expiration date, and the amount of reagents used. Documentation for media purchased pre-prepared, ready-to-use (including reagent water purchased from outside sources) must include manufacturer, lot number, type of media received, date of receipt, expiration date of the media, and pH of the media. Records must be retained by the laboratory in accordance with Volume 1, Module 2, Section 5.4.6.2

Bob preferred keeping these redundancies in Module 5 so as to not lose the requirement. Robin commented that she didn't like the layout/location of all of the media/reagent requirements.

Having reached the end of the scheduled time, the meeting adjourned at 15:33 Eastern. The next meeting of the Microbiology Expert Committee will again be 2 hours long and will be held on Friday, July 12 at 1:30 PM Eastern.

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

## Attachment A - Participants

### Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information
Hunter Adams 2026 <b>Absent</b>	City of Wichita Falls	Lab	hunter.adams@wichitafallstx.gov
Robin Cook (Vice Chair) 2024* <b>Present</b>	City of Daytona Beach	Lab	cookr@codb.us
Cody Danielson (Chair) 2025 <b>Present</b>	Oklahoma DEQ	Lab	Cody.Danielson@deq.ok.gov
Maria Fayard 2026* <b>Present</b>	ORELAP	AB	maria.j.fayard@oha.oregon.gov
Maria Friedman 2025* <b>Present</b>	California ELAP	AB	gamfriedman@gmail.com
Matt Graves 2025* <b>Absent</b>	ERA	Other	matt_graves@waters.com
Jessica Hoch 2025 <b>Present</b>	Texas Comm. on Env. Quality	Other	jessica.hoch@tceq.texas.gov
Silky Labie 2026* <b>Present</b>	ELCAT, LLC	Other	elcatllc@centurylink.net
Ashley Larssen 2024* <b>Absent</b>	Pace Analytical	Lab	ashley.larssen@pacelabs.com
Elizabeth Lesold 2027* <b>Present</b>	NYSDOH ELAP	AB	elizabeth.lesold@health.ny.gov
Brian Mercer 2027* <b>Present</b>	City of Plantation	Lab	bmercerc@plantation.org
Patsy Root 2027* <b>Present</b>	IDEXX	Other	Patsy-Root@IDEXX.com
Bob Royce 2025* <b>Present</b>	New Jersey DEP	AB	Robert.Royce@dep.nj.gov
Tina Shidel 2027* <b>Present</b>	Pace Analytical	Lab	tina.buttermore@pacelabs.com
Elisa Snyder 2026 <b>Absent</b>	City of Austin - Austin Water	Lab	elisa.snyder@austintexas.gov
Ilona Taunton Program Administrator <b>Absent</b>	The NELAC Institute	NA	ilona.taunton@nelac-institute.org
Paul Junio TNI Scribe <b>Present</b>	The NELAC Institute	NA	paul.junio@nelac-institute.org

\* - eligible to serve another term

**Attachment B**  
**Action Items – MEC**

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
104	Implementation Guidance for Temperature Distribution and Equilibrium.	Committee	TBD	See note in 5/11/21 minutes. 4/11/23: Working on Temperature Distribution. 7/11/23: Working on Equilibrium; Anticipated January 2024
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.
114	Work on Questions for the Credentialing Exam	Cody		Get to Jerry as soon as possible.
115	Committee motions, minutes, and votes as needed	Cody	Ongoing	Captured in meeting minutes whether in meeting or via email

## 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 Paul Junio.		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.