

Microbiology Expert Committee (MEC) Meeting Summary

August 13, 2024

I Welcome and Roll Call:

Cody the meeting to order at 11:05AM Eastern on August 13, 2024, by teleconference. Attendance is recorded in Attachment A – there were 11 members present. Associates present were Nigel Allison, Lindsey Arnaud, Debbie Bond, Antoine Chamsi, Thekkekalathil Chandrasekhar, Anagha Chitre, Bryan Disch, Sviatlana Haubner, KeShawne Ingram, Carl Kircher, Deanna Kiska, 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.

VI. Review Draft Standard Language

The committee continued reviewing the spreadsheet that Cody had created to summarize all of the email comments. That spreadsheet is attached with these minutes. *[note that due to a reformatting that followed this meeting, section numbering in these minutes does not match that of the Standard]*

The final item on the spreadsheet was touched upon at the close of the July 25 meeting. The following change was made to Section 8.3.5.2 b ii on Ovens, and affirmed by the Committee: ~~The laboratory must check ovens used to sterilize for sterilization effectiveness monthly with appropriate biological indicators.~~ At least once during each month that an oven is used to sterilize, the laboratory must demonstrate the effective sterilization with use of appropriate biological indicators. The laboratory must maintain records for each cycle that include date, cycle time, temperature, contents, and analyst's initials. The laboratory must use temperature sensitive tape with the contents of each run to indicate that the contents have been processed.

Cody summarized the NEMC session by saying that there were some great comment as the members in attendance walked through the proposed Module 5. Cody asked if there were any other overall comments.

Notes from NEMC:

The language from Module 2 regarding Technical Specialist (as of 8/12/24) was read to the attendees. This included 4.1.7.2 (requirements) and 5.2.6.1 (qualifications). Module 5 6.0 Verification and Validation were discussed. 6.1 had been added and may not be needed based on what is found in Module 2. Robin suggested including the language from Section 4.3 of Module 2 (If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation

is to be followed.) for clarity. Ashley liked that suggestion. This led to a discussion of the importance of that change, and it was suggested to add that language to Section 2 Scope - The essential QC procedures applicable to microbiological analysis are included in this module. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. Records must be retained by the laboratory in accordance with TNI Module 2, Section 5.4.6.2.

Robin had a question regarding temperatures in Module 2 Section 6.4.6.1. Paul expressed a concern with the language of 'at the measurement used' thinking that could become problematic. Patsy liked the current wording better ('within the range of use').

Robin asked about the definitions of quarterly and annually. Paul pointed out that a committee could choose to be more stringent by stating 'every three months'. Cody said that she had no issue with year, annual or quarterly.

Cody asked about sterility checks – they must be done with a final concentration of single strength media. Patsy and Liz agreed. Maria Friedman asked if the method didn't already say that? Robin replied that it wasn't always stated, and that it applies beyond just Standard Methods if we include it in Module 5. Maria said she would expect labs to know single or double strength based on what they're sterilizing. We shouldn't want to use single if the procedure changes. Robin said that it seemed like we needed it included, to which Maria said that was fine. Jessica said that single strength is to assure that the right concentration is used. Seeing labs do it wrong is reason to include it. Ashley agreed. Robin asked if the wording in 8.2.1.1 d was sufficient (The laboratory must perform a sterility check on each batch of dilution water prepared in the laboratory and on each lot of pre-prepared, ready-to-use dilution water ~~with non-selective growth media~~. The concentration of the non-selective growth media must be single strength after the addition of dilution water.) Cody asked if this could be made more clear, and Liz responded that this is clear if it is read. Cody noted that this wouldn't be required in the preamble as it is covered here. There was agreement on that point.

Cody asked if 'support tests' would cover the issues we have had with Reagent Water Testing. Paul suggested adding this statement at the beginning of Section 8 – '1 An analysis that is performed to support the reporting of compliance data does not require certification,' That language might also be helpful for the other Technical Modules. Maria Friedman said that it might not apply to all ABs. Robin said that they are allowed to be more stringent. Robin suggested relying on a Quality System, but the consensus was that this was clearer. Cody thought that between this addition to Section 8 and the requirement in Module 2 Section 6.4.1.1, it should cover this issue that has come up before.

Shelf life dates have been interpreted as expiration dates for Module 2. The Committee doesn't want to grant that allowance for Module 5. If Module 2 would remove 'media' from 6.4.1.1, that would help us. Robin asked if we could have Module 2 state that Module 5 won't allow for the use of expired reagents and such. Cody commented that just removing 'media' won't be sufficient for what we want. Chandra pointed out that re-test dates vary by vendor. Cody can see them applying to Chemistry but not Microbiology. Could we have a note added in Module 2. Liz commented that she didn't like notes. Maybe that section of Module 2 could point out that other Modules may have differing requirements. Paul thought maybe Module 2 and 5 could point to each other somehow.

Regarding 8.2.1.5, Module 2 has done a lot of work. They intend to add 'lot' to their list of items to be captured. We may not need this at all, since final pH is covered elsewhere. 8.2.1.5 was deleted by acclimation.

Having reached the end of the scheduled time, the meeting adjourned at 15:03 Eastern. The next meeting of the Microbiology Expert Committee will be back at its normal 90 minute length and will be held as scheduled on Tuesday, September 10 at 1:30 PM Eastern. *[EDIT – After the meeting, Cody indicated that a potential conflict for her is not an issue, so the September and October meetings could be held at their regularly scheduled dates/times.]*

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 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* Present	ORELAP	AB	maria.j.fayard@oha.oregon.gov
Maria Friedman 2025* Present	California ELAP	AB	gamfriedman@gmail.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* Absent	ELCAT, LLC	Other	elcatllc@centurylink.net
Ashley Larssen 2024* Present	Pace Analytical	Lab	ashley.larssen@pacelabs.com
Elizabeth Lesold 2027* Present	NYSDOH ELAP	AB	elizabeth.lesold@health.ny.gov
Brian Mercer 2027* Present	City of Plantation	Lab	bmercerc@plantation.org
Patsy Root 2027* Present	IDEXX	Other	Patsy-Root@IDEXX.com
Bob Royce 2025* Present	New Jersey DEP	AB	Robert.Royce@dep.nj.gov
Tina Shidel 2027* Absent	Pace Analytical	Lab	tina.buttermore@pacelabs.com
Elisa Snyder 2026 Present	City of Austin - Austin Water	Lab	elisa.snyder@austintexas.gov
Ilona Taunton Program Administrator Absent	The NELAC Institute	NA	ilona.taunton@nelac-institute.org
Paul Junio TNI Scribe Present	The NELAC Institute	NA	paul.junio@nelac-institute.org

* - eligible to serve another term

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 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
116	Verify changes made in Module 2 and how they affect Module 5	Cody/Paul	Ongoing	

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.