

Microbiology Expert Committee (MEC) Meeting Summary

July 25, 2024

I Welcome and Roll Call:

Cody the meeting to order at 11:05AM Eastern on July 25, 2024, by teleconference. Attendance is recorded in Attachment A – there were 11 members present. Associates present Nigel Allison, Thekkekalathil Chandrasekhar, Anagha Chitre, Stacey Chmura, Bryan Disch, Joe Guzman, Sviatlana Haubner, Deanna Kiska, , Morgan Lawrence, and David Lo. Paul Junio attended in the absence of Ilona Taunton as the scribe for minutes.

II Approval of Agenda

This meeting was held as a continuation of the meeting on July 12, 2024, and consisted of a continued review of draft language in the Standard.

III. 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]*

Line 22 - 7.3.6.b.vi.a – As written, detergent may be required where it isn't applicable. Changed to 'Where applicable, detergents designed for laboratory use must be used.'

Line 25 – it was verified that shalls had been changed to musts.

Line 28 – Introduction changed to explicitly refer to Module 2 - The evaluation of laboratories for this discipline is in conjunction with a quality system as specified in the ~~general requirements module~~ TNI Module 2.

Line 29 – It was noted that a new Section 4 will contain the specific requirements for Technical Specialist in each of Module 3 through 7 (as needed). This was one of the causes for the previously mentioned re-numbering of the Module.

Line 30 – A question was raised on whether or not a reference method required any verification other than a PT sample based on how 6.1 was written. A new 6.1 was added which says 'Verification of reference methods must be completed by the laboratory prior to first use. For example, by performing a demonstration of capability.'

Line 31 – A suggestion was made to clarify the requirements in Calibration Section 8.1.1. The language was changed to "Calibration and verification procedures for all support equipment including conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments must meet the requirements of TNI Module 2, Section 5.5.13.1. The procedures must be documented and must refer to the applicable reference methods." From "The laboratory must have documented procedures for calibration, verification, and QC of support equipment including conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments. These procedures must refer to applicable reference methods."

Line 32 – Since 8.2 Continuing Calibration was 'reserved' in the previous version, the Committee decided to just delete it in this version.

Line 33 – To clarify the intent of the requirements of 8.3.1, the wording of ‘quality of the reagents and media’ was changed to ‘quality, selectivity, and sterility of standards, reagents, materials, and media that are’.

Line 34 – In order to clarify the intent of the Committee, the language in 8.3.1.2 b was changed from ‘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.’ To ‘To ensure the identity and traceability of positive and negative culture controls, the laboratory must use reference cultures that have been obtained from a recognized national collection, organization, or a manufacturer recognized by the accreditation body.’ The committee felt that putting the emphasis on ‘the laboratory must’ was a key in this section.

Line 35 – The committee removed redundant language in 8.3.1.4 regarding record retention (which is already covered in Module 2). ‘Results of the above analyses must meet the specifications of the required method. Records of analyses must be maintained for five (5) years.’ Becomes ‘Results of the above analyses must meet the specifications of the required method.’

Line 36 – Sample receipt criteria from Module 4 are included in Module 5 due to its clarity. That language is as follows: ‘All samples that require thermal preservation shall be considered acceptable if the arrival temperature of a representative sample container is either within 2°C of the required temperature or the method specified range. For samples with a specified temperature of 4°C, samples with a temperature ranging from just above the freezing temperature of water to 6°C shall be acceptable. Samples that require thermal preservation are considered acceptable if the arrival temperature of a representative sample container meets the method or mandated temperature requirement.

i. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 1.7.4.a. *[EDITOR’S NOTE – this reference needs updating]* In these cases, the samples shall be considered acceptable if the samples were received on ice.

ii. If sample analysis is begun within fifteen (15) minutes of collection, thermal preservation is not required.

iii. Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample within fifteen (15) minutes of collection.

The ‘Note’ that previously discussed intent was removed. *[EDITOR’S NOTE – this language may give an extension above the 10°C sample receipt temperature that is typically observed and should be reviewed to not give additional leeway above 10°C.]*

Line 37 – Section 8.3.5.2 b i on Autoclaves was revised for clarity. The changes are as follows:

1. The laboratory must evaluate the performance of each autoclave initially by establishing its functional properties and performance, for example, heat distribution characteristics with respect to typical uses. Autoclaves must meet specified temperature tolerances. Pressure cookers must not be used for sterilization of growth media.

2. The laboratory must demonstrate proper sterilization temperature by use of a continuous temperature recording device or by use of a maximum registering thermometer with every cycle. The laboratory must, at least once during each month that the autoclave is used, demonstrate the effective sterilization with use of appropriate biological indicators. ~~The selected biological indicator must be effective at the sterilization temperature and time needed to sterilize lactose media.~~ The laboratory must use temperature-sensitive tape with the contents of each autoclave run to indicate that the autoclave contents have been processed.

3. The laboratory must maintain records of autoclave operations for every cycle. Records must include: date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time

(may be recorded as time in and time out), and analyst's initials.

4. Autoclave maintenance, internally or by service contract, must be performed annually, and must include a pressure check and verification of temperature device. Records of the maintenance must be maintained in equipment logs. ~~When~~ If the temperature is verified to be acceptable and it has been determined and documented that the autoclave has no leaks, pressure checks can be documented using the formula $PV = nRT$ it is acceptable to state the pressure has been verified.

5. The laboratory must ~~check~~ verify the autoclave ~~mechanical~~ timing device quarterly against a ~~stopwatch~~ and document the actual time elapsed. When discrepancies are identified, the laboratory must implement and document appropriate corrective actions.

Not found in the spreadsheet, but based on the discussion of the sterilization section, the following change was made to Section 8.3.5.2 b ii on Ovens:

~~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.

The committee arrived at the end of the summary of comments. Cody asked everyone to review the new version of Module 5 following its re-formatting. The meeting adjourned at 13:00 ET. The next meeting will be held Tuesday, August 13, 2024 at 1:30 PM ET.

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* Absent	ORELAP	AB	maria.j.fayard@oha.oregon.gov
Maria Friedman 2025* Absent	California ELAP	AB	qamfriedman@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* Present (In 11:15)	ELCAT, LLC	Other	elcatllc@centurylink.net
Ashley Larssen 2024* Present	Pace Analytical	Lab	ashley.larssen@pacelabs.com
Elizabeth Lesold 2027* Absent	NYSDOH ELAP	AB	elizabeth.lesold@health.ny.gov
Brian Mercer 2027* Absent	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* Present	Pace Analytical	Lab	tina.buttermore@pacelabs.com
Elisa Snyder 2026 Absent	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

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.