Microbiology Expert Committee (MEC)
Meeting Summary

October 10, 2023

1. Roll Call:

   Cody, Chair, called the meeting to order at 1:30pm Eastern on October 10, 2023, by teleconference. Attendance is recorded in Attachment A – there were 10 voting members present. Associates present: Anagha Chitre, Bryan Disch, T. Chandra, David, Deanna Kiska, Elizabeth Resold, Jennifer Best, Joe Guzman, Nigel Allison, Sviatlana Haubner, Tiffany J Carey and Tina Buttermore.

   The September minutes were reviewed. A motion was made by Silky to approve the September12, 2023 minutes as written. The motion was seconded by Maria with no further discussion. The motion was unanimously approved.

   (Addition: A motion was made by Robin on December 4, 2023 by email to approve the 2/8/22, 3/8/22, 4/12/22, 6/14/22, 7/12/22, 9/13/22, 2/14/23, and 3/14/23 minutes as written. The motion was seconded by Maria Fayard on December 4, 2023 and unanimously approved.

   Votes: On 12/4/23 - Robin, Jody, Elisa, Maria Fayard, Hunter, Matt, Enoma, Christabel, Ashley, Cody. On 12/5/23: Silky)

2. Revised DRAFT Standard

   Ilona reminded people that the appeals process ends October 16th. The Committee will then be able to prepare the DRAFT update and the summary of changes to re-post the DRAFT Standard for 90 days.

3. Credentialing Exam

   Cody is looking for input on questions for the Module 5 part of the Credentialing test. Send questions to Cody and Robin. Looking for another 30 questions - Ilona will confirm.

   Ilona also requested a copy of the questions that have already been used. She will forward this when received.

4. Implementation Guidance – Equilibrium

Cody provided 3 documents with today's agenda. One is a document called "Qualification of temperature-controlled storage areas. The other documents can be found in Attachment D.

Jennifer asked what would stop a state from doing more. They have the right to do that.

Should or shouldn't create guidance? Jennifer noted that there are things you will put in the Standard and things you can't so you put it into guidance. She is concerned that people don't like that EPA "enforces" this guidance … but it is called guidance. They don't want to do it.

Ilona noted that when the Policy Committee reviewed SOP 3-105, they initially thought the title should be changed - implementation tips, best practices, etc … Implementation Guidance is not a requirement. It is supposed to be helpful in implementing the standard, but it is not enforceable. Ideally more than one recommendation should be made so it is clear that they are not a requirement.

Jennifer confirmed that EPA is in a similar position. Guidance is not enforceable, but it is strongly recommended.

Ilona noted that it is good to include different options in an Implementation Guidance … but you can also include one, but needs to be clear that it is only guidance.

Cody shared, discussed and modified the documents in Attachments D and E.

No decisions were made. Discussion will continue next month.

5. New Business

None.

6. Next Meeting and Close

The next meeting will be on November 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 3:02 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*) **Absent**	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*) **Present**	KC Water	Lab	ashley.larssen@kcmo.org
Jody Frymire (2025) **Present**	IDEXX	Other	Jody-Frymire@idexx.com
Jessica Hoch (2025) **Absent**	TCEQ	Other	Jessica.hoch@tceq.texas.gov
Elisa Snyder (2026) **Present**	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*) **Present**	California	AB	qamfriedman@gmail.com
Silky Labie (2025*) **Present**	ELCAT LLC	Other	elcatllc@centurylink.net
Ilona Taunton (Program Administrator) **Present**	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 Distribution. 7/11/23: Working on 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.
114	Work on Questions for the Credentialing Exam	Cody		Get to Jerry as soon as possible.

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.

Attachment D: DRAFT – Temperature Distribution Testing – 6-13-23

Laboratories must be aware of the requirements of methods and regulations when performing and making decisions related to this testing. References are located at the end of this document and contain additional options as well as requirements outside of the TNI Standard.
Not directly related to temperature distribution testing but included for information purposes: temperature can best be maintained with incubators that circulate air and contain open metal/wire or perforated shelves. Temperature can best be maintained in waterbaths that circulate water and have gabled lids (especially when set at higher temperatures).

Question 1: The Standard requires that the laboratory assess the uniformity of temperature distribution prior to first use after installation or service. Why and when does this testing need to be performed?

Uniformity of temperature distribution testing is used to identify hot or cold spots within incubators and waterbath units. A hot or a cold spot is an area of the incubator/waterbath that does not hold temperature within the acceptable incubation range of the test. For some analyses, the range of temperature for incubation is +/- 0.5°C while others are as small as +/- 0.2°C. This means that some method requirements play a large role in how much variation is allowed. 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.
In addition to determining a baseline prior to first use after initial installation or service, this testing can also be done for reasons listed below (please note this is not an exhaustive list):

- Best practice for checking unit performance when an incubator/waterbath is moved to a new location within the building or into a new building
- To trend functionality of incubator/waterbath unit over time; as twice daily checks may not catch fluctuations
- Part of a corrective action (for example, if the laboratory is having issue with controls or PT samples)
- To test the impact of HVAC or power fluctuations,

Question 2: What are some ways that a laboratory can perform this testing?

Determining temperature distribution or performing a temperature distribution study should be conducted in the absence of performing any sample analyses. The following are examples of ways laboratories can perform this testing, which are not in any specific order. Should the lab utilize another approach, it is the laboratory's responsibility to document effectiveness to this requirement of the Standard.

1. Temperature mapping – This method uses temperature sensors placed in various points inside the incubator to measure the temperature distribution at those points. The sensors record the temperature at regulator intervals, and the data can be analyzed to determine whether the temperature is uniform throughout the incubator or if there are any hot or cold spots.

   Temperature mapping can be done manually or automatically, depending on the type of sensors used.
   If using manual temperature measuring devices that do not automatically log data, a glass door incubator is helpful because the door does not need to be opened when taking the measurement. Alternatively, data loggers, thermocouples and locktags can be used so measurements are taken remotely.

All measuring devices should be temperature corrected. If possible, digital thermometers should be platinum resistant to ensure the most reliability. Temperature monitoring systems should be verified even if they have a NIST certificate.
Best practice is to place a temperature measuring device in all four corners and the middle of each incubator shelf or the waterbath. For example, if the unit is less than 2 cubic meters, at least 9 temperature measuring devices should be used. If unit is 2 - 20 cubic meters, at least 15 temperature measuring devices should be used. Ideally, measuring devices should be placed and read at the same time, but can be moved and measured over time. Measuring devices should be allowed to stabilize before testing.

Figure 1. Example of Temperature Mapping Using Thermocouples

2. The laboratory will determine the frequency of temperature readings- once an hour is a suitable frequency. If the measuring devices are within an incubator or waterbath where the door or cover need to be opened, it is recommended not to take readings more often than once an hour. Best practice would be to take measurements for at least the duration of a working day, up to 24 hours (for devices that log data) to better reflect a full incubation cycle for most tests. For example, manufacturer guidance for Tecta instruments.

Question 3: What should be done with the data gathered from this testing?
Data collected from the temperature distribution testing is used to identify areas of temperature fluctuation and to determine if all areas within the incubator or water bath can maintain the acceptable temperature range for the method(s) to be used. If hot or cold spots are identified, all activities related to identifying and correcting should be documented. The laboratory has several options to address the issue including, but not limited to:

- Ensure the hot or cold spot is not due to error (ex: incorrect temperature probe or probe not placed appropriately)
- Adjust the incubator or water bath's settings
- Recalibrate the temperature control system of the incubator or waterbath.
- Ensure nothing is blocking insulation or airflow or nothing is impairing circulation of water
- Service or repair of the unit
- Taking the unit out of use
- Not allowing sample incubation on shelves/areas with hot or cold spots

For example, if the method requires a 35 ±0.5°C incubation and areas of an incubator shelf were reading 34.0°C, those areas can be marked as not for use to incubate samples. In the picture below, samples can only be incubated within the blue lines.

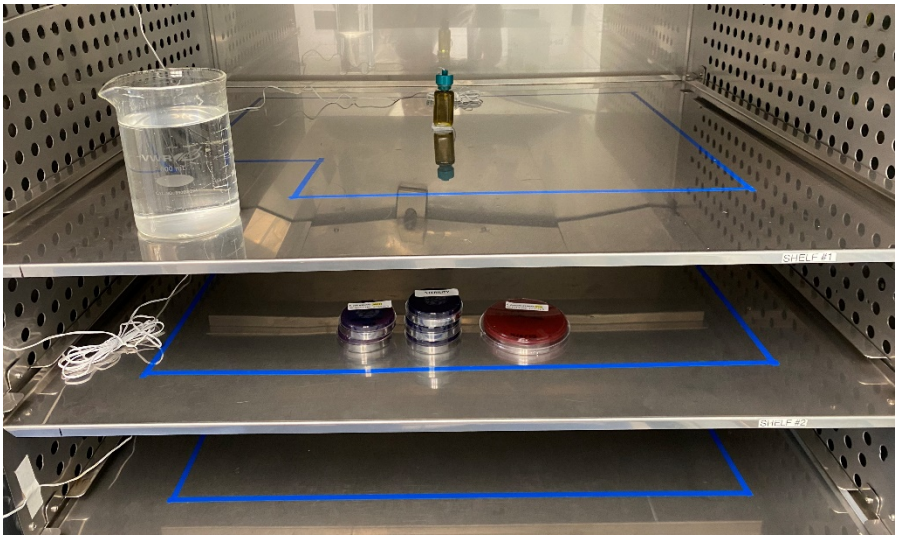
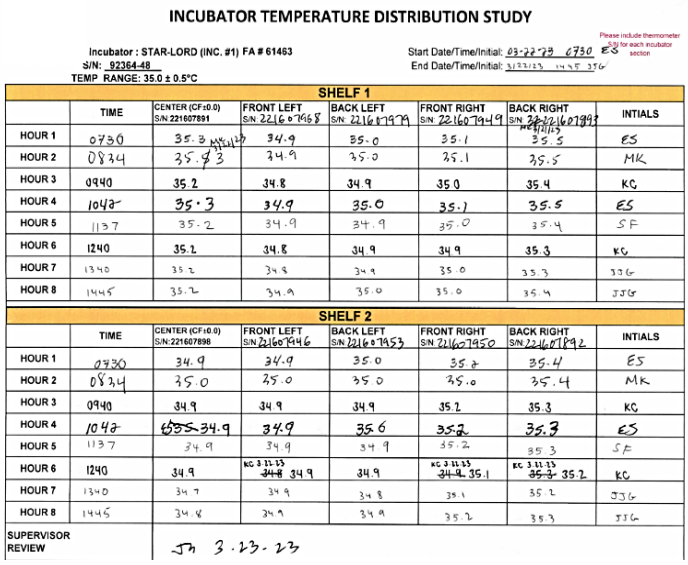


Figure 2. Examples of Taping Areas to be Used for Incubation

The laboratory must maintain procedures for this testing in accordance with V1M2 4.2.8.5. Documentation of this testing and decisions made as a result of this testing must be stored in accordance with V1M2 4.13.



INCUBATOR TEMPERATURE DISTRIBUTION STUDY

Incubator : STAR-LORD (INC. #1) FA # 61463
S/N: 92364-48
TEMP. RANGE: 35.0 ± 0.5°C

Start Date/Time/Initial: 03-22-23 0730 ES
End Date/Time/Initial: 3/23/23 1445 JJG

Please include thermometer S/N for each incubator section

SHELF 1

	TIME	CENTER (CF=0.0) S/N:221607891	FRONT LEFT S/N: 22160 7968	BACK LEFT S/N: 22160 7979	FRONT RIGHT S/N: 22160 7949	BACK RIGHT S/N: 22160 7992	INTIALS
HOUR 1	0730	35.3 MK 3-22-23	34.9	35.0	35.1	35.5	ES
HOUR 2	0824	35.3	34.9	35.0	35.1	35.5	MK
HOUR 3	0940	35.2	34.8	34.9	35.0	35.4	KC
HOUR 4	1042	35.3	34.9	35.0	35.1	35.5	ES
HOUR 5	1137	35.2	34.9	34.9	35.0	35.4	SF
HOUR 6	1240	35.2	34.8	34.9	34.9	35.3	KC
HOUR 7	1340	35.2	34.8	34.9	35.0	35.3	JJG
HOUR 8	1445	35.2	34.9	35.0	35.0	35.4	JJG

SHELF 2

	TIME	CENTER (CF=0.0) S/N:221607898	FRONT LEFT S/N:22160 7946	BACK LEFT S/N:22160 7953	FRONT RIGHT S/N:22160 7950	BACK RIGHT S/N:22160 7892	INTIALS
HOUR 1	0730	34.9	34.9	35.0	35.2	35.4	ES
HOUR 2	0824	35.0	35.0	35.0	35.0	35.4	MK
HOUR 3	0940	34.9	34.9	34.9	35.2	35.3	KC
HOUR 4	1042	~~35~~ 34.9	34.9	35.6	35.2	35.3	ES
HOUR 5	1137	34.9	34.9	34.9	35.2	35.3	SF
HOUR 6	1240	34.9	KC 3-11-23 ~~34.8~~ 34.9	34.9	KC 3-11-23 ~~34.9~~ 35.1	KC 3-11-23 ~~35.3~~ 35.2	KC
HOUR 7	1340	34.7	34.9	34.8	35.1	35.2	JJG
HOUR 8	1445	34.8	34.9	34.9	35.2	35.3	JJG
SUPERVISOR REVIEW		JH 3-23-23					

Figure 3. Examples of Documentation for Temperature Distribution Study

TNI Citation References:

V1M5 1.7.3.7.b.v.a

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.

V1M2 4.2.8.5

Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.

V1M2 4.13.1.2 Control of Records

All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to
prevent loss. Retention times of records shall be established.

Additional References:

Standard Methods 24th Edition

- Section 9020B.4.n
- Section 9030
- Section 9030B

Manual for the Certification of Laboratories Analyzing Drinking Water 5th Edition Chapter 5

- Section 3.4.1
- Section 3.4.3

ISPE Good Practice Guide: Cold Chain Management, published May 2011

Lives-International.com

https://www.lives-international.com/blog/306-how-many-sensors-should-i-use-in-a-thermal-mapping-study

Attachment E - Guidance for Equilibrium Testing

(Red Language is discussions from 9/12/23)

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:

"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.

Give some info: could be the most samples you could/have put in this incubator. 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.

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.

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

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

Small lab handbook:

Full load is addressed, temp maintenance addressed, day of use addressed, traceability addressed

Recycle language from SLH

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 an propose it per SOP 3-114

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

Guidance has all kinds of requirements

Instead, the MEC can say: this is what we mean, and this is how you can comply

Does not mean only way to comply, but is meant as help

SOP 1-105 can help us instead of SOP 3-114