Microbiology Expert Committee (MEC)
Meeting Summary

July 11, 2023

1. Roll Call:

   Robin Cook, Vice-Chair, called the meeting to order at 1:30pm Eastern on July 11, 2023, by teleconference. Attendance is recorded in Attachment A – there were 7 voting members present. Associates present: Anagha Chitre, Antoine Chamsi, Brian Mercer, Bryan Disch, Deanna Kiska, Debbie Bond, Joe Guzman, Ke'Shawne Ingram, Maria Fayard, Nigel Allison, Stacey Chmura, Thekkekalathil Chandra, Regina K. and Tina Buttermore.

   There was not a quorum, so meeting minutes could not be reviewed.

   The following people are planning to be at the Minneapolis meeting on August 1, 2023: Elisa, Chandra, Matt Graves, Anagha, and Cody.

2. DRAFT Standards

   The Response to Comments document should be posted soon. Bob Wyeth is the one that actually prepares the post and sends it to all the appropriate groups/people. The NELAP AC gets a copy, etc. When I went to prepare the table it was locked initially, but Cody sent me a new copy and we were able to add the additional information needed in the table to close it out. We are still ahead in the completion of our Standard.

3. Understanding Microbiology Training Series

   Part 4 is almost ready for presentation – July 27th. There are about 80 attendees involved in the training. The feedback on the class has been great.

4. Implementation Guidance Document – Temperature

   Robin pulled up the latest version of this document. All changes from the June 2023 meeting were accepted. Robin turned on track changes and a copy after discussion was placed into Attachment D.

   Comment on page 2 – It talks about best practice putting a device in four corners in the middle of each shelf but the reference in the example says just the top and bottom shelf for the four corners and one in the middle of the unit.

   The text does not match the picture. There is not a reference that it had to be on every shelf.

Implementation guidance will not say “must”. It is an option that meets the Standard.

Joe noted that you can do one shelf at a time, but they had extra thermometers so they could set up more at one time. It is not required. It is guidance, not a Standard requirement.

Need to be sure it is not too prescriptive – this is only an example. Don’t call it best practice.

Page 1 Paragraph 2 talks about perforated shelves, but this is not in the picture. Deanna sent Cody a picture that needs to be inserted instead. Her picture does not show area taped off because use of perforated shelves makes this unnecessary.

5. Guidance Document - Equilibrium

The following information was sent with the agenda for today’s meeting. We want to address this because it is in the 2016 Standard, but not in the DRAFT Standard.

- SHOULD find out full load
- SHOULDN’T overload incubator
- Don’t overload the incubator, find out what your max load is
- Might only be a couple of paragraphs, especially since we are taking it out of the next standard
- Then it becomes a best practice rather than a requirement
- Use this testing to determine how many racks of samples should be placed in the incubator rathe than how long is appropriate to come to temperature
- Can do on an empty incubator to see baseline, then do a load study w/room temperature appropriate bottles/trays/tubes at 100% capacity (whatever that looks like for the lab)
- Then determine at what % load capacity is appropriate for routine incubations
- Perhaps the lab makes the requirement that all samples need to be prewarmed before incubation.

Discussion:

- A definition should be included for equilibrium.

- Include information on why it is important.

- When we talk about equilibrium, what is the reasonable time for incubators to reach equilibrium? That'll partly depend on the load.

- There's an open door test where you open the door for five minutes and the unit has to return to its temperature range within one hour. Need to review more information on this.

- A number of people do not think there is a benefit in doing this.

6. New Business

   None.

7. Next Meeting and Close

   The next meeting will be face-to-face in Minneapolis, MN on August 1, 2023.

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

   Cody adjourned the meeting at 2:39pm Eastern.

Attachment A

Participants

Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information
Cody Danielson (Chair) (2025) **Absent**	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) **Absent**	TCEQ	Other	Jessica.hoch@tceq.texas.gov
Elisa Snyder (2023*) **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) **Absent**	NYC DOHMH	Lab	eomoregie@health.nyc.gov
Christabel Monteiro (2024) **Absent**	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*) **Absent**	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				

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: CHANGES TO GUIDANCE

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).

Commented [CR1]: Our picture needs to match. Currently, it does NOT! Deanna sent you a few. perforated shelves dont seem to have the same issue with having to tape off usable areas.

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~~For example, 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.

Commented [CR2]: The refercne does not say this. Do we want to edit this to reflect the same as the reference or do we as the expert committee want to leave it as our best professional judgement?

Commented [CR3]: Let's make sure that we are not too prescriptive in the langauge so as to not allow for doing one shelf at a time as many labs currently do. There are more ways to acheive this.

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.

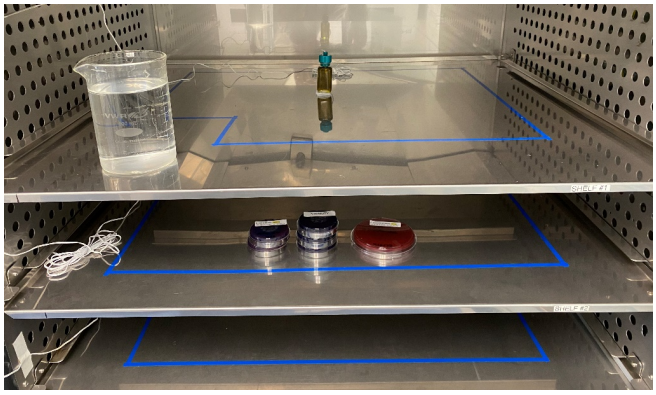
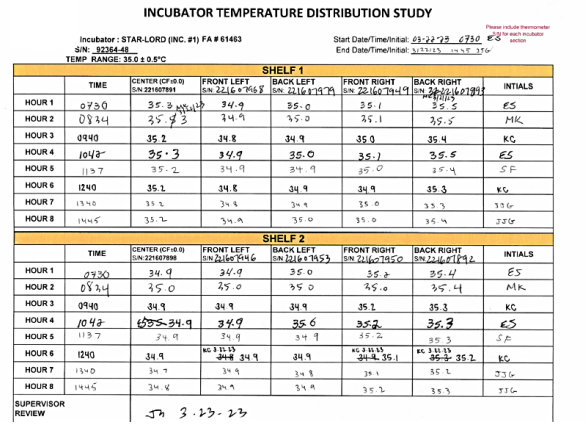


Figure 2. Examples of Taping Areas to be Used for Incubation

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: 92264-48
TEMP. RANGE: 35.0 ± 0.5°C

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

Please include thermometer ID for each incubator section

SHELF 1

	TIME	CENTER (CF±0.0) S/N 221407891	FRONT LEFT S/N 2216×7468	BACK LEFT S/N 2216×7479	FRONT RIGHT S/N 2216×7449	BACK RIGHT S/N 2216×7487	INTIALS
HOUR 1	0730	35.8	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	KG
HOUR 4	1048	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	KG
HOUR 7	1340	35.2	34.9	34.9	35.0	35.3	JTG
HOUR 8	1445	35.2	34.9	35.0	35.0	35.4	JTG

SHELF 2

	TIME	CENTER (CF±0.0) S/N 221407898	FRONT LEFT S/N 2216×7446	BACK LEFT S/N 2216×7453	FRONT RIGHT S/N 2216×7450	BACK RIGHT S/N 2216×7492	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	KG
HOUR 4	1048	~~685~~ 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	KG 3.22.23 ~~34.8~~ 34.9	34.9	KG 3.22.23 ~~34.4~~ 35.1	KG 3.22.23 ~~35.5~~ 35.2	KG
HOUR 7	1340	34.7	34.9	34.8	35.1	35.2	JTG
HOUR 8	1445	34.8	34.9	34.9	35.2	35.3	JTG
SUPERVISOR REVIEW		JTG 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