

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

June 10, 2014

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:37pm EST by teleconference. Attendance is recorded in Attachment A – there were 6 members present. The following associate members were also present: Jennifer Best (EPA), Carl Kircher and Randi McCuin.

The minutes will not be reviewed at this meeting because only 6 members were present. Robin will continue to work through the standard and the missing committee members can give additional comments via email or at the next meeting

Associate members need to let Robin and Ilona know they own a copy of ISO 17025 so they can be included in distributions of the draft working standard updates.

2. Standard Review

1.7.3.7 b) i):

Robin walked through the changes made at the last meeting to see if there were any additional comments.

Elizabeth asked about section 1.7.3.7 b) i) – “... verified at the temperature of use ...” She asked if someone is using an incubator that is supposed to be 35 +/- 2 degrees – does the thermometer check have to be done at 35 or can it bracket at 30-50 degrees?

It was noted that in Texas a single point cannot be used.

Module 2 states “range of use” and the micro standard will now also add the option of a single point. New language:

1.7.3.7 b) i):

Temperature Measuring Devices

Temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum resistance thermometers used to assess and document equipment temperatures shall be the appropriate quality to meet specification(s) in the method. The graduation and range of the temperature measuring devices shall be appropriate for the required accuracy of the measurement. Temperature measuring devices shall be verified at the range of use, to national or international standards for temperature. Verification

shall be performed at least annually (see TNI Volume 1, Module 2, Section 5.5.13.1). This verification may be accomplished by a single point provided that it represents the method mandated temperature and use conditions.

1.7.3.7 b) ii) a): It was asked if $PV=nRT$ should be explained. Left as is.

Jennifer noted that she thinks labs should request these checks from an outside service company, but understands something needs to be left in for a lab in remote area that may not be able to get service.

1.7.3.7 b) ii) b): Ovens used for sterilization.

Leave as is.

1.7.3.7 b) iii):

Leave as is.

1.7.3. b) iv):

Leave as is.

1.7.3.7 b) v):

Email sent out by Dwayne on 6/5/14: TNI V1M5 1.7.3.7.b.v.2 old designation FOR DISCUSSION

This is an area that we had been working on previously under the incubator section and we had come up with some initial language.

2. *An exception to the twice-daily temperature measurement documentation is permitted for the last day of the incubation period when samples are removed from the incubator or waterbath, the **initial** temperature(s) is **subsequently** measured and documented **when at that time**, and no other samples are or will be present in the incubator or waterbath that day.*

I'm generally not a fan of exceptions in regulations or standards I find that they usually cause more problems than they were created to address. If we as a committee want to keep this exception then I would suggest some re-wording. I have some suggestion above (red – deletion; blue - addition).

It currently says the “initial temperature is subsequently measured and documented”. Is this the initial temperature from a day ago when the analysis began or is this the initial test for that (the second or third) day when the test ends. What exactly does “subsequently measured” mean? Does this mean the temperature is taken when the samples are taken out of the incubator and read (I think this was the intent of the wording – not sure)?

If my general practice as a laboratory is to record temperatures at 10AM and 3 PM and my tests are done at 9AM am I required to take a temperature at all that second or third day or is my temperature from 2PM the previous day acceptable? What if I remove my samples at 2 PM that day and don't have any other samples? Do I have to take the second temperature that day according to the exception, even though the second temperature would be during normal business hours for most labs? Am I required to take the temperature when I remove the samples for the second reading or was the morning temperature sufficient?

The way the Standard is currently written – if you go in on the weekend to take samples out in the morning – you would note temperature and still have go back in the afternoon and note temperature again. Some assessors don't require an afternoon temperature check if the samples were removed. This is not consistent. Item 4 does allow for the use of continuous temperature monitoring devices.

The committee all agreed that the point is to have language that makes it clear there is not interest in taking the temperature of an empty incubator. After discussion, the following language will continue to be worked on. Robin will clean it up for another review at the next meeting:

- 1The uniformity of temperature distribution in incubators and water baths shall be established prior to first use. Temperature of incubators and water baths shall be documented twice daily, at least four hours apart, on each day of use when samples are under test. Under test is defined as the time period that the sample is in an incubation phase of the method.
4. For tests where samples are under test during weekends or holidays, the laboratory must have a system in place to ensure that the temperature monitoring requirements are meet for the entire test period. Data loggers, continuous temperature monitoring devices, or other temperature monitoring equipment can be used as long as they can be calibrated in accordance with TNI, Volume 1, Module 2, Section 5.5.13.1 for Support Equipment.
5. An exception to the twice-daily temperature measurement documentation is permitted for the last day of the incubation period when all samples are removed from the incubator or waterbath, the initial temperature(s) is subsequently measured and documented, and no other samples are or will be present in the incubator or waterbath that day.

3.

1. The uniformity of temperature distribution in incubators and water baths shall be established. Temperature of incubators and water baths shall be documented twice daily, at least four hours apart, on each day of use. An exception to the twice-daily temperature measurement documentation is permitted for the last day of the incubation period when samples are removed from the incubator or waterbath, the initial temperature(s) is subsequently measured and documented, and no other samples are or will be present in the incubator or waterbath that day
2. An exception is made for 1. above. For tests where samples are under test during weekends, holidays, or other times where the laboratory is not staffed, the laboratory must have a system in place to ensure that the temperature requirements are met while the laboratory is not staffed. Data loggers, continuous temperature monitoring devices, min/max thermometers, or other temperature monitoring equipment can be used as long as they can be calibrated in accordance with TNI Volume 1, Module 2, Section 5.5.13.1 for Support Equipment.

Jennifer noted that EPA recommends that two thermometers be used in an incubator. Robin commented that this has never been in the standard before and perhaps this belongs in the Lab Manual instead. There was agreement.

1.7.3.7 b) vi):

Jennifer commented on Section 3. EPA thinks it is only when the formulation of the detergent changes. Ordering the same detergent is OK. Elizabeth noted they just keep the manufacturer's detergent analysis and Texas has been fine with this. After discussion, the following changes were made:

Labware that is washed and reused shall be tested for possible presence of residues that may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test **initially**, and each time the lab changes **detergent formulation** or washing procedures.

1.7.5 a): Sample Handling

Dwayne sent the following email on 6/5/14. There was some discussion by email and the discussion continued during the meeting.

TNI VIM5 1.7.5.a FOR DISCUSSION

1.7.5 Sample Handling

- a) Samples that require thermal preservation shall be considered acceptable if the arrival temperature of a **representative** the 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 1.7.5.a) due to insufficient time between sample collection and delivery to complete the cooling process. In these cases, the samples shall be considered acceptable if the samples were received on ice with evidence that the cooling process began within fifteen minutes of sample collection.*
 - 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 the sample and either begins the analysis or refrigerates the sample within fifteen (15) minutes of collection.*

1) Maybe a definition of the word representative in this context is needed or some re-wording. In Pennsylvania we interpret representative here to mean representative of a

collection point for example. So a “temperature blank” or in some cases taking the temperature of just one sample from a cooler would not be acceptable.

2) I have some recommended additions to this section in blue. The way it is worded now some laboratories are fixating on the “received on ice” comment to the exclusion of everything else. The federal requirement is that any preservations begin within 15 minutes of collection. I know we have the one section that says laboratories need to follow more stringent state and federal requirements but I’d like to try to re-word it so the standard does not unintentionally lead laboratories down the wrong path. I’m not 100% happy with what I added so if anyone has any other suggestions that would be great.

Some examples of problems are the sample collector brings the samples in not on ice and the laboratory throws some ice on the samples prior to officially receiving them. The samples are received at a higher temperature then when they were collected or transferred from another laboratory but are received as acceptable because they were “on ice”. Samples collected at 12 noon on one day and received at 1159 the next day at room temperature but received as acceptable because they were “on ice”.

Patsy asked about how cooling is verified and suggested some alternative language.

There were concerns raised about how long it takes for samples to go down to the required temperature. There were comments about people bringing in a sample immediately that was not on ice and having to go away to put it on ice and come back. Others talked about samplers driving around in their cars wasting time to get the temperature down. Jennifer noted that EPA accepts samples that were collected 2 hours prior and only put the temperature of receipt without any repercussions. If it is after 2 hours then the data needs to be flagged and there are concerns about the temperatures.

It was noted that the end user of the data decides whether the data is acceptable or not. The lab should only note the temperature at receipt.

After further discussion the committee agreed on the following language:

Samples that require thermal preservation shall be considered acceptable if the arrival temperature of a representative sample meets the method or mandated temperature requirement.

- i) Samples that are collected and delivered on the same day may not meet the requirements of Section 1.7.5.a or the method, if the time frame between collection and delivery is less than 2 hours (too short for the cooling process to complete). In these cases, samples shall be considered acceptable if the samples were received on ice with evidence that the cooling process had begun and the temperature of the sample(s) (or representative sample) is recorded upon receipt.
- 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 the

sample and either begins the analysis or refrigerates the sample within fifteen (15) minutes of collection.

This completes the review of the standard. Robin will go through it and make sure all the changes are included for committee review before the next meeting in two weeks. The committee needs to finalize the standard at the next meeting to get it posted in time to do the public presentation of the standard at the meeting in Washington, DC.

3. Action Items

A summary of action items can be found in Attachment B. The action items were reviewed and updated.

4. New Business

None.

5. Next Meeting and Close

The next meeting will be June 24th at 1:30pm EST.

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

Robin adjourned the meeting. The meeting ended at 3:30 pm EST.

**Attachment A
Participants
Microbiology Expert Committee (MEC)**

Members	Affiliation	Balance	Contact Information	
Robin Cook (Chair) Present	City of Daytona Beach EML	Lab	(386)671-8885	cookr@codb.us
Patsy Root (Vice-chair) Present	IDEXX Laboratories, Inc	Other	(207)556-8947	patsy-root@idexx.com
Karla Ziegelmann- Fjeld Absent	Microbiologics, Inc	Other		kfjeld@microbiologics.com
Donna Ruokonen Present	Microbac Laboratories, Inc	Lab	(219)769-8378 Ext 110	druokonen@microbac.com
Colin Fricker Absent	Analytical Services, Inc	Lab		colinfricker@aol.com
Deb Waller Absent	NJ DEP	AB	(609)984-7732	debra.waller@dep.state.nj.us
Dwayne Burkholder Present	Pennsylvania DEP	AB	(717)346-8213	dburkholde@pa.gov
Mary Robinson Present	Indiana State DOH	AB	(317)921-5523	mrobinson@isdh.in.gov
Elizabeth Turner Present	North Texas Municipal Water District	Lab	(972)442-5405 Ext 535	eturner@ntmwd.com
Po Chang Absent	Texas Commission on Environmental Quality	AB	(512)239-4876	Po.chang@tceq.texas.gov
Gary Yakub Absent	Environmental Standards, Inc.	Other	(610)935-5577	gyakub@envstd.com
Ilona Taunton (Program Administrator) Recording	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – MEC

	Action Item	Who	Expected Completion	Actual Completion
1	Review Method Codes and send comments to Robin for Dan Hickman.	Deb	TBD	
4	Review Handbook and Method Codes before next meeting.	ALL	5/7/13	Handbook Complete.
12	Research possible effects of using bromine and whether it needs to somehow be included in the standard. Does not look like it.	Deb	November 2013 Meeting	
19	Provide EPA interpretation on temperature readings to Ilona. She will have it posted on the website.	Robin	1/31/14	
25				

