

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

January 28, 2014

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:00pm EST in Louisville, KY. Attendance is recorded in Attachment A – there were 8 members present.

The January 14th minutes will be reviewed with today's minutes at the February 11, 2014 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.

The PowerPoint Presentation for today's meeting can be found in Attachment D.

2. Standard Interpretation Request (SIRs)

SIR #98 and #132

Discussion:

Robin's feeling is that buffer water that touches the bacteria, media or reagents must be checked monthly. If used for only blanks, then it is not necessary.

Debbie feels that it is necessary to monthly re-verify all open lots.

Donna, Patsy, Colin and Mary agree that verification by the lab is not necessary when using an accredited vendor.

Robin: It will be difficult for accreditors to buy into taking the manufacturer's information as a substitute for testing in the lab.

Colin: The manufacturer's information should be accepted and we should push the standard to allow for this. If the check is going to be required, it should be done statistically.

Deb: Do you push for use of manufacture's information or to let lab's check a lot once? She agrees with Colin's concern about how they are checked if a lab is doing this.

Lynn (Minnesota, AB): Sterile water must have a sterility check. Colin asked why it is being checked again after the manufacturer's check. Lynn commented that there are concerns about whether something happened during shipment. If they accepted the Certificate of Analysis, there would be a question about the quality of the vendor's analysis. The vendor is not accredited.

Minnesota requires one check per lot. Minnesota is not opposed to changing this part of the standard.

Herman Alamene (lab): If it is in the standard – it is what is required.

Jennifer Best (EPA): There is a conflict with the manufacturer checking their own product. Also ... in the past when there has been a problem, the manufacturer tells them it is probably a lot problem, but they can't provide any further assistance. Checking it one time is better than not checking it at all.

Lab: They have had problems in the past with something from a manufacturer and had to go back to all their clients to tell them about the contamination. She prefers to continue to test it to avoid these types of issues. Patsy asked if it would make any difference if the vendor's were accredited, but the feedback was that this lab would still test it.

Donna stated that vendor qualification by the laboratory may be one way that would help allow ABs to accept the vendor Certificates of Analyses. If there are problems with an approved vendor, there are avenues available to the laboratory that should provide resolution and corrective action.

Method specifics cannot be handled by TNI. The labs need to contact the accreditor if they have method issues.

Incubator Temperature Monitoring SIR:

The SIR will be answered as 'Yes'. The laboratory is required to check the temperature twice per day on the day of use as it is a full 24hours.

There is draft language that will still require some changes, such as 'period' of use.

Colin asked if we should provide guidance on data loggers that may go out of temp for a short while (2-minutes). Should the data be scrapped? This still needs to be considered.

Jennifer from Minnesota believes that the lab should ask the AB about policies on this topic.

Debbie will clean up the language.

3. Standard Review

The committee has started making changes to the standard. Robin asked that people continue to send her their comments and concerns.

Ilona provided copies of the SIRs that have been finalized. These topics need to be reviewed to make sure they are included in the standard update.

Incubator Temperature Monitoring

Robin reviewed the discussion surrounding this topic and asked for feedback.

Paul Junio: Add a last sentence to Clause 1.7.3.7(b)(v)(1), to read as follows: “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.”

Checking Chlorine Residual

The once a month check in the current language is being proposed to be eliminated. It is not practical. There is no added benefit. Why check some and not all?

The important thing to grasp in the language change is that all the requirements must be met or every sample must be checked. The sampler still has to do their checks.

Paul clarified that the intent is that this wording is per sample.

Sterilization Equipment

The text for ovens was moved under this heading for ovens being used for the purpose of sterilization.

v) Incubators, Water Baths, Ovens

There was discussion about checking temperatures with data loggers, min/max thermometers, alarms, etc ... and whether this should be spelled out in the standard.

Could language be added to the currently proposed language such as:

The use of data loggers and min/max thermometers with a mechanism to notify lab staff of an out-of-control event may be used as an alternative to the twice daily incubator checks.

Jennifer Best: Expressed the concern that some labs don't check their data loggers and ABs will need to work out an acceptable monitoring mechanism with the lab. She would like to leave more to the state to determine what they accept. Attendee: This could build inconsistency between ABs and make it difficult for laboratories working in multiple states. This will lead to Standard Interpretation Requests. It cannot be left to the AB.

Paul Junio: A min/max doesn't give you the ability to record a specific temperature at a specific time during the time the thermometer is in use. The wording cannot be to record the temperature at a later time from a data logger. This doesn't work for min/max.

Paul Junio provided the following language consideration by email during the meeting:

v) *Incubators, Water Baths, Ovens*

- 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.*

I think it's important to note that the exception is getting created in the second item, or you will get someone who will say 'Part 1 requires you to read the temperature twice per day, so that overrules what is said in Part 2.'

I changed to "while the laboratory is not staffed" from "the entire test period" to avoid allowing someone to not record temperatures during the entire period, and just relying on the data loggers, etc.

Robin asked about use of tapes for sterilization. Deb confirmed that sterilization tape is available for ovens. The use of tape needs to be added to ii) b) – text regarding ovens.

Standard Interpretation Request (SIR)

The SIR Summary document Ilona sent to the committee was reviewed.

1st has been addressed.

2nd has been addressed.

3rd has been addressed.

4th has been addressed.

5th has been addressed.

Previous SIRs have been addressed in the standard updates.

4. Open Discussion

Robin started the discussion by asking: What don't you like about the current Standard?

Nilda: Asked about how to implement the chlorine check. To avoid contamination you would need more bottles. There is a mentoring class being offered on Thursday that will cover this. Nilda also mentioned that the Microbiology Standard has no discussion on qualifying data, while the Chemistry Standard does.

Robin: We need to keep in mind that Legionella is coming and it needs to be kept in mind when we write the standard.

Patsy and Mary: ii) Ready-to-use media. They feel that media past the expiration date should not be used. They would like to see this section eliminated. Colin thinks there is some media that would be good after the expiration date, so he is not comfortable making any blanket statements.

He would prefer to keep some type of language to allow this. The current language is that it needs to be verified each day of use beyond the expiration date.

There were other examples in the room where manufacturers are putting expiration dates that are not realistic. One example was Alconox.

Carrie Miller commented that she thinks using expired media is not ethical when reporting data to the clients. The client expects that the media is not expired.

Trinity: Expressed concerns that there are times that the data is acceptable because it meets the client's needs.

Another view was expressed that you have to document what you are doing. If you have procedures for using media or a chemical beyond the expiration date and they are documented in your quality procedures, your AB will review your procedures and agree or disagree. This keeps you in compliance. There may be specific examples where you would not re-verify a media and this should be stated in your lab's policy.

Nilda: Asked if Demonstration of Uncertainty has been discussed for this standard. It has not.

5. Action Items

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

6. New Business

Continue to review the Standard Robin sent and look for opportunities for improvement.

7. Next Meeting and Close

The next meeting will be February 11th at 1:30pm EST.

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

A motion to dismiss the meeting was made by Donna and unanimously approved. Seconded by Patsy. The meeting ended at 4:35 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 Present - Phone	Microbiologics, Inc	Other		kfjeld@microbiologics.com
Donna Ruokonen Present	Microbac Laboratories, Inc	Lab	(219)769-8378 Ext 110	druokonen@microbac.com
Colin Fricker Present	Analytical Services, Inc	Lab		colinfricker@aol.com
Deb Waller Present	NJ DEP	AB	(609)984-7732	debra.waller@dep.state.nj.us
Dwayne Burkholder Present - Phone	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 Absent	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
Ilona Taunton (Program Administrator) Present	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.
11	The issue of how to recertify media will be looked at by Colin.	Colin	January Meeting	He will be working on it during the holidays and getting input.
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 Meeting	
17	Expand on Patsy's email response to SIR #133 and distribute to committee for review.	Robin	2/10/14	
18	Contact Gary Yakub to confirm his membership on the committee.	Robin	1/31/14	
19	Provide EPA interpretation on temperature readings to Ilona. She will have it posted on the website.	Robin	1/31/14	

