Microbiology Expert Committee (MEC)
Meeting Summary

February 11, 2014

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:30pm EST by teleconference. Attendance is recorded in Attachment A – there were 6 members present. Associates: Randy McCuin, Carl Kircher (30 minutes) and Jennifer Best.

Patsy motioned to accept the December 10th minutes with two typo corrections. Donna seconded the motion and it was unanimously approved.

Patsy motioned to accept the January 14th minutes. The motion was seconded by Elizabeth and unanimously approved.

The January 28th minutes were distributed for review. Donna's notes from the beginning of the meeting were added to the minutes this morning. Donna made a motion to accept the January 28th minutes. The motion was seconded by Karla and unanimously approved.

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 Interpretation Request (SIRs)

SIR #98 and #132

Robin sent the following by e-mail:

Based on the conversations that we had on the recent calls, via e-mail and our face-to-face in Louisville here is my first blush response. Let's discuss on our call.

Under the current standard, the requirement is to check the water once per lot for those materials that come in individual bottles or once per month when using a bottle that lasts longer than one month. If the water is to be in contact with the organisms such as would be used for preparation of media, reagents or as a dilution carrier, then the requirements of verification is required along with the verification of sterility. The standard does not specify who must do these checks simply that they must be done.

The largest issue here is will a manufacturer COA (Certificate of Analysis) be accepted? So we will need to reach a consensus on that portion before we can move forward with this SIR. Consensus does not mean we all agree or are happy about it, but can we live with it, please keep that in mind as we discuss it.

Let's reserve comment on this until the call so that it can be captured in our minutes. If you have additional comments after that time, please forward to the group and we can include them as part of our record.

Robin thinks the real question asked is if a CoA can be used, but this is difficult to answer based on what it in the standard. It was commented that ABs can choose to accept CoA's because the standard does not say they can't. Some states do accept them. The standard should encourage consistency and this is an area that needs to be addressed in the standard update this committee is working on.

Pasty asked if Robin's draft is based on the standard. She does not think that any kind of interpretation related to whether ABs should accept CoAs can be made based on the standard.

Jennifer asked for some background on SIRs and the process. A brief summary was provided by Ilona and other committee members. She asked about this committee's authority in making recommendations in responding to SIRs. SIRs help identify issues with the standard and ultimately help improve the standard. Responses to SIRs cannot add or delete language in the standard. Jennifer is concerned that public health is not being made a priority. Patsy reminded everyone that labs follow regulatory requirements first and if there is a public health issue – it will be covered in regulatory requirements before a standard update can be made.

Robin raised the concern that the standard cannot be so proscriptive that it tells a lab how to run its operation. There needs to be enough flexibility for innovation that meets the standard. There are differences between how a small lab or large lab operates, but they both meet the standard.

Jennifer is concerned that not specifically responding on the use of CoAs makes the program inconsistent between ABs.

Jennifer also expressed concern in accepting CoAs because the lab does not verify the manufacturer used appropriate techniques to verify the material. She has seen some poor CoAs in the past. Perhaps documentation that the lab called the manufacturer to verify how the analysis was done would satisfy an ABs concerns. Jennifer thought a guidance document should be prepared for people to know what to look for if a CoA is used.

Ilona commented that starting to define how CoAs should be used is outside of just this committee. There are other parts of the standard that accept CoAs (i.e. standards) and further discussion might impact other parts of the standard. Is there an expectation that the manufacturer of a standard has performed their verification using a specific standard? How is the use of certified standards discussed in other parts of the standard?

Patsy commented that if certification of vendors is looked at, like what is done in Europe, this concern would be eliminated. Should TNI be looking at certification of vendors? Would this take care of consistency?

Should CoAs be addressed further in the standard? This is a future conversation with the Quality Systems Expert Committee. Perhaps a conversation with the NELAP AC would be appropriate too.

Robin recommended the language below. Committee members are to review the response and provide any additional comments by email.

Under the current standard, the requirement is to check the water once per lot for those materials that come in individual bottles or once per month when using a bottle that lasts longer than one month. If the water is to be in contact with the organisms such as would be used for preparation of media, reagents or as a diluent, then the requirements of verification as stated in 1.7.3.5 9 (c) are needed along with the verification of sterility. The standard does not specify who must do these checks simply that they must be done. Contact your individual AB for whether or not a manufacturer COA will be accepted.

(Note: Patsy provided the following suggestion by e-mail on 2/11/14:
Under the current standard, the requirement is to check the purchased water once per lot ~~for those materials that come in individual bottles or~~ and, in addition, once per month when using a bottle that lasts longer than one month. If the water is to be ~~in contact with the organisms such as would be~~ used for preparation of media, reagents or as a diluent, which will put it in contact with microorganisms, then the requirements of verification as stated in 1.7.3.5 9 (c) are needed along with the verification of sterility. ~~The standard does not specify who must do these checks simply that they must be done. Contact your individual AB for whether or not a manufacturer COA will be accepted~~.)

SIR #133:

The committee is responding that this is not a SIR because the standard is clear in what must be done. The committee is working on this language in the standard update.

This is the original response suggested by Patsy and comment:
The section of the 2003 NECLAC Standard indicates: "Temperature of incubators and water baths shall be documented twice daily, at least four hours apart, on each day of use. "
*This means if samples are in the incubator or water bath, the temperature of the incubator or water bath must be recorded twice that day. For example, if a sample is retrieved from the incubator or water bath at 9 AM, the temperature can be recorded **at that time** and then again in 4 more hours, or no earlier than 1 PM that same day.*

It seemed the general opinion of the MEC was that no interpretation was needed, but an example would be helpful.

This was thoroughly discussed in Louisville, KY and changes are being made to the standard.

Jennifer does not think this should be addressed in the standard.

3. Standard Review

Robin pulled up the revised standard document and the committee began reviewing wording changes/additions.

(1.6.2 e): If there is no established criteria, the lab needs to address this. The AB reviews this during their assessments.

No one objected to the language changes.

Given the time, Robin quickly summarized the changes in the document. Robin will send the document to Ilona and she will distribute it to committee members and associates who own copies of ISO 17025.

4. Action Items

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

Work on changes to the standard and send them to Robin.

5. New Business

None

6. Next Meeting and Close

The next meeting will be March 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 seconded by Mary. It was unanimously approved. The meeting ended at 2:59 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**	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 **Absent**	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) **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	Complete
19	Provide EPA interpretation on temperature readings to Ilona. She will have it posted on the website.	Robin	1/31/14	
20	Forward standard with revised language to Ilona for distribution to the committee.	Robin	3/10/14	

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter in October 2013	n/a	