

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

April 8, 2014

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:40pm EST by teleconference. Attendance is recorded in Attachment A – there were 7 members present. The following associate members were also present: Randi McCuin (TetraTech), Jennifer Best (EPA), Shawn Kassner (Phenova) and Barbara Sullivan (Phenova).

The February 11th and March 11th minutes were reviewed. Patsy motioned to accept the minutes and the motion was seconded by Elizabeth. The motion passed unanimously.

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

Robin continued to read and talk through the standard:

1.6.1 No comments.

1.6.2 No comments.

1.6.2.1 No comments.

1.6.2.2 No comments.

1.6.3 Ongoing DOC – No changes in these subsections.

1.7 Technical Requirements

1.7.1 Calibration - No comments.

1.7.2 Continuing Calibration – No comments.

1.7.3 Quality Control

1.7.3.1 Sterility Checks and Method Blanks

This was separated in the 2012 standard. In the older standard the distinction between sterility checks and method blanks was not made.

The introductory language under Method Blanks (a) was removed and placed as an introduction under 1.7.3.1: The laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization or environmental exposure.

1.7.3.1 a) Method Blanks

Robin: This was accepted in Florida. She had a three port manifold. She would sterilize quite a few funnels at the same time. She would verify the sterility of the funnels by sacrificing one and checking with TSB. Robin randomly laid out the samples so that the blank was random – not always same funnel or same place.

If one of Robin's blanks failed – she would look at all of the data. If samples looked fine and were clean, she would qualify the blank and move on.

Jennifer thinks it is important to clarify frequency of method blanks. Is it one per manifold or how it done? Robin and Randi thought should be one period. Jennifer felt it should state one per manifold. Robin thought this encourages labs to use one manifold and she thinks this increases possible contamination.

The committee discussed different types of ways to set-up the runs. Dwayne runs a blank per funnel in PA and not by manifold. Jennifer is concerned that this is being done differently between states and this leads to inconsistency. She feels it should be specified. Shawn noted that there are often laws or rules that specify how method blanks are handled and this limits what TNI can put in the standard. The DW manual specifies only minimum of one at beginning and end and doesn't specify per manifold, per funnel, etc....

Mary has not seen this question in Indiana. Her labs assume per funnel.

Robin asked that people review the language based on today's discussion and propose any changes needed. Robin would like the labs to have the flexibility to use some common sense and to not put a lot of restrictive language in the standard.

a) ii) Dwayne asked about the last line. After discussion it was decided to leave as is.

1.7.3.1 b) Sterility Checks

There was discussion on what was the appropriate percentage of checks.

Patsy did not see the need for checks that are already done by vendors. Jennifer doesn't think manufacturers catch all the problems that are going out. Manufacturer errors are caught by the labs that are doing checks.

Jennifer commented on Patsy's comment about vendors accredited to ISO standards. She does not see EPA approving this, so labs should continue to run these checks.

Po noted that in clinical labs checks are done every day. He thinks that NELAP labs are not getting checked enough. Checking once per lot is not enough.

Jennifer had three issues with taking the manufacturers check: 1) the lab does not know the manufacturer tested them appropriately, 2) you need to be sure nothing happened in transport, and 3) manufacturer only tests a small percentage of what is manufactured.

Robin noted that labs only check a small percentage too. She thinks if the checks are done, the committee she look at procedures to make them effective. All things that should be sterile should be checked – not just a few things. Robin thinks the once per lot check was a compromise many years ago. It was better than no checks.

One of the previous SIRs the committee looked at raised the discussion of whether the language allows taking a Certificate of Analysis from the vendor. Jennifer commented that the standard allows for contracting a lab to do the analysis and this does not mean a certificate of analysis can be used. The manufacturer would not qualify as a contracted lab.

Jennifer asked the ABs on the call what they accept. Most required the lab to do the analysis, but one does accept the manufacturer sterility check on water because the certificate states the method for the check and it is the EPA method.

It was stated that chemistry labs accept Certificates of Analysis. Jennifer commented that chemistry labs have additional standards and low level standards that continue to check standards, so you cannot compare a chemistry lab to a microbiology lab. There is also less opportunity for contamination of chemistry standards.

Jennifer commented that she would like to see more specific language in the standard. She would prefer to see specific language that states Certificates of Analysis cannot be used. Po agreed.

Elizabeth noted that in perchlorate analysis there are also sterile requirements, but no requirements that the sterility needs to be checked.

Shawn and Ilona commented that it is OK to add specific checks in the standard that are microbiology relevant and these checks would not affect the rest of the standard. It would need to be stated as such so that it is not in conflict with the other sections of the standard.

Robin thinks that stating Certificates can not be used will cause problems. Jennifer commented that the intent was that the analysis be done by the laboratory or a contracted lab. It does not open the door to manufacturer certificates.

Robin would like some example language sent by email during the next month if people think language needs to be added. Robin asked that language recommendations be

submitted in a single email and not in an edited copy of the entire standard. Just send the specific change.

Ilona will send the latest update of the standard after each meeting.

Robin asked that everyone continue to review the standard in detail and be prepared to make comments as we continue to review it together on the next call.

3. Action Items

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

4. New Business

1. Ilona will send Robin schedule information to meet standard update goals.

5. Next Meeting and Close

The next meeting will be May 13th 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 3:10 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 Absent	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 Present	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	
19	Provide EPA interpretation on temperature readings to Ilona. She will have it posted on the website.	Robin	1/31/14	
21	Email vote on final language of the SIRs.	All	3/18/14	Complete
22	Provide final response on SIRs to LASEC.	Robin	3/18/14	Complete
23	Send proposed language for sections worked on 4/8/14.	All	5/11/14	

Attachment C

Backburner / Reminders – MEC

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