Microbiology Expert Committee (MEC) Meeting Summary

October 28, 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. The following associate members were also present: Jennifer Best (EPA), Brad Stawick and Carl Kircher (called in at 2:40pm).

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 plans to review the sections that still need some work.

Section 1.7.5 a) i)

Robin pulled up the changes made to the standard after the last call.

Jennifer asked about the 15 minute requirement and the requirement to be on ice. She asked if TNI is intending to require something beyond what the Total Coliform Rule requires? Samples are encouraged to be shipped on ice, but it is not required. TNI is requiring more.

An issue was also raised about how to determine if the 15 minute requirement is met.

The lab handbook is guidance and this may be a good way to give recommendations to sample collectors:

- Put it on ice immediately.
- Don't leave the sample on the dash board.
- Don't drive around until the temperature comes down. Etc ...

A note should be added to the standard to clarify the purpose – samples should be preserved immediately and analyzed as soon as possible.

After discussion this section now reads:

 a) Samples that require thermal preservation shall be considered acceptable if the arrival temperature of a representative sample container meets the method or mandated temperature requirement. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of this section or the method. In these cases, the samples may be considered acceptable if the samples are received on ice with evidence that the cooling process has begun.

NOTE: The intent is for the samples to be preserved immediately and analyzed as soon as possible.

Section 1.7.5 c)

Dwayne had a comment about this section in his 10/27 email:

Section 1.7.5.c "Samples not meeting the requirements of this section must either be rejected or appropriately quailed." Qualified instead of quailed. The way this is worded makes it appear a laboratory can chose to reject the sample or report it qualified which is not the case. For drinking water at least the result is invalid and can't be reported. By reported I am referring to reporting to the regulatory agency not issuing a report to the client.

Dwayne thinks this wording sets the lab up for failure because for DW it cannot be reported. Others think it is a redundant statement. It is already part of Volume 2.

The committee decided to delete this section.

Section 1.7.3.1 b) ii)

Robin looked back at Comment 17.

The comment should be incorporated.

Section 1.7.5 b) – Comment 22

Robin thinks this should be ruled non-persuasive.

Robin does not think the standard should define what type of chlorine should be tested. There was agreement.

As far as addressing what a lab must do if chlorine is present – this is something the lab should have in their Quality Manual. Some labs qualify the results and others go out and resample.

This is actually addressed in V1M2 Sections 5.8.6 and 5.8.7 through the discussion on qualification. This reference was added to the title for section 1.7.5.

Section 1.5.2:

"Naturally contaminated" was deleted. Also want "not statistically different". The section now reads:

Precision – Perform at least ten (10) replicate analyses with both the proposed and reference method, using a sample containing the target microorganisms of choice. The results shall show that the precision of the proposed method is not statistically different.

The committee reviewed the comments emailed by Dwayne on 10/27/14. Robin still plans to incorporate Colin's comments into the comment summary table and include information on persuasive and non-persuasive with reasoning.

From Dwayne (in italics):

I know it is short notice but I wanted to make some comments on the newest version before tomorrow's meeting so everyone had time to think. Most of them are concerning Colin's original comments that are included in the revision.

<u>Section 1.6.1.d:</u> "Where possible the DOC shall be performed in conjunction with a supervisor for the appropriate method. In situations where no suitable supervisor exists, or for a first DOC in the laboratory, the use of proficiency samples or certified reference materials is required." What does this mean? Is this to be a side by side analysis of samples by the supervisor and analyst? Isn't an acceptable supervisor required for a laboratory?

Elizabeth is concerned about making these requirements more difficult than they need to be.

The committee determined Colin's comment to not be persuasive.

The committee reviewed Dwayne and Colin's comments and this section was changed to:

1.6.1.d: All demonstrations shall be documented. All data applicable to the demonstration shall be retained and readily available at the laboratory.

<u>Section 1.6.3.2.c</u> "Acceptable results for a minimum of three blind proficiency test samples for target organisms in each field of accreditation." I'm not sure what this means. Does this mean a CDOC will need to contain 3 separate PT studies. For presence/absence PTs a set of 10 samples is required and because PTs are treated the same as environmental samples cannot be split up between analysts for official PTs used to meet the lab's PT requirements.

Robin thinks Colin's comment is not correct – DW certification already requires the use of a 10 sample set for PT analysis. Colin's comment was determined to be non-persuasive.

This section now reads:

 $1.6.3.2\ c)$: Acceptable results for blind proficiency test sample for target organisms in each field of accreditation.

<u>Section 1.7.3.1.a.ii</u> "The sterility check should involve the processing of a deionized water sample and incubation of the membrane in a suitable non-selective medium such as tryptone soya broth." Do we want to give this explanation? Tryptic Soy? Should involve/Must involve?

Colin's comment in this section is non-persuasive because it is already addressed.

<u>Section 1.7.3.1.d.iv</u> "Results of the above analyses shall meet the specifications of the required method to records of analyses shall be maintained for five (5) years." It doesn't make sense now with the deletions and additions made.

This section was corrected to:

 $1.7.3.1 \; d) \; iv)$: Results of the above analyses shall meet the specifications of the required method. Records of analyses shall be maintained for five (5) years.

<u>Section 1.7.3.2</u> Colin's comments on performing a method blank every 10 samples or using a UV light box. This section is currently deleted – should be included again.

This was added back in

This section now reads:

1.7.3.2 ii): ... In addition, laboratories shall insert a method blank after every ten (10) samples or sanitize filtration units by UV light (254-nm) after sample filtration.

<u>Section 1.7.3.3</u> Colins' comment on including a minimum number of target colonies for the duplicate count requirement.

Colin's comment is considered non-persuasive. Committee members were not comfortable requiring a minimum of twenty (20) target colonies. Jennifer thinks he got the concept of 20 from another part of the method that is not relevant to this.

Jennifer commented that it is important that actual colonies be read – a plate with no colonies does not test the analyst's ability to count. She understands Colin's concern, but does not think a number should be required.

This section now reads:

1.7.3.3: For methods that specify colony counts such as membrane filter or plated media, duplicate counts shall be performed monthly on one positive sample, for each month that the test is performed. If the laboratory has two or more analysts, each analyst shall count typical colonies on the same plate. Counts shall be within 10% difference to be acceptable. In a laboratory with only one microbiology analyst, the same plate shall be counted twice by the analyst, with no more than 5% difference between the counts.

<u>Section 1.7.3.6.b</u> "If there is any doubt as to the validity of the result then the target organism shall be identified using commercially available metabolic identification

tests." Is this in regard to performing methods or quality control? For example for SM 9222B m-Endo needs to be confirmed by LTB/BGLBB and either EC/EC+MUG/NA+MUG. Does this add an ID test kit to the method (which is not approved)?

Colin's comment was determined to be non-persuasive because it does not add any value. Elizabeth noted that the method already defines how this is done. Carl noted that if the method is followed – there should be no question on the validity of the results. A kit would not be acceptable.

This section now reads:

1.7.3.6 b): To ensure that analysis results are accurate, target organism identity shall be verified as specified in the method (e.g., by use of the completed test, or by use of secondary verification tests such as a catalase test or by the use of a selective medium such as brilliant green (BG) or E. coli (EC or EC + MUG) broth.

Also – In section c – the following was deleted: If there is any doubt as to the validity of the result then the target organism shall be identified using commercially available metabolic identification tests.

<u>Section 1.7.3.7.b.v.i</u> We require the laboratory to establish the "uniformity of temperature distribution" in incubators here. Do we also want to add to establish the time it takes to re-establish temperature after a full sample load is added. The reason I ask is with more laboratories using data loggers for recording incubator temperatures an issue is arising with the temperature dropping outside of the required limits and triggering an alarm. Is this a problem? Is there an acceptable amount of time to reestablish temperature which could be documented? I kinda remember this being a requirement before. Do chromogenic/fluorogenic methods take into account a specific period of time to reach incubation temperature?

Dwayne would like to see the old standard requirement in the 2003 standard put back in. Robin noted that the 2003 standard required it, but did not say what to do with it. Dwayne will Draft some language for the committee to look at.

Also, there are a lot of misspelled words and incorrect words that spellcheck doesn't show in the document. I didn't have time to list them all but this is something that should be addressed before sending out another WSD.

Section 1.7. 3.6 d) ii) 2)

Elizabeth had one additional question about Colin's comments. She and Jennifer think the following statement should be deleted: Tests should be quantitative wherever possible. Robin added some additional language and the section now reads:

1.7.3.6 d) ii) 2): Each pre-prepared, ready-to-use lot of medium (including chromo/fluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested with at least known pure positive culture control (i.e target organism) as appropriate to the method (i.e

quantitative results for quantitative method) . This shall be done prior to first use of the medium.

Robin will send an updated copy of the MWDS to everyone for review. She hopes to vote on the standard at the next meeting – so everyone was requested to be present.

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 confirmed by email. Robin would like to target 11/13/14 for the next meeting. (Addition: Meeting scheduled for 11/18/14).

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 3:34 pm EST.

Attachment A Participants Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information		
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(Chair)	Beach EML				
Present					
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(Vice-chair)	Laboratories, Inc				
Absent					
Karla Ziegelmann-	Microbiologics,	Other		kfjeld@microbiologics.com	
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Present					
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Absent					
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Present					
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(Program Administrator)	montute			<u>institute.org</u>	
Recording					
Recording					

Attachment B

Action Items – MEC

			Expected	Actual
	Action Item	Who	Completion	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	
27	Notify CSDP that Elizabeth will be representative on Standards Review Council.	Robin	10/10/14	
28	Insert Colin's comments into the Comment Summary table and note status – persuasive or non-persuasive with reason.	Robin	11/13/14	
29	Update Modified Working Draft Standard and prepare for final approval by the committee.	Robin	11/13/14	
30				
31				
32				

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter in October 2014	n/a	