Microbiology Expert Committee (MEC)
Meeting Summary

November 18, 2014

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:35 pm EST by teleconference. Attendance is recorded in Attachment A – there were 5 members present. The committee decided to meet to review comments on the standard, but no changes will be finalized without consultation with the entire committee. The following associate members were present: Jennifer Best (EPA), Carl Kircher and Brad Stawick.

Minutes will be reviewed at the December 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. Modified Working Draft Standard

Robin sent out the standard after the meeting on October 28th. She asked for comments and any proposed language changes. There were a few emails, but she did not receive any recommendations for language changes or additions.

Robin commented that Colin's notes in the last copy of the MWDS standard need to go into the WDS comment spreadsheet so that responses can be prepared for commenters.

Robin asked if the group is ready to send out the standard as a modified working draft standard. The committee decided to go back through the emails received since the last meeting.

Proposed changes to 1.7.3.7.b.v (add as number #1):

Robin reviewed the discussion that happened by email after the last meeting regarding capacity load. Robin liked the modified second option best and others agreed:

"The uniformity of temperature distribution and time required after test sample addition to re-establish equilibrium conditions ***under full capacity load*** in incubators and water baths shall be established prior to first use after installation or service."

Carl asked if a small lab would be able to read this language and understand it.

Robin made modifications:
The uniformity of temperature distribution and equilibrium condition in incubator and water baths shall be established prior to the first use after installation or service. The

equilibrium check shall include time required after test sample addition to re-establish equilibrium conditions under full capacity load as appropriate for the intended use.

Jennifer assumed they would figure out the highest amount of samples they might run and present this data to their assessor. Carl suggested that it would be appropriate for a lab to state their full capacity in the QA Manual. This is what he would assess against.

Robin asked everyone to look strictly at the science. The lab needs to know how long it takes for the incubator to reach temperature after test sample addition.

Jennifer said most labs don't want to buy new incubators – so this criteria holds the lab accountable to have the correct incubator. She also noted that there are issues where a number of samples are put in the incubator and it takes some time for them to come temperature – the lab doesn't know that the samples really are being incubated at a specific temperature during the entire time required by the method. Part of that time may be time to come up to temperature.

After the discussion – Carl and Dwayne agreed with the language proposed above by Robin. Robin made the changes in the standard.

Mary commented that some of the other regulations require an annual check as well. Robin is not concerned because the more stringent requirements take precedence.

Carl Kircher's Comments (10/31/14 - Italics)

Section 1.5(b): I like the requirement that laboratories shall participate in proficiency testing programs for both reference and non-standard methods. However, that implies that there are such programs exist for Salmonella, Viruses, and other more exotic organisms. Do these programs in fact exist? Worse yet, are laboratories therefore precluded from getting NELAP-accredited for Legionella et. al. because to PTs are available?

Discussion:
Colin clarified by email that a legionella PT scheme does exist.

Robin noted – if a PT is not available – it is not available. Robin suggested adding the statement "if it is available". Language was added to the standard: where available.

Section 1.7.3.1(a) Sterility Checks: I read the items listed under (i)-(v), and as an Assessor I am hard-pressed to think where laboratories would NOT have the requisite "equipment" to do these sterility checks (thus allowing the use of a contracted laboratory to do the sterility checks). Perhaps the meaning or intention was for laboratories that do not have the "requisite materials and supplies"? An example of this would be Colilert labs. that may not have Tryptic Soy Broth to do the sample bottle sterility checks (?).

Discussion: Robin agrees with Carl's sentiment. It was suggested to drop the second to the last sentence, but support for this was mixed. Brad felt it should only state that it must be done, but not discuss how it should be done. Dwayne noted that PA does allow labs to send out this check to another lab. They don't force a lab to buy additional equipment.

Robin thought the language should be left in because it will be a benefit to labs – especially the smaller ones. There was general agreement and no change was made.

Section 1.7.3.1 The laboratory shall ensure that the quality of the reagents and media is appropriate for the test concerned: Section (d) has a good description on what is needed for purchased reagent water, but what about for purchased buffered dilution-rinse water? As an Assessor, am I free to apply the same criteria in (d)(ii), (d)(iii), and (d)(v) (with the possible exception of "specific conductance")?

Discussion:
Carl commented the monthly quality checks are only valid for one month – that is how FL applies it.

Robin responded that the answer to Carl's question is currently "yes" based on the language in the standard. This could produce an onerous requirement on the labs. Robin asked for comments from the labs on the call. Purchased water that is opened would need the testing done. The following language was added to 1.7.3.1 v) last line: Purchased reagent water that has been <u>opened</u> for longer than the testing intervals …

Most on the call felt that unopened bottles should be fine.

Carl emphasized that based on the part of the standard that requires a reagent to be checked to make sure it meets requirements, it would mean that the purchased buffered dilution-rinse water would need to be checked. You do testing once it is used for a test. A powder cannot be tested until it is actually used to make media.

Robin commented that what you test for depends on what it is used for.

Carl did not have any specific wording change recommendations and commented that different assessors are going to apply the standard differently in this section.

This discussion was tabled to the end of the call.

Section 1.7.3.6(a): The draft I have has underlined language of <u>once per lot</u> at the end of the sentence. For laboratory-prepared batches of growth and recovery media, is it the Expert Committee's thinking that each batch of prepared media also be checked to assure that target organisms respond in an acceptable and predictable manner?

Discussion:
Does it need to be each laboratory prepared batch? The 22nd edition of Standard Methods - 9020 states – Dilution water bottled should be checked for sterility, pH, and volume at

a frequency of each batch or lot. In Standard Methods paragraph 5c it says: Bottles prefilled with dilution water available commercially are acceptable. Before use of each batch or lot, conduct sterility tests, check one per lot or a set percentage for pH and volume and examine the dilution bottles for precipitate. Discard if precipitate is present.

Robin asked Jennifer if the DW Certification Manual has anything. Jennifer said the last manual does not distinguish between laboratory and purchased water.

Dwayne commented that the language in 1.7.3.6(a) should read once per lot or batch. The committee agreed and this wording change was made. This is what is required in other sections of the standard.

Section 1.7.5(c): The last word of the sentence is "quailed." Is this a typo and should be "qualified"?

Discussion:
Fixed.

Continued Discussion on 1.7.3.1:

Robin reviewed what is now included under 1.7.3.1. She asked if buffered dilution water needs to be added as e) and if the current e) should be f). There was agreement.

The committee worked on the following language that was added to the standard draft:

e) Dilution water, however used, includes buffer water and/or peptone water. The quality of the water shall be monitored for sterility, pH and volume once per lot or batch whether purchased or lab prepared.

Next Steps:

Colin's comments will be removed from the MWDS the committee has been using and then Robin will accept changes for a clean read. It will then be sent to the committee for a quick review (comments back by late afternoon on Wednesday) and to Jan for formatting and typo corrections. The committee will be asked to vote on the modified working draft standard by email with the expectation that the voting request will go out Wednesday evening and all committee members will be asked to vote by Friday 1pm Eastern on November 21st. This time frame will allow the committee to schedule a webinar on December 22nd so that all comments will be received by the committee before the winter face-to-face meeting.

(Addition: After further conversation by email, the following motion was made and voted on:

Donna motioned that the committee approve the Modified Working Draft Standard as distributed by Robin on 11-18-14 with the following modifications:

- *Section 1.7.3.7iii: Volumetric Equipment*
  *~~Volumetric~~ ~~e~~**E**quipment used for measuring volume shall be verified as follows…*
- *Scientific names throughout the document should be in italics – E. coli in 1.6.2.2d), E. coli in 1.7.3.6b).*
- *1.6.2.2(d): b-glucuronidase should be β-glucuronidase.*
- *1.7.3.1a)i) needs a period at the end of the sentence*
- *1.7.3.1e) missing word second sentence? "The quality of the dilution water…"*
- *1.7.3.6d))ii)2. Missing words?"…with at least one or more known pure positive culture controls…"*
- *1.7.3.7b)i) Missing words? "Temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum resistance thermometers shall be used to assess and document equipment temperatures and shall be the appropriate quality to meet specification(s) in the method."*
- *1.7.3.7b)ii) missing letter designations for each separate paragraph under Autoclave 1.?*
- *1.7.3.7b)v)2. Grammar? "During periods when samples are under test, the laboratory shall ~~must~~ have a system in place to ensure the temperature of incubators and water baths are ~~shall be~~ documented twice daily, at least four hours apart."*

The motion was seconded by Patsy. The vote was taken by email:

Donna – For (11/20/14)
Patsy – For (11/20/14)
Gary – For (11/20/14)
Mary – For (11/20/14)
Deb – For (11/20/14)
Elizabeth – For (11/20/14)
Karla – For (11/20/14)
Robin – For (11/20/14)
Colin – For (11/20/14)
Dwayne – For (11/21/14)
Po – For (11/21/14)

The motion passed with a unanimous vote – 11 – For, 0 – Against, 0 – Abstain. The MWDS was prepared for posting and sent to the TNI Website Administrator for posting for public comment on 11/21/14.)

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 scheduled by email. A webinar is tentatively planned for December 22, 2014 to present the Modified Working Draft Standard.

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 3:35 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) **Absent**	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 **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 **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
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.
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	Complete
30	Prepare final update of MWDS for committee to vote on and for Jan to clean-up for final TNI posting.	Robin	11/18/14	
31	Send out information for Email vote on MWDS.	Ilona	11/20/14	
32	Send approved version of MWDS to TNI Web Administrator for posting.	Ilona	11/21/14	

Attachment C

Backburner / Reminders – MEC

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