

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

February 3, 2015

1. Roll Call and Minutes:

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

The January meeting minutes were distributed and will be approved at the next teleconference.

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. MWDS Comment Summary

The comments received on the Modified Working Draft Standard (MWDS) were compiled into a summary table and sent to the committee to discuss. Each comment was numbered in the table.

Comment 1:

Persuasive. Edit accordingly.

Comment 2:

Persuasive. Edit accordingly.

Comment 3:

Persuasive. See Comment 2 above.

Comment 4:

Persuasive. Edit accordingly.

Comment 29:

Propose adding language to clarify the requirement for each analyst to have documentation of a continuing DOC every 12 months:

1.6.1.2 Thereafter, ongoing DOC (Section 1.6.3), **must be performed and documented at least every 12 months** as per the quality control requirements in Section 1.7.3, is required.

1.6.3.1 The laboratory shall have a documented procedure describing ongoing DOC that includes how the laboratory will identify data associated with ongoing DOCs. The analyst(s) shall demonstrate ongoing capability by routinely meeting the quality control requirements of the method, laboratory SOP, client specifications, and/or this Standard. If an analyst has not documented ongoing DOC within the previous. If the method has not been performed by the analyst in a twelve (12) month period, an initial DOC (Section 1.6.2) shall be performed **prior to performing analysis**. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.

The committee looked at the suggested word change to Section 1.6.1.2 and were concerned about the reference to Section 1.7.3. Initially they were not sure which module 1.7.3 was in, but it was determined it was Module 5.

Persuasive. Patsy suggested the following wording and Dwayne agreed:

1.6.1.2 Thereafter, ongoing DOC (Section 1.6.3), **must be performed and documented at least every 12 months**.

Robin would like to look at the wording in the other Modules to make sure Module 5 is consistent.

Comment #5:

Persuasive. "Positive" is being added between "one" and "sample". It would read:
Analysis of one *positive* sample ...

Comment #6:

It was recommended that the following sentence be deleted: These sterility checks may be performed by a contracted laboratory if the laboratory does not have the requisite equipment to perform them.

Steve asked if this sentence is left in, does it have to go to an accredited lab? Can the vendor supply the analysis?

Robin asked if the community has been OK with the language as stated here? Then why can't this be done by the vendor or done by the lab itself?

Jennifer stated that the vendor results shouldn't be accepted because something can still happen in shipping to the lab. The lab should still check it.

Patsy noted that sterility checks are performed following ISO Standards in her company. The concern about shipping from the vendor to the lab should be similar to the concern that it be shipped to another lab for analysis.

Marsha, City of Portland: It was commented that it is important to check because they have seen instances of damage in shipping.

Robin recommends calling this persuasive and taking the sentence out.

Steve asked what verified means in the previous sentence. He also commented that this is not the only place in the standard where this language is an issue.

The recommendation is to delete the following language:
Certificates of analysis provided by vendors shall be verified by the laboratory. These sterility checks may be performed by a contracted laboratory if the laboratory does not have the requisite equipment to perform them.

Deb and Steve Arms are still concerned that the remaining language does not say who needs to do the checking. Patsy noted some states do accept the vendor certificates, but they are not NELAP states. The standard should be written for our organization and not for states that are not in the program.

Persuasive: Remove language as stated above and add “checked *by the laboratory* once per purchase ... “.

Note: Need to find a place that retaining of Certificates of Analysis can be placed.

Jennifer Best: Use language similar to “Certificate of Analysis must be retained by the laboratory as part of its record keeping system”.

Section 5.6.4.2.a. in Module 2 has a requirement for keeping Certificate of Analysis for standards, reagents, reference materials, and media.

Comment 7 is suggested change for Comment #6. Correct table.

Comment 8:

Jennifer Best feels strongly that something needs to be added. The loop is not closed. The committee thinks this is included in the methods.

Persuasive. Need to figure out where to put this. Not necessarily in this section.

Comment 9:

Robin believes this is in the method. Steve Arms noted that sometimes it is OK to include a requirement from a method that is applicable to all samples.

The methods have to give an incubation time.

Persuasive. It will take some work to figure out language. It applies to performance checks and sterility checks.

Steve Arms suggested writing the response to the purpose of why it needs to be done – for the slow growers.

Robin disagrees that you get more helpful info for more than 24 hours. If the tests she runs are only for 24 hours – 24 hours in the right amount of time. It needs to state that it brackets the duration of the test of interest.

Dixie Marlin had a wording suggestion: The laboratory shall ensure that all media testing and quality of the reagents and media used is appropriate for the test concerned.

Comment 10:

See Comment 9.

Comment 30:

Persuasive. Edit accordingly.

Use the suggested language with a few possible changes.

Comment 11 and 31:

Dwayne commented that 30 and 31 go together, so completion of 30 takes care of 31 too.

Dwayne also said Comment 11 is related – so this is taken care of too.

Comment 12:

Non-Persuasive. Appears to be a problem with the commenters copy, but committee does not see issue in their version.

Comment 13:

Dwayne commented that it is not meant to say – here is a list of bacterial inhibitors. Everyone was in agreement. It would be difficult to list everything and requirements can change in the methods. It is not an all inclusive list.

Steve is concerned that this section is full of the passive voice and he would like to see this changed. Robin asked Ilona to forward this concern of passivity voice in the standard to the CSDP EC. This is relevant to more than the Microbiology standard. Steve brought this up in Comment 28. He thinks this is part of the reason for the question – the passive voice doesn't make it clear.

Non-Persuasive

Comment 14:

Reagents are covered in Section 5.6.4.2 of Module 2. Perhaps this reference needs to be added. Reagents will be kept in accordance to (*define references*). The committee needs to confirm the correct reference.

Persuasive. Persuasive in the intent of the comment, but will handle it differently than suggested.

Comment 15:

The intent of the language is to sanitize after each sample if using UV. No change in language.

Comment 16:

This is correct. A positive sample has to be used. There is no other way to count colonies or identify colonies without a positive sample.

Comment 17:

Persuasive. Edited accordingly.

Comment 18:

Non-Persuasive. They may not be using Standard Methods and sometimes it is on the bottle. Methods and programs typically cover it.

Comment 19:

“C” is meant to be more generic.

Non Persuasive.

C is selectivity, reference cultures and D relates to the working cultures.

Comment 20:

Patsy suggested a language change: ... with one or more known pure positive controls that produce typical or expected results per the method.

There was concern that someone might think known is quantity and not target organisms.

Instead: ... with one or more known pure target organisms that produce typical results based on the method.

Persuasive with the language above.

Comment 21:

See Comment 20 above.

Comment 22:

Cathy didn't want us to say "No pets in the lab", she wanted it to say "No Animals". Every WET lab Deb audits has Micro in the same area and this language could cause a problem.

Robin suggested going ahead and adding no pets.

Paul Junio suggested leaving this alone. If the QC is passing, what is the issue?

Jennifer Best said the standard is not all-inclusive. You can't include everything.

Robin looked into Standard Methods to see if there is anything included – but could not find anything related to pets.

Persuasive. Making an edit. Delete the last sentence about plant food etc.

Comment 32:

We do not want to use bullets. It will be appropriately designated.

Persuasive. It will be edited accordingly.

Comment 23:

There is agreement with the concept, but this should fall under normal record requirements. This is also in Module 2 – All records must be retained.

The comment is ruled Non-Persuasive. It is already covered.

Jennifer Best said she has heard complaints about labs not printing their datalog information and only writing a number into their labs sheet. The original observation is the data logger and this printout must be maintained.

4.13.2 and 4.13.3 in Module 2 cover all of this.

Comment 24:

Non-Persuasive. This was intended.

Comment 25:

Comment 25 and 26 should be combined. Comment 25 is recommended new language.

There was much discussion on this topic. There were concerns about samplers not handling this ethically, different guidance in different areas,

It is being ruled Persuasive.

Comment 27:

Persuasive. Edit accordingly.

Comment 28:

Will look for more committee input before this is decided.

Robin will begin making the changes discussed above in the MWDS – Track Changes. She will distribute this before the next meeting.

Ilona will update the MWDS Comment Summary before the end of next week.

Bob Wyeth asked that the Standard be balloted by email so that a VDS will be ready for the committee to approve in March. He would like a copy of the edited version as soon as possible so the SRC can take a look at it and make comments before it is finalized as the VDS.

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 by teleconference and planned by email.

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 5:01 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 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 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 - Phone	Indiana State DOH	AB	(317)921-5523	mrobinson@isdh.in.gov
Elizabeth Turner Present – Phone until 3pm Eastern	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 Present	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	
34	Send Steve Arms' comments on the MWDS to the CSDP EC.	Ilona	1/16/15	Complete
35	Update the Comment Summary table discussed during the meeting and send to Ilona.	Robin	1/13/15	Complete
36	Clean-up Summary Table and prepare responses to commenters.	Ilona	1/16/15	Complete
37	Finalize Charter and forward to CSDP.	Ilona	1/16/15	Complete
38	Update MWDS table with comments from 2/3 meeting. Distribute to committee.	Ilona	2/13/15	
39	Update the MWDS-Final-Track Changes with the changes discussed.	Robin	2/16/15	
40	Send CSDP EC a copy of the edited standard ASAP so the SRC can begin a review before the VDS is finalized.	Robin/Ilona	TBD	
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