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

**March 10, 2015**

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:30pm EST by conference call. Attendance is recorded in Attachment A – there were 4 members present. Associate Members present: Carl Kircher, Jennifer Best, and Aaren Alger (PA).

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 Standard updates.

2. Draft Voting Draft Standard

Robin asked everyone to look at the most recent version of the Draft Voting Draft Standard (VDS) distributed by email. She would like to continue to discuss the Certificate of Analysis (COA) issue. Ilona reminded everyone that a copy of the Draft VDS needs to be sent to SRC before it is finalized for committee vote and posting.

Dwayne updated Section 1.7.3 of the Standard to include active voice instead of passive voice. This was distributed to the committee on 2/19/15. In response, Robin asked the committee to consider: *Do we remove the flexibility of the states to accept C of A's by changing the wording here? I am not really asking whether or not they should, I am really asking does that remove the ability of an AB to use some professional judgment should they choose to do so. Now the follow up question is, do they really want to make a judgment call or are they looking for the std to tell them specifically? Are they taking a C of A because the std has not specifically spelled out that they can't? I really just want to make sure that if we do or don't make the change that we are doing so with intent. I know the group has discussed the use of C of As at great length and I don't mean to start another debate regarding that specific issue, just about how much flexibility to use profession judgment should be in the std.*

Robin asked Po if he will be looking to the Standard for whether to accept certificates of analysis (COA). He responded No.

Robin asked where Carl is finding in Module 2 the language to enforce that people verify vendor certificates of analysis. He stated there is a section about a lab not using purchased materials or supplies without checking or verifying they meet requirements. In the 2003 Standard this is in Section 5.4.

Carl is fine with the language Dwayne recommended by email on 2/19, but he suggested sending the Standard through just as it is right now even if it may leave the language open for Standards Interpretation Requests.

Po looked at 1.7.3.1 and commented that there are requirements for verification. He is fine with this. He does not want the flexibility. His personal experience leads him to require the lab to perform the tests. He saw problems in the past.

Mary commented that she is torn. She understands that it would be good for labs to confirm, but she would rather not put more work on a lab when it is not necessary.

Aaren Alger commented that in PA they expect to verify sterility, media, etc … using positive negative controls. They are allowed to subcontract these checks. This was decided because shipping will only cause a problem in a negative way … so low risk. They don't think Micro and Chemistry are the same and they don't want to only accept the vendor's CoA. They think materials can be affected by shipping. She does not want the ABs to have flexibility – all ABs should be doing the same thing. Leaving it flexible opens the Standard up to an SIR.

Robin commented that she heard Aaren say labs can subcontract the test. The current Standard language now says the lab must analyze it themselves.

Carl noted that FL requires that the sterility test be done by the lab. It would be inappropriate for it to be sent out. He would not like to see the language changed.

Robin will take this information and make sure the language reflects the discussion. She understands that the committee would like to make the changes Dwayne suggested and will incorporate these changes.

Patsy added comments to the document Dwayne prepared. She asked for a change from "Validation" to "Verification". Robin commented that it needs to be left as validation so it corresponds with all the other modules. Though "verification" may be more appropriate – it would be difficult to make this change at this time.

3. SIR #285

Robin wanted to review the SIR being looked at to see if there is any impact on the Draft VDS. She went back to Section 1.7.3.3. She couldn't find any help in Standard Methods to answer SIR #285.

After discussion with a number of ABs, Robin came to the following conclusion: If you are reporting a number you should be able to reproduce that number and if you should be able to reproduce that number then another analyst counting the same plate or same tube or the same multi well container should be able to reproduce that number as well. Therefore if you report a number you should do a duplicate count.

Robin confirmed that she is not talking about every sample. This would be once a month per method. Carl thought this was a great idea. Po commented that the committee needs to understand this would apply to a lot of tests and asked if this is necessary.

Robin commented that if the intent was for all enumerative methods to have duplicate counts, then the clarification should cover this.

The last sentence in Section 1.7.3.3 needs to be re-worded. It should not include "plate". The goal is to make sure they are interpreting the results the same way.

Carl cautioned that if the enumerative is added to the SIR – this could be viewed as adding to the Standard. Robin said the response is that it is not required in the current Standard – the intent was different. The new Standard is being changed to address this. Carl had to leave the call.

Jennifer noted that the EPA cert manual does not require doing comparison counts anymore.

9020 – 22nd Edition – Paragraph 9. Robin read the requirement. This language would help clean up what we currently have.

The language in Section 1.7.3.3 now reads:

For methods that specify counts (i.e. cfu/100mL or MPN/100mL) such as membrane filter, plated media or other methods which specify a quantitative result, duplicate counts shall be performed monthly on one (1) positive sample, for each month that the test is performed. If the laboratory has two or more analysts, each analyst shall count typical results on the same sample. Counts shall be within 10% difference to be acceptable. In a laboratory with only one microbiology analyst, the same sample shall be counted twice by the analyst, with no more than 5% difference between the counts.

Robin went back to the SIR and the current Standard language. She commented the language only applies to membrane filter or plated media. To say it applies to all enumerative methods would be putting a requirement above what is actually in the Standard. The response needs to say that it only applies to membrane filter or plated media. Robin will Draft a response to the SIR for committee comment. She would like to hit the 45 day time table to get a response back to Lynn.

4. Action Items

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

5. New Business

    - The Quality Systems Expert Committee is trying to modify Module 2 to make Module 5's language on thermometer checks consistent. They preferred the Module 5 language to what is currently in Module 2.

6. 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 2:31 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 **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 **Absent – Aaren Alger stepped in.** | 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 **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. |
| 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 | |
| 41 | Prepare Draft Response to SIR for committee review. | Robin | 3/10/15 | Extended to April meeting. |
| 42 | Update Standard and Comment Table based on changes made during the 2/17 meeting. Distribute to committee. | Robin | ASAP | Complete |
| 43 | Update Standard with changes made during the 3/10 meeting. | Robin | 3/17/15 | |
| 44 | Send Draft VDS to SRC for comment. | Robin | 3/17/15 | |
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**Attachment C**

**Backburner / Reminders – MEC**

| | Item | Meeting Reference | Comments |
|---|---|---|---|
| 1 | Update charter in October 2015. | n/a | |
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