Microbiology Expert Committee (MEC)
Meeting Summary

July 14, 2015

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 9 am Central in Chicago, IL. Attendance is recorded in Attachment A – there were 9 members present.

Minutes will be considered at the next teleconference meeting in August.

2. Voting Draft Standard (VDS) Response to Comments Summary

Ilona prepared a table that was sent out to summarize the votes received with comment. All comments were accompanied by an affirmative vote. There were no negative votes. In summary, there were 26 Affirmative votes, 3 Affirmative with Comment, 0 Negative with Comment and 3 Abstain.

Robin reviewed the three comments received and the Committee began drafting responses:

Comment 1:

This came up during the final review before posting and Jan (administrative reviewer) thought there were so many levels it would be inappropriate to add another level and bullets were better. The committee wants to go ahead and add the a), b), c) , etc … This is an editorial change and has no impact on the standard. Persuasive if this can be done.

Comment 2:

This comment is not suggesting any change to the Standard. It seems more like a Standard Interpretation Request (SIR). The committee will answer the comment, but no change is needed in the Standard. Non-Persuasive.

The Committee looked at the specific questions and discussed responses that could go back to the voter.

Question 1:
This is part of the method and if it is more stringent – the more stringent procedure must be followed.
Question 2:
Robin pulled the relevant section of the VDS Standard up. If you are not using funnels then you would not need to do this.

Question 3:
This is not a change. It is what everybody does. The commenter is correct that it can show up in other ways, but having these results means you don’t have to redo anything. You don’t have to wait to see you have a problem. This requirement has been in the Standard since 1999.

Comment 3:
This can’t be done because we don’t know what kind of system is being tested. Non-Persuasive. The Committee cannot specify which type of disinfection to test for because it is dependent on the distribution system it is hooked up to.

The committee continued to look at the language. Colin suggested that the Committee change it to disinfectant. This would also be more consistent with the Drinking Water Standard. The Committee decided to make this editorial change.

These responses will need to be finalized in the VDS Response to Comments Summary and the committee will need to determine if the changes made to the Standard based on the comments are substantive or non-substantive/controversial. If they are non-substantive (as anticipated), the standard will be moved on to an Interim Standard and only the actual changes made to the VDS will be posted for another vote. Each commenter will be sent a written response to the comment and the VDS Response to Comments summary will be posted with the Interim Standard at the time of the vote.

Robin will distribute the responses to Committee members to finalize the language.

(Addition: Note the file did not save on the USB stick and the table was re-created during the 8-18-15 teleconference).

3. Small Laboratory Handbook

Robin described the history and process of updating the Small Laboratory Handbook. The Quality Systems Expert Committee is coordinating the update of the Handbook and has asked the Committee to update the Microbiology section.

Patsy suggested that each person on the committee take a part of the standard and look at it for possible handbook notations. She also confirmed it is the 2015 standard that is being used.

Robin opened the floor to ask for suggestions, but none were given.
Robin pulled up the VDS and began reviewing it with the Committee so people could volunteer to review specific sections and provide text for the Handbook.

Section 1.2 (Robin):
The Standard is the basic minimum. A more stringent program, method or requirement always takes precedence. This needs to be included in the handbook.

Section 1.5 (Patsy):
Deb noted that most of the small labs won’t need this because they don’t use custom methods. It would make sense to note what this section applies to and how it is used by people that are not “working outside of the box”. Talk about the difference between reference and non-reference methods. Colin agreed that this is a huge amount of work that he does not expect a small lab to use. Labs do a verification and not all do validations.

Deb noted that some states allow reporting results outside of method ranges. She asked if that would require validation. The response was “no”.

Section 1.6 (Deb, Donna):
This section itself has addressed this issue (1.6.2.2). Deb would like to expand and use more examples. This will cover initial and continuing.

Melissa Pipes: She did some initial DOCs with MPN. She is confused how to do the percent recovery comparison. Deb said in the guidance she will give examples for the various technologies/methods.

If a lab wants to do something different, in many cases it is fine, but the lab should check with their AB.

Donna asked about a guidance document on how to do Method Uncertainty. She asked if the Committee can prepare guidance documents and other training and implementation help documents.

Ilona noted that all the above is possible. There can be examples included in the Handbook or they can be included on the website as an example that can also be used for both the Quality Manual Template update and Handbook. Guidance documents need a formal review by the Policy Committee before works starts on the document.

Donna will look at preparing a few example SOPs.

Robin will suggest to QS that they include “How to Add a Method” to the handbook.

Section 1.7 (Need Volunteers):
This section needs to be broken up between different people because it is so large.
Sterility Checks:
Patsy thinks the sterility check and method blank need to be handled separately.

Method Blanks:
This section has identical language to the 2009 Standard.

Footnote 23. Many people have commented on this in the Method Update Rule (MUR) and the expectation is that it will be changed.

Michelle Wade commented that she wants to see if it grows something in it.

Colin noted that you need to pick a bug that grows on the media. Just need a basic check – don’t need to run all the different strains, etc …

Robin asked how can one say nothing grows on their TSP if they’ve never seen anything grow on it. Can you be sure something would grow if it was present?

Jennifer Best is concerned that the assessors don’t have the experience they need to do micro assessments. She thinks sometimes aides don’t help because it lowers the bar of what the assessor really needs to know.

The Handbook will continue to be discussed and worked on during upcoming meetings as time allows. Ilona will send the micro section of the current Handbook to the committee members.

4. Action Items

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

5. New Business

• None.

6. Next Meeting and Close

The next meeting will be determined 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 11:55 am Central.
<table>
<thead>
<tr>
<th>Members</th>
<th>Affiliation</th>
<th>Balance</th>
<th>Contact Information</th>
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<tbody>
<tr>
<td>Robin Cook (Chair)</td>
<td>City of Daytona Beach EML Lab</td>
<td>(386)671-8885 <a href="mailto:codkr@codb.us">codkr@codb.us</a></td>
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<td>Elizabeth Turner Present</td>
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<td>Gary Yakub Absent</td>
<td>Environmental Standards, Inc. Other (610)935-5577 <a href="mailto:gyakub@envstd.com">gyakub@envstd.com</a></td>
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<td>Ilona Taunton (Program Administrator) Present</td>
<td>The NELAC Institute n/a (828)712-9242 <a href="mailto:Ilona.taunton@nelac-institute.org">Ilona.taunton@nelac-institute.org</a></td>
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<tr>
<td>Action Item</td>
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<tr>
<td>1</td>
<td>Review Method Codes and send comments to Robin for Dan Hickman.</td>
<td>Deb</td>
<td>TBD</td>
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<tr>
<td>4</td>
<td>Review Handbook and Method Codes before next meeting.</td>
<td>ALL</td>
<td>5/7/13</td>
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<td>12</td>
<td>Research possible effects of using bromine and whether it needs to somehow be included in the standard. Does not look like it.</td>
<td>Deb</td>
<td>November 2013 Meeting</td>
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<tr>
<td>19</td>
<td>Provide EPA interpretation on temperature readings to Ilona. She will have it posted on the website.</td>
<td>Robin</td>
<td>1/31/14</td>
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<tr>
<td>41</td>
<td>Prepare Draft Response to SIR for Committee review.</td>
<td>Robin</td>
<td>3/10/15</td>
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<td>47</td>
<td>Draft response to SIR #285 and send to Robin for distribution and voting.</td>
<td>Deb Robin</td>
<td>6-16-15</td>
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<td>48</td>
<td>Distribute the VDS Response to Comments table with Draft responses to all committee members.</td>
<td>Robin</td>
<td>7-21-15</td>
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<tr>
<td>49</td>
<td>Send Word version of current Handbook to committee members.</td>
<td>Ilona</td>
<td>7/31/15</td>
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## Backburner / Reminders – MEC

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<tr>
<th>Item</th>
<th>Meeting Reference</th>
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<tr>
<td>1</td>
<td>Update charter in October 2015.</td>
<td>n/a</td>
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