Microbiology Expert Committee (MEC) Meeting Summary

January 26, 2021 Virtual Conference

1. Roll Call:

Kasey, Chair, called the meeting to order at 3:45pm Eastern on January 26, 2021 by teleconference. Attendance is recorded in Attachment A – there were 7 voting members present: Hunter Adams, Cody Danielson, Jody Frymire, Kasey Raley, Elisa Snyder, Michael Carpinona and Vanessa Soto Contreras. There were 62 participants attending the meeting.

Kasey asked that Committee members let her know if they have taken the recorded Committee training.

Kasey reviewed the agenda for the meeting and no changes were made. See Attachment A for agenda and contact information.

2. Update to Standard

Kasey pulled up the list of questions and comments that came in from the December 1, 2021 Public Webinar. A copy of this list can be found in the January 12, 2021 meeting minutes. She shared how the Committee organized the comments relative to the changes the Committee proposed for the Public Webinar. The Committee is now starting to DRAFT language changes in the Standard based on the original proposed changes and the comments received. She emphasized the Committee is just getting started and no language is final.

She reviewed the initial changes made by the Committee. She asked for comments as she reviewed the information. She Reviewed Items 1 to 4. She noted that the Committee recently put together some Implementation Guidance on method blanks for filtration techniques. It is being reviewed by the LASEC.

Item 5

This is where the Committee left off at their last meeting.

It was asked if the Committee is looking at ISO/IEC 17025:2017 as you are modifying the standard? Just curious if you are looking to move towards a risk based standard?

Kasey noted that micro has not been actively comparing the standards. She feels Micro has always been somewhat risk based – trying to not make the Standard overly

proscriptive. They do follow the methods. Kasey pointed to Section 1.7.3.1. How do you define a lot? If the same lot comes in the next time, do you have to test it? Do you have to test each shipment you receive? The Committee is wrestling with this. How proscriptive do they need to be?

It was asked if a sister lab is the same as a satellite lab? We have a parent lab doing QC of supplies and media and sending it to a satellite lab. Both are under the same quality system but different locations. Is it still necessary to do QC at each location? I is the same. This is what the Committee is wrestling with. They need to be doing it at the receiving location. SIR 331 addressed this question. The SIR can be found under the Lab Accreditation tab.

If they don't have to test the same lot when shipped at separate times, why would I have to test it if it is going to a separate location? If you put laboratory of use, you are taking away that choice. The Committee is aware of this and is looking at it.

Kasey reviewed Section 1.7.3.3. There was an SIR that has been posted related to this section. The MPN table tells you what the number is, but it does not tell you how to identify a positive well and that is the point of this exercise. Need to make sure everyone is identifying a positive the same.

Any method that specifies a count needs to make sure people doing that are verified. Reproducibility.

The Committee re-focused on the Lot question. Kasey noted that good laboratory practice is to test the shipment that comes in. There was general agreement in the comments.

A comment was made about storage and Kasey reminded everyone we are talking about things being shipped.

It was noted that a separate section of the standard calls for labs to store supplies appropriately.

What if something gets left on the truck? Comes a day later. Would the late arrival need separate testing? This is the same order and lot# of what came in the day before. You don't know what happened later in the day while it was still on the truck. Was the temperature increased, etc ...?

Some labs give supplies received an internal number so they can show it was tested.

The Committee will continue to do more work on this. Kasey thanked everyone for the comments.

<u>Item 5 (con't)</u> – Reproducibility Section 1.7.3.3

Add "multi-well" to the list. It will address the questions. They hesitated on doing this because they can't keep adding every new technology.

Also change "positive sample" to "positive result".

It was commented that this also includes multiple-tube fermentation. It is a quantitative result. The Standard does make it clear: "other methods which specify a quantitative result." Instead of adding MTF – add "All other methods ...". Is there a problem having a list? It was suggested to delete all the examples and just focus on: For all methods that specify counts. Don't list examples. There was lots of support for this direction.

Update last sentence – change "sample" to "result".

Item 6

The Committee wants to improve the flow of information and move things around. This does not change any requirements. 1.7.3.6 c) to 1.7.3.2. This is an editorial change.

Item 7 – Section 1.7.5.2

This deals with exemptions on chlorinated samples. Add to end of first paragraph: Alternatively, the laboratory does not need to test as above if all the below exemptions are met. Delete: unless all the following conditions are met.

There were no comments.

Kasey also noted that the Committee will be changing "non-selective" to "nonselective".

3. Implementation Guidance

The Committee has been asked to provide guidance on incubator equilibrium checks. Dwayne Burkholder (Pennsylvania) emailed a guidance document that the Committee will consider in preparing this guidance. It does not look like there is anything in the Small Laboratory Handbook. Guidance will be helpful since many ask about it.

4) Q and A

Someone asked about status changes to Technical Manager requirements. The Committee gave their DRAFT to Quality Systems Expert Committee. The goal is to have the language somewhat similar across all the modules.

There was a question about the satellite lab not being able to do the check, but this doesn't make sense. They have to do DOCs and QC. They should have what they need. The consensus is that they need to do it. They can get the materials from the parent lab.

Kasey thanked everyone for participating and invited people to join the Committee as an Associate member.

5. New Business

None.

6. Next Meeting and Close

The next meeting will be held by teleconference on February 9, 2021 at 1:30pm Eastern.

Kasey adjourned the meeting at 4:52 pm Eastern.





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