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

**December 8, 2020**

1. Roll Call:

   Kasey, Chair, called the meeting to order at 1:30pm Eastern on December 8, 2020 by teleconference. Attendance is recorded in Attachment A – there were 10 members present. Associate: Christopher Fuller, Dwayne Burkholder, Carl Kircher, Robin Cook and Nigel Allison.

   Committee minutes will be reviewed and voted on by email.

   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.

2. Public Meeting

   Kasey noted that she prepared a list of all the comments/Q&A she received from the webinar. This list can be found in Attachment D. General comments were not included in the list (e.g., thank-you notes).

   There were a lot of questions about the sterility checks. One person said they are not set-up to do it, but this doesn't make sense. Since there were so many comments, the Committee should make sure the language is really clear.

   When you use the bottles, you are saying the bottles are clean. Then they need to be checked after they leave the lab. Wouldn't someone want to do the sterility check to reduce their risk?

   Ilona and Cody asked about the possibility of trip blanks? General thought was not to do this.

   Need to look in the small lab handbook. Is it clarified there?

   All comment related to sterility check were marked as Item 1. It was the first presented change in the presentation. The second presented change comments are marked as Item 2, etc …

   Water testing of purchased water. - Item A. The Committee should look at adding Item A items to the Standard.

Plan to do a guidance document on how to establish the uniformity of temperature distribution and equilibrium conditions in incubators and water baths prior to first use after installation or service.

Item 1

There was a lot of concern about the sterility checks change. This change was based on an SIR.

The Committee looked at the Standard to see what it applies to. The SIR question deals with media and then it asks about IDEXX bottles.

The Committee worked on some possible language change in the Standard and there was general agreement with the following:

Section 1.7.3.1.a.ii: The laboratory shall perform a sterility check on one (1) funnel per lot of pre-sterilized single use funnels using non-selective growth media. The laboratory shall perform a sterility check on one (1) funnel/object per sterilization batch sterilized in the laboratory with non-selective growth media.

Item 2

There was some discussion on possible language changes, but nothing was finalized. This will be further discussed in January.

3. Membership

Kasey reported that two Committee members would like to renew their membership for another term. One would like to change his membership to an associate member.

Kasey will send resumes she has received to the Committee by email. She will plan to have a membership discussion and vote at the end of the January meeting. She encouraged associate members to complete an application on the TNI website to become a voting member.

4. Winter Meeting

The virtual conference meeting will be a working meeting. Ilona will follow-up with Jerry because Microbiology is not yet on the program schedule. *(Addition: Microbiology will meet on Tuesday from 3:30-5pm Eastern.)*

5. Action Items

See Attachments B and C for updates to action items.

6. New Business

Ilona noted that TNI *was recently informed that Shall should be Must if you want it to be enforceable.*
*(Addition: This was discussed at the December CSDP Executive Committee meeting and they are recommending that as Standards are changed, move from the use of the word 'shall' to the use of the word 'must' and add definitions of "shall", "should", "may" and "can" to Module 2.*

7. Next Meeting and Close

The next meeting will be held by teleconference on January 12, 2020 at 1:30pm Eastern. A Webex invite will be distributed earlier that day.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Kasey adjourned the meeting at 2:55 pm Eastern. (Motion: Cody. Second: Mike C. Unanimous approval.)

**Attachment A**

**Participants**
**Microbiology Expert Committee (MEC)**

| Members | Affiliation | Balance | Contact Information |
|---|---|---|---|
| Kasey Raley (Chair) (2023) **Present** | Pace Labs | Lab | Kasey.Raley@pacelabs.com |
| Michael Carpinona (2022*) **Present** | NJ DEP | AB | Michael.Carpinona@dep.nj.gov |
| Cody Danielson (Vice-Chair). (2022*) **Present** | Oklahoma | AB | Cody.Danielson@deq.ok.gov |
| Jessica Hoch (2022) **Present** | TCEQ | Other | Jessica.Hoch@Tceq.Texas.Gov |
| Lily Giles (2022*) **Present** | Louisiana | AB | Lily.Giles@LA.GOV |
| Mary Robinson (2022*) **Present** | Indiana | AB | mrobinson@isdh.IN.gov |
| Michael Blades (2021*) **Absent** | ERA | Other | mblades@eraqc.com |
| Jody Frymire (2022*) **Present** | IDEXX | Other | Jody-Frymire@idexx.com |
| Vanessa Soto Contreras (2023) **Absent** | Florida DOH | AB | Vanessa.SotoContreras@flhealth.gov |
| Elisa Snyder (2023*) **Present** | City of Austin – Austin Water Division | Lab | elisa.snyder@austintexas.gov |
| Hunter Adams (2023*) **Absent** | City of Wichita Falls – Water Purification | Lab | hunter.adams@wichitafallstx.gov |
| Enoma Omoregie (2021*) **Present** | NYCDEP | Other | eomoregie@health.nyc.gov |
| Christabel Monteiro (2021*) **Present** | ESC | Lab | cmonteiro@esclabsciences.com |
| Patrick Roundhill (2023*) **Absent** | New Leaf Management, LLC | Lab | patrickroundhill@gmail.com |
| Ilona Taunton (Program Administrator) **Present** | The NELAC Institute | n/a | Ilona.taunton@nelac-institute.org |

**Attachment B**
**Action Items – MEC**

| | Action Item | Who | Expected Completion | Actual Completion |
|---|---|---|---|---|
| 76 | Provide an update on what has been done with the method codes and database after Jennifer's review and internal EPA meetings. | Jennifer | 4/10/18 | 6/9/20: Ask Jennifer for a follow-up. 11/9/20 – Not available for a follow-up. |
| 102 | Start working on public webinar presentation. | Kasey, Cody | TBD | 11/9/20 – Webinar scheduled for 12/1/20. 12/8/20 – Webinar was completed on 12/1/20. Complete |
| 103 | Send membership candidates and resumes to voting committee members to review prior to January meeting. | Kasey | 1/4/2021 | |
| 104 | | | | |

**Attachment C**

**Backburner / Reminders – MEC**

| | Item | Meeting Reference | Comments |
|---|---|---|---|
| 1 | Update charter (if needed) in November 2019. | n/a | Ongoing |
| 2 | Review Method codes and send comments to Robin for Dan Hickman. | | Moved to back-burner on 6/9/20. |
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Attachment D: Summary of Q&A/Comments from Public Webinar

| Question/Comment | Status |
|---|---|
| I will like you clarify the thermometer calibration check and how to apply the factor (betwee the NICT thermometer and the daily use thermometer) for the rountine daily use thermometer. | NA |
| We supply IDEXX bottles that were pre-lot tested in the parent lab to our sister labs. They used the QC lot testing info for QC. Do they need to set up their own or can they use their negative controls as QC test? | Item 1 |
| So does this mean that when we sterilize the funnels, we can put a flask together with that batch and we can QC the flask instead of the funnel? Is that what I am understanding? Thanks! | Item 2 |
| Is there any specifics on how the sterility check is performed? Do you rinse the funnel with water and add the water to non-selective media? Is there a standard for how much contact the media has to come into contact with the funnel? | NA |
| Related to the sterility check at the location of use, we have labs around the state that receive sample bottles from us in order to perform work for us. We check the sterility on those sample bottles. Is this a problem? | Item 1 |
| We provide the bottles to our samplers and then they drop the samples off at the contracted lab. | Item 1 |
| For 1.7.3.1.a: Is the sister laboratory the same as a satelite laboratory? Or could the QC checks be evaluated by the main laboratory and delivered to the satelite laboratories? | Item 1 |
| IF a lab send samples to another lab already in the bottle, how would they check those bottles? IN the case that Cody discribed the lab would only be required to narrate that the sample bottles were not from them. | Item 1 |
| The parent lab does all QC lot testing for colilert testing to supply the sister labs (treatment plant labs). They are not set up to do their own sterility checks using TSB but can they use method blank as QC check? | Item 1 |
| So the responsibility is on the lab using the sample bottles. | Item 1 |
| Would documentation of the sterility check that we did on the sample bottles I asked about be sufficient for the contract lab? | Item 1 |
| You are saying each batch needs a check with at least one object. | Item 2 |
| It would be very difficult for the contract laboratories to ensure that they are getting the sample bottles in advance and checking sterility prior to receipt of the samples. We have 15 labs around the state. | Item 1 |
| What is the difference between performing sterility checks before providing bottles to the client (shipped to client and back) and before they are shipped to another lab for analysis (sub-contract)? | Item 1 |
| It's an operational procedure. We order all of the sample bottles (chemistry included) and ship them to our own samplers around the state. The samplers | Item 1 |

| Question/Comment | Status |
|---|---|
| then collect the samples and drop off at the contract lab closest to the collection site. | |
| The samplers often keep sample bottles on hand for spills and other "surprise" events, as well, that we would have previously sterility checked. | Item 1 |
| In the case of contract labs. Lab A does the sterility check, ships bottles to samplers, samplers fill bottle and return it to a lab. Empty bottles are not being exchanged between Lab A and another lab (as in the parent and sister lab example). | Item 1 |
| Is there an expiration on the sterility check of purchased reagents/supplies, or is the check good until the manufacturer expiration? | NA |
| Have the committe have taken into consideration that some sister lab may not have the resources to perform their own sterility check adn that is the reason why the parent is performing the sterility check? | Item 1 |
| Do we have to measure the reagent water quality after PM is done? | NA |
| Is there a resource that will help the labs on how to conduct all these sterility checks, specially the funnels? | NA |
| Is same rule apply to disposable filtration unit with filter? | Item 2 |
| Clarify again dilution from each sample versus samples. | Item 4 |
| For the water laboratory monitoring... once a month, will that apply to reagent water bought? will we still need to monitor for everything once a month even if we buy it? | NA |
| If lab uses a 3-filtration unit manifold, does it mean that for that manifold a series of 10 samples can be filtered with a start and end blank (for batch of 10)? | Item 4 |
| In the filtration unit - you have to run a method blank before and after the filtration series, so why does it need a method blank every 10 samples, if there is one in the beggining and close of each sample? | Item 4 |
| what about sample in one funnel, However each samples requiere 5 dilutions? | Item 4 |
| How does thiss apply to idexx bottles with purchase water. | NA |
| If we filter 14 samples using disposable unit(one unit for each sample). How many blank we need to run? | Item 4 |
| Maifold has 3 filterunits. samples are tested using the 3 filter units. After 10 successive filtrations, method blank is done. Should a method blank also be done once ecah unit has ben used for 10 samples? | Item 4 |
| Ammonia is no longer a requirement? | Item A |
| so it says shall have documented records, the purchased water comes with documents, but does that mean we need to do it monthly as well or when in use?¬what i mean is the document it comes with... would that satisfy the requirement?¬ | Item A |

| Question/Comment | Status |
|---|---|
| Our filtration manifolds have up to 6 filtration units. If all 6 are used during filtration, are the beginning and end checks required for all filtration units used? | Item 4 |
| Does that that mean per lot number | Item 2 |
| so would you suggest to do it monthly per lot number? | Item A |
| If you perform and have positives on mutiple methods - Does EACH analyst have to do a duplicate count on EACH method? | Item 5 |
| What if you have four (4) analysts? Do they all have to check? | Item 5 |
| Would that apply to SimPlate count? | Item 5 |
| For those drinking water labs that don't get positives they have to do a quarterly spike to ensure they see a positive result. | Item 5 |
| And duplicates for each analyst? | Item 5 |
| Would that apply to Biosolids Method 1680? or is this just for liquid matrix samples? | Item 5 |
| Is it required to perform specify counts on MTF method? | Item 5 |
| For Quanti-Tray analysis- we parallel count the positive wells. Can we compare the MPN values rather than the positive wells? | Item 5 |
| so if you have four analysts you do four counts total , not two per analyst? | Item 5 |
| We have to do it on HPC testing as well | Item 5 |
| You mentioned RSD for precision, cna you use the log calculation of Deviation for shared readings (interanalyst and intralab)? | Item 5 |
| For more than 2 analysts, 10% difference means the RSD is less than or equal to 10%, correct? | Item 5 |
| If the testing method is not perform for a month, is it need to prepare matrix sprike? | Item 5 |
| Can we use our own sample or it is need to be purchased | Item 5 |
| Should TNI add Balance & Weights, in section 1.7.3.7 b) ? | NA |
| If we have 4 analysts working different shifts, is it acceptable to have 2 analysts duplicate reading on one sample, and the other 2 analysts reading on another sample for the same test method? Or do all 4 analysts have to read the same positive sample? | Item 5 |
| for the count comparisons the formula for percent difference should be defined. | Item 5 |
| If the water is suspected to be chlorinated, but the conditions are met, the lab does NOT need to check for chlorine? | Item 7 |
| ¬For precision (RSD or %D), using log calculation does not equte to %? Is that a problem? Also is it RPD of average result for HPC or SimPlate?¬ | Item 5 |
| are the quarterly uv light checks only required if using the uv light for disinfection, not for viewing fluorescence? | NA |
| Did you say One sample for all four microbiologists? | Item 5 |

| Question/Comment | Status |
|---|---|
| The duplicates have to be on the SAME sample... How can that be done with schedules for 4 or more analysts? | Item 5 |
| If a lab uses only 100 ml purchased reagent water for sample prep. Can you ignore the monthly water monitoring, as long as you are monitoring requirements per lot as per vendor certificates | Item A |
| Reagent water - Do we need to test all the required parameters after PM (e.g., TOC in addition to NH3)? | Item A |
| Is disinfectant residual need to be check on ground water samples or non-potable water samples? | Item 7 |
| Is there anything on the lab bottle and media C of A is does not have to be rechecked in the lab? for example volume check? | NA |
| How long are the sterility checks good for? If the reagent/supplies are indiviually sealed is the check good until the manufacturer expiration? | NA |
| Our laboratory buys all water (dilution or sterile water), and you are saying that the lab must make sure the water quality is checked. Besides the sterility check - does that mean we have to send at least one per batch for metals, cond, etc. analyses? | Item A |
| ¬Guidance on how to establish the uniformity of temperature distribution and equilibrium conditions in incubators and water baths prior to first use after installation or service would be useful. And also what to do with that information | Guidance Doc |
| ¬Micro analyst IDC = would QC (+/- controls count as IDC vs 4 replicates (similar to chem); how about PT, QC? What if the method does not have IDC accpetance limits?¬ | NA |
| Wow! thats a lot of burden and expensive for a laboratory, taken into consideration that the lab must be certified on those analysis. | NA |
| where can we find the requirements or more infor in the membership? | NA |
| How do we manage blanks that shows hits, are the samples following the the blanks reportable | NA |
| If no positives, would a sample need to be spiked (I think was asked?) | Item 5 |
| Does the media fluorescence check (SM 9223B) have to be done before incubation or after incubation? If after, is it to be done after 24 hours or 48 hours? | NA |
| If a brand thermometer is used for the very first time in the lab. The manufacture on the certificate of analysis says to do the next calibration after 2 years. The Method requires to do the calibration every year. What will you do? | NA |