Microbiology Expert Committee (MEC)
Meeting Summary

January 12, 2021

1. Roll Call:

Kasey, Chair, called the meeting to order at 1:30pm Eastern on January 12, 2021 by teleconference. Attendance is recorded in Attachment A – there were 11 members present. Associate: Nigel Allison, Jennifer Best, Erin Consuegra, Robin Cook, Dwayne Burkholder, Tiffany Carey, Chris Fuller (joined 2pm EST) and Tina Buttermore.

The November and December 2020 Minutes were distributed by email for review. The November minutes were not reviewed in December. A motion was made by Cody to approve the November 10, 2020 and December 8, 2020 minutes as written. The motion was second by Hunter and unanimously approved. The minutes will be posted on the TNI website.

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. 2021 Goals and 2020 Accomplishments

Ilona displayed last year's presentation with the 2020 Goals and 2019 Accomplishments on Webex. The Committee reviewed the language and Kasey and Cody prepared an initial DRAFT. The final version will be included in Attachment E.

Ilona asked about whether more work needs to be done on Method Codes. Jennifer Best commented that work on codes has not been moving forward in EPA so this would make it difficult for TNI to continue. It will be left on the backburner.

3. Work on Comments from Public Webinar

The Committee planned to start where they left off on Item 2 comments (see Attachment D prepared during the December meeting). Kasey reminded labs that Item 1 dealt with testing of supplies at the destination laboratory. Cody noted that the Committee actually received an email this month with a concern about Item 1. If there is concern about it losing integrity during shipment, should the Committee consider testing once per shipment and not just once per lot. Robin Cook agrees with this concern and it should be tied to shipment. Robin also commented that she doesn't see an issue like this often because microbiology supplies often have a short hold time, so there isn't an issue of

another lab stockpiling it and sending another shipment of the same batch. Bottles are a different situation. It should be clarified. A lab is more likely to a shipment of multiple lots in a shipment than the same lot in multiple shipments.

There is a concern that the Committee may be complicating this. It would be difficult to define lot. Robin noted that maybe the Committee should look at a definition. Jennifer Best commented that she doesn't think this should be defined. It should be common sense. Is it a manufacturer's lot or a lot from the lab? Etc … If the lab receives a shipment in February and another one in March … each of these shipments would have been exposed to different things because they are separate shipments. Jennifer reminded people that the states are responsible for the implementation of the Program. They have to make decisions and apply common sense. We can't come up with every scenario. If you leave it up to the labs, you are asking them to decide the risk. Is this appropriate?

Robin suggested looking to see if there is a definition for Lot in the Glossary. If it doesn't exist or the Committee thinks it needs to be expanded, this should be discussed with the Chair of the CSDP EC since he is also working on the Glossary. Kasey will also bring up Lot on the next CSDP EC call.

The issue raised in the webinar was related to "sister" laboratories. It was pointed out that there is an exception in Section 1.7.3.1.d.iii.

Kasey will send a copy of the Standard if a committee member does not have one and they are actively working on the Standard. The copy can only be used for Committee use and cannot be distributed to anyone else.

Jody asked Kasey to send her the language being looked in the Standard at so she can work on some suggested language. Kasey noted that everything in red/track changes are the changes. The black text is the original text of the 2016 Standard.

Robin asked that the language be clarified to: The laboratory of use, except where specified, shall demonstrate and document ….

Item 2 dealt with sterility checks. The Committee started work on language in the Standard during the last call but ran out of time.

Does the Committee want non-selective or nonselective? It is hyphenated in the Small Lab Handbook and hyphenated sometimes in Standard Methods. Jennifer Best noted that Standard Methods just got a new style editor … so this may change. Jennifer will check into it and get back to the Committee.

Item 3 – Specific Conductance to Connectivity. Trying to harmonize with Standard Methods. Easy fix.

Item 4 – Method Blanks. The Committee created an Implementation Guidance for this one. Kasey read the guidance. Cody suggested putting the middle sentence at the end. There was general agreement. The change was made.

Jody asked if "shall" should be "must". Kasey noted that CSDP EC is looking at this.

There are only a few more items to cover.

4. Membership

The call was ended for attendees and non-voting Committee members (Associate Members).

Kasey distributed information about the candidates by email.

Christabel and Enoma have agreed to a second term. A motion was made by Cody to approve a second term for Christabel and Enoma. The motion was seconded by Mike B. and unanimously approved.

Mike Blades has requested to not serve a second term as a voting member but will continue as an Associate member.

Kasey and Cody stated they would be willing to serve another year as Chair and Vice-Chair. There were no other volunteers to serve in these roles. A motion was made by Enoma to have Kasey and Cody serve as Chair and Vice-Chair for 2021. The motion was seconded by Hunter and unanimously approved.

The new candidates for membership are Robin Cook and Ashley Larssen. A motion was made by Cody to add Robin Cook and Ashley Larssen for their first 3-year term starting on February 1, 2021. The motion was seconded by Enoma and unanimously approved.

5. Action Items

See Attachments B and C for updates to action items. Kasey took a look at Action Items.

6. New Business

None.

7. Next Meeting and Close

The next meeting will be held at the TNI Virtual Conference on January 26, 2021 from 3:30 – 5pm Eastern. The next regular teleconference will be on February 9, 2021 at 1:30pm Eastern.

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

Kasey adjourned the meeting at 2:52 pm Eastern. (Motion: Cody. Second: Mike B. Unanimous approval.)

Attachment A

Participants
Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information
Kasey Raley (Chair) (2023) **Present**	Eurofins Eaton Analytical, Inc.	Lab	KaseyRaley@eurofinsUS.com
Michael Carpinona (2022*) **Absent**	NJ DEP	AB	Michael.Carpinona@dep.nj.gov
Cody Danielson (Vice-Chair). (2022*) **Present**	Oklahoma	AB	Cody.Danielson@deq.ok.gov
Jessica Hoch (2022) **Absent**	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
	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*) **Present**	City of Wichita Falls – Water Purification	Lab	hunter.adams@wichitafallstx.gov
Enoma Omoregie (2024) **Present**	NYCDEP	Other	eomoregie@health.nyc.gov
Christabel Monteiro (2024) **Present**	ESC	Lab	cmonteiro@esclabsciences.com
Patrick Roundhill (2023*) **Present**	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. 1/12/20 – update – Complete Leave on Backburner/Reminder list.
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	Complete
104	Implementation Guidance for Equilibrium.	Committee	TBD	
105	Discuss definition of Lot with Chair of CSDP EC.	Kasey Paul Junio	2/11/21	
106	Send new membership information to the CSDP EC Chair for approval.	Ilona Kasey	2/11/21	

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.

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

Attachment E: Microbiology Expert Committee 2021 Goals and 2020 Accomplishments

Microbiology

2020 Accomplishments

During the 2020 calendar year the TNI Microbiology Expert Committee (MEC) began the process for revising Volume 1 Module 5 of the 2016 TNI Standard by preparing a Recommended Changes Summary table and holding a public webinar in December to receive feedback from stakeholders. The MEC responded to 2 Standard Interpretation Requests and submitted Implementation Guidance to the LASEC regarding frequency of method blanks related to samples. In addition, the TNI Microbiology Expert Committee assisted the Quality Systems Expert Committee with ongoing drafts of the Technical Manager language for future revisions of the Standard.

2021 Goals/Plans

- Continue process for Volume 1 Module 5 revision.
- Respond to Standard Interpretation Requests.
- Prepare Implementation Guidance regarding Incubator Equilibrium checks.
- Review Charter.