Microbiology Expert Committee (MEC)
Meeting Summary

September 11, 2018

1. Roll Call and Minutes:

Robin Cook, Chair, called the meeting to order at 1:30pm Eastern by teleconference on September 11, 2018. Attendance is recorded in Attachment A – there were 7 members present. Associate Members: Mary Robinson.

The August 9, 2018 minutes were sent by email. A motion was made by Patsy to approve the August 9, 2018 minutes as written. The motion was seconded by Mike and unanimously approved. They will be posted on the TNI website.

The May and June minutes still need to be approved, but not everyone could pull them up to review them. These will be revisited at another meeting.

2. SIR – 2016 Standard

Robin reviewed the following SIR received from Lynn Bradley:

SIR #331

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.1 a)
Describe the problem: The 2016 TNI Standard is clear in V1M5 section 1.7.3.1 a) that all materials and supplies… must be checked by the laboratory once per lot, or as appropriate (for media). It is understood that this means that the manufacture's certificate is not adequate, and it is the laboratory's responsibility to verify and document sterility. The question then is, does this laboratory check have to be on-site or can lots be checked corporately? Example: 120mL IDEXX bottles are purchased by a laboratory, checked, stored and forwarded to a sister laboratory (located in a different State) as needed. Since the first laboratory checked them, and there is easy access to that lab's records, does the sister lab need to check the same lot again?	

Robin commented that if we don't accept the manufacturer's certificate, there isn't any difference as described above.

Patsy commented that this is in the Standard to ensure nothing happened during shipment. The sterility needs to be checked at the lab location using them.

Kasey pointed out that is a separate lab.

Patsy commented that even if manufacturer certificates are accepted in the future, they should not be accepted for sterility. Sterility should be checked by the receiving lab.

What if they are sealed? Everyone agreed it doesn't make a difference.

The committee drafted language for a response:

The laboratory location using the materials is responsible for performing the sterility check. Using the example provided, each sister laboratory is required to perform their own sterility check. The sterility check does not need to be performed until the items are received in their final location of use. Again, using the example provided, the initial receiving laboratory does not need to check sterility unless they are also using some of that lot.

There are networks that centralize some ordering and then the items are distributed to laboratories in the network. Things that can be affected during shipping need to be checked at the final location of use.

Robin will send out the DRAFT response to the Committee for any comments before voting by email.

3. 2016 TNI Standard Training

The Microbiology training is scheduled for October 11, 2018.

Ilona clarified that the training will be somewhat similar to what was done in Houston, but it will be expanded to include implementation help based on the Small Lab Handbook, SIRs and any other areas

Robin asked the assessors on the call what kind of issues labs are having:

- Adding correction factors to thermometers.
- Correction factors based on NIST calibration check. Need to take this into account when checking the calibration of lab thermometers.
- Method uncertainty calculation for microbiology.
- Single point calibration – when is it acceptable to use it?
- Are there things people can begin implementing now? (Ilona will send Robin a copy of the presentation being worked on for this Thursday. Jerry has a slide on this. She can expand on it if useful.)
- Inhibitory residue test.

Ilona noted that a 10 question quiz with answer key will be needed. The Committee can also be thinking about how to give the quiz - throughout the training or at the end.

Robin will be going out to California in February 2019 to help with some of this same type of training.

Robin asked the group to continue thinking about what to include in the training. She would also welcome some question ideas. There will be a lot of email correspondence coming from Robin over the next month.

4. Action Items

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

5. New Business

Vanessa reviewed a Technical Director requirement issue in regards to an applicant with a clinical/nursing background. Robin noted that people that come from a clinical lab setting and into the environmental setting struggle. Vanessa noted the person does have environmental lab experience, but her education is clinical. Her degree is BS in Clinical Lab Science (a medical technician). Robin reviewed the language in the Standard. It is clear that the degree must be in specific areas or there is an additional paragraph that gives some flexibility but only for being a technical director over three tests and no other tests. This application could be a problem. Vanessa is the AB and can make the final decision. If the limited scope works … this might work.

Robin has gotten some information from Jennifer about Method Codes, but she hasn't had a chance to review it. It summarized some of the challenges she has run into. This will be tabled until November.

Technical Director – Deb is still working on this. An update will be sent to the committee for review in the next few months. The ABs need something they can assess to.

6. Next Meeting and Close

The next meeting will be held by teleconference on October 9, 2018 at 1:30pm Eastern.

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

Robin adjourned the meeting at 2:34 pm Eastern.

Attachment A
Participants
Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information
Robin Cook (Chair) (2019) **Present**	City of Daytona Beach EML	Lab	cookr@codb.us
Patsy Root (2019) **Present**	IDEXX Laboratories, Inc	Other	patsy-root@idexx.com
Lew Denny (2021*) **Absent**	Flowers Chemical Laboratories – North	Lab	lewdenny@comcast.net
Jessica Hoch (2019*) **Present**	TCEQ	AB	Jessica.Hoch@Tceq.Texas.Gov
Deb Waller (2019) **Absent**	NJ DEP	AB	debra.waller@dep.nj.gov
Dwayne Burkholder (2019) **Absent**	Pennsylvania DEP	AB	dburkholde@pa.gov
Michael Blades (2021*) **Present**	ERA	Other	mblades@eraqc.com
Brad Stawick (2019*) **Absent**		Lab	Brad.stawick@stawicklabmgt.com
Kasey Raley (Vice-chair) (2020*) **Present**	Eurofins Eaton Analytical, Inc.	Lab	KaseyRaley@eurofinsUS.com
Vanessa Soto Contreras (2020*) **Present**	Florida DOH	AB	Vanessa.SotoContreras@flhealth.gov
Gary Yakub (2020) **Absent**	Environmental Standards, Inc.	Other	gyakub@envstd.com
Enoma Omoregie (2021*) **Absent**	NYCDEP	Other	eomoregie@health.nyc.gov
Christabel Monteiro (2021*) **Present**	ESC	Lab	cmonteiro@esclabsciences.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
1	Review Method codes and send comments to Robin for Dan Hickman.	Deb	TBD	
19	Provide EPA interpretation on temperature readings to Ilona. She will have it posted on the website.	Robin	1/31/14	
74	Send questions for ABs regarding method codes to Robin.	ALL	3/15/18	
76	Provide an update on what has been done with the databases after Jennifer's review and internal EPA meetings.	Jennifer	4/10/18	
78	Forward link to PDFs on DW website with rule, method and analyte information.	Jennifer	3/31/18	
81				

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter (if needed) in October 2018.	n/a	Ongoing