Microbiology Expert Committee (MEC)
Meeting Summary
San Antonio, TX

January 18, 2022

1. Roll Call:

   Cody, Chair, called the meeting to order at 10:15am Central in San Antonio, TX on January 18, 2021 by teleconference. Attendance is recorded in Attachment A – there were 3 voting members present: Cody Danielson, Ashley Larssen and Elisa Snyder. There were not enough members present to do any committee business.

2. Committee Update

   Cody reviewed the Committee's accomplishments in 2021 and the goals for 2022 (Attachment A).

3. Formal Comments to DRAFT Standard

   Cody reviewed comments received to the posted DRAFT Standard.

   Comment 1:
   The Committee thinks this will likely be voted Persuasive. Cody pulled up the DRAFT Standard to show what was proposed. This will likely be updated in the new Standard.

   It was commented that certified and accredited are not definitions in TNI. It is not clear what these mean. Do they have to be TNI accredited for the parameter?

   Paul Junio noted he believes this is addressed in Module 2 – "In compliance with the Standard". Ilona noted that compliance with the Standard is different than being an accredited or certified lab. Need to look at exact wording.

   Need to evaluate this information and look for impact on the Standard.

   Comment 4: Looking at making it persuasive too.

   Comment 3: Cody pulled this up in the Standard. The committee is looking at making this Non-Persuasive. They believe this is addressed in the Standard and do not want to be too proscriptive. They made updates to Section 1.7.3.1.

   Cody reminded people that the DRAFT standard can still be viewed by looking at historical news items when it was posted for comments.

Comment 2:

A number of people leave it in the water bath so you don't have the fluctuation that air incubators have. Seems like this should be better addressed.

One person noted they are using a non-circulating water bath. Cody does not think this needs a distribution test. Need to make sure you don't over warm. Since it is not being used for the analysis, it is not held to the same requirements. Hot and cold spots are a problem with non-circulating water baths … so could be a problem if you are using it for the analysis. You'd want to do a full load study.

Comment 5: This was related to a previous SIR. The Committee is looking at making this Persuasive.

Comment 7: Looking at Persuasive on this one too.

The Committee is still working on #6. Need to look at "verification" language in Module 2 to see if more language is needed.

The remaining comments have not been looked at yet. She reviewed what the comment entailed and ask for comments:

Comment 8 - Labs in attendance were not concerned about this. It is hard to define what an object would be. Use language such as "representative in size" to help define what an object would be.

Comment 9 -
Implementation guidance was prepared for this one and incorporated into the Standard. Offhand, Cody thinks the group might call this non-persuasive. Implementing the guidance into the standard.

Comment 10 -
Similar to one above. They will both be considered.

4. Implementation Guidance

The Committee still needs to work on Implementation Guidance on how to do equilibrium testing.

The Standard implies blanks need to be run even if all filtration units aren't being used. Maybe change wording to "Filtration units in use".

5. Microbiology Training

Cody presented a course idea the Committee is considering – Understanding Microbiology. See Attachment A for DRAFT course description.

This is not just a review of the standard. Basic skills and techniques will be discussed.

Cody noted that she would like to make a list of questions people have so these can be addressed in the class.

- Provide examples of typical ways to deal with issues many labs confront. How much glowing is glowing? How do you decide?
- Use pictures! Color pictures. Keep color blind people in mind.
- Is there any way this can be assessor training? Ilona commented it could be a component. Depends on the final list of Learning Objectives.
- Is this meant for competency? Ilona suggested coming to the meeting on Thursday where this will be discussed.
- Carl Kircher provided a list of things that should be considered when developing the class. He was asked to participate in the class development so these ideas can be included. He also noted that microbiology testing has 3 phases: Presumptive phase, Confirmed phase and Completed phase testing (many people don't do this anymore.)
- Enumerative and quantitative methods - explain difference
- Should emerging technologies be addressed: viruses, immunoassay, etc.
- Could this be a series of classes instead of one class? Wish there would be more time to follow-up on this. Do several shorter trainings instead of one or two long ones.
- How long do you incubate a sterility check?
- Doing QC for new media?
- Positive and negative controls.
- Major problems AB sees are related to meeting holding times and preservation checks.
- Pay attention to incubation times.
- Maybe do the training in person? Do a kick-off in NEMC with the option to do in person. The webinar component is very important to people.
- Carl Kircher: Presumptive, pre phase and completed phase testing. How to you verify things are pure. Being able to tell the difference of enumerative testing and

quantal methods (MPN). CFU vs MPN. Advanced courses: consider some advanced topics.

- Carl Kircher: Major problems for micro are preservation checks and meeting holding times (8 hours). Constant and consistent test conditions, include in micro training. Immunoassay or polymerase chain reaction does this follow module 4 for chemistry or microbiology? Which module to follow.

- Include not only basics for QC but include going above and beyond to include all the QC needed. Suggest not to have 1 3 hour course, but a series of courses.

6. SIR 423

There was an SIR just received for the committee to address:

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.6.d

Describe the problem:
In a recently published SIR of V1M5: 1.7.3.b.i, the interpretation allows the media performance testing language of "at a minimum with first use" to be applied by the laboratory as "before first use, or with the first used". V1M5: 1.7.3.6.d states that each batch of ready-to-use lot of medium and each batch of medium prepared in the laboratory shall be tested with at least one or more known negative and positive culture control 'prior to first use of the medium".

These sections do not specify that the culture controls must be performed "by the laboratory" (as stated in V1M5: 1.7.3.1.a for sterility checks), nor do they specify "the laboratory shall perform" the culture controls on media (as stated in V1M5: 1.7.3.1.a.i for sterility checks). V1M5: 1.7.3.6.d states that the media must be tested with known positive and negative culture controls prior to first use, but not why whom.

Are positive and negative culture controls that have been performed by the media manufacturer for pre-prepared, ready-to-use medium or medium prepared in the laboratory, or both acceptable to meet this TNI requirement?

It needs to be done at the sister labs - that is the intention.

Can you go down with cleaning method procedure for soft water or do you need to edit the method for that? It was suggested to speak with the AB on this.

Paul Junio reminded people that until an SIR is final … it is not final. Must be published on the TNI website.

Ilona gave a summary of the SIR process and Maria Friedma (Chair, LASEC) confirmed Ilona's summary and gave a little more detail on when LASEC and the SIR subcommittee meet.

5. Next Meeting and Close

The next meeting will be February 8, 2022 via conference call at 1:30pm Eastern.

Cody adjourned the meeting at 11:57 pm Central.

Forum on Environmental Accreditation
TNI Microbiology Expert Committee

Working Meeting
January 18th, 2022
San Antonio, TX

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Meet the Microbiology Expert Committee

Name	Role	Organization	Group
Cody Danielson	Chair	OK DEQ	Lab
Robin Cook	Vice Chair	City of Daytona Beach	Lab
Hunter Adams	Voting Member	City of Wichita Falls	Lab
Vanessa Soto Contreras	Voting Member	Florida DOH	AB
Jody Frymire	Voting Member	IDEXX Laboratories	Other
Lily Giles	Voting Member	Louisiana DEQ	AB
Jessica Hoch	Voting Member	TCEQ	Other
Ashley Larssen	Voting Member	KC Water	Lab
Christabel Monteiro	Voting Member	ESC Lab Sciences	Lab
Enoma Omoregie	Voting Member	NYC DOHMH	Lab
Mary Robinson	Voting Member	Indiana State Dept of Health	AB
Elisa Snyder	Voting Member	City of Austin-Austin Water	Lab
Ilona Taunton	Program Administrator	The NELAC Institute	N/A

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Microbiology Expert Committee

- **2021 Accomplishments**
  - Completed Volume 1 Module 5 DRAFT Standard.
  - Completed 2 SIRs.
  - Updated Charter based on new Strategic Plan.
  - Completed Implementation Guidance on Membrane Filtration Blank.
  - Chair participated on Competency Task Force related to Technical Manager requirements.
- **2022 Goals**
  - Complete Volume 1 Module 5 update.
  - Develop "Understanding Microbiology" Webinar course.
  - Continue to respond to Standard Interpretation Requests.
  - Prepare Implementation Guidance regarding Incubator Equilibrium checks.
  - Support Quality Management System's efforts to finalize language for Technical Manager/Technical Expert.

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Microbiology Expert Committee

Meeting Agenda
January 18th, 2022

I. Welcome and Roll Call. This meeting will be a working meeting (if quorum)
II. Approve December Minutes (if available and quorum)
III. Membership
  I. The MEC is actively seeking out Other and AB stakeholder members. If you are interested, please submit an application
IV. Discussion of Official Comments to the DS
  I. Input from audience welcome
V. Discussion of Microbiology Technical Training
  I. Input from audience welcome
VI. New SIR 423
VII. Additional Questions/Comments

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Microbiology Expert Committee

"Understanding Microbiology" Webinar Course

- The MEC has been tasked with developing and presenting a webinar course. The following suggestions have been made:

- Plan for a 2-3 hour class
- Create a test to be taken at the end of the class
- The training will not be over the Standard, but how to implement QC requirements of the standard and other regulator programs as well as training on Microbiological techniques

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Microbiology Expert Committee

"Understanding Microbiology" Webinar Course

- The MEC has been tasked with developing and presenting a webinar course. The following description has been suggested:

This course will focus on the basic skills and techniques, such as aseptic technique and serial dilution, along with some basic knowledge required to successfully perform microbiological analysis of environmental samples. This course will also outline some of the required QC components of Module 5 of the 2016 TNI standard and various regulatory programs, and how these requirements can be implemented. Analysts seeking to expand their knowledge beyond the standard by learning details regarding method selection as it relates to regulatory program approved methods and how-to approaches of QC practices should take this course.

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Microbiology Expert Committee

"Understanding Microbiology" Webinar Course

- The MEC has been tasked with developing and presenting a webinar course. The following topics have been suggested:

- Brief program requirements
- A brief description of the theory behind the methods
- What the analysis measures
- How the measured result relates to wastewater quality
- An overview of how the analysis is performed
- Basic quality control
- Some tips for optimal method performance
- Some common issues with method performance, and how they may be avoided or overcome

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Microbiology Expert Committee

SIR 423 for Micro (12/26/21)

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.6.d

Describe the problem:

In a recently published SIR of V1M5: 1.7.3.b.i, the interpretation allows the media performance testing language of "at a minimum with first use" to be applied by the laboratory as "before first use, or with the first used". V1M5: 1.7.3.6.d states that each batch of ready-to-use lot of medium and each batch of medium prepared in the laboratory shall be tested with at least one or more known negative and positive culture control "prior to first use of the medium".

These sections do not specify that the culture controls must be performed "by the laboratory" (as stated in V1M5: 1.7.3.1.a for sterility checks), nor do they specify "the laboratory shall perform" the culture controls on media (as stated in V1M5: 1.7.3.1.a.i for sterility checks). V1M5: 1.7.3.6.d states that the media must be tested with known positive and negative culture controls prior to first use, but not why whom.

Are positive and negative culture controls that have been performed by the media manufacturer for pre-prepared, ready-to-use medium or medium prepared in the laboratory, or both acceptable to meet this TNI requirement?

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Microbiology Expert Committee

SIR 423 for Micro (12/26/21)

- The following SIRs are applicable to SIR 423:

Standard Interpretation

Standard: 2016
Section: V1M5, Section 1.7.3.1 (b)

REQUEST:

V1M5: 1.7.3.1.b.i states, "All media shall be tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, and growth inhibition). These tests shall be performed at a minimum with first use."

Is the intention to require that the 'minimum' testing MUST be performed during/with first use, or is 'before first use' acceptable?

TNI FINAL RESPONSE:

Performance testing is required to be performed before the first use, or with the first use. The laboratory may determine the approach they prefer.

Standard Interpretation

Standard: 2016
Section: V1M5, Section 1.7.3.1 (g)

REQUEST:

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 also clear that the laboratory must perform and document the quality of the reagents and media used as appropriate for the analytical method. If there is, does this laboratory check have to be on-site or can lots be checked concurrently? Example: 500mL EDDX 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?

TNI FINAL 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. A sterility check does not need to be performed until the items are received in their final location of use.

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Microbiology Expert Committee

SIR 423 for Micro (12/26/21)

- Also applicable to SIR 423 is the DS of V1M5:

1.7.3	Quality Control
1.7.3.1	Quality, Selectivity, and Sterility of Standards, Reagents, Materials, and Media
	The laboratory performing the sample analysis, except where specified in Section 1.7.3.1.d.ii and Section 1.7.3.1.d.iii, shall perform and document the quality of the reagents and media used as appropriate for the analytical method.

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Microbiology Expert Committee

SIR 423 for Micro (12/26/21)

- Suggested response, utilizing language from existing completed SIRs and language from the DS:

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.6.d
Committee Comment:	
Response: The laboratory location using the materials shall perform and document the quality of the reagents and media used as appropriate for the analytical method. Using the example provided, each sister laboratory is required to perform their own testing with positive and negative culture controls. This quality control check does not need to be performed until the items are received in their final location of use. This has been clarified in the Draft Standard of V1M5 in Section 1.7.3.1.	

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Contacts/Comments

Please feel free to reach out to the Microbiology Expert Committee:

CHAIR	Cody Danielson	cody.danielson@deq.ok.gov
VICE-CHAIR	Robin Cook	cookrobin@codb.us
PROGRAM ADMINISTRATOR	Ilona Taunton	ilona.taunton@nelac-institute.org

If you are interested in joining the Committee as an Associate or Voting member, please fill out an application- we would love to have you as part of our team!

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