Microbiology Expert Committee (MEC)
Meeting Summary

August 10, 2021

1. Roll Call:

   Cody Danielson, Vice Chair, called the meeting to order at 9am Eastern by webinar on August 10, 2021 during the TNI Accreditation Forum. Attendance is recorded in Attachment A – there were 4 members present. Associates present: Carl Kircher, Debbie Bond and Paul Junio.

   Cody reviewed the agenda for the meeting and no changes were made.

2. Membership

   The Committee is currently recruiting new members. Membership currently includes 4 ABs, 6 Labs and 3 Others.

3. Discussion of Proposed Changes to Microbiology V1M5

   Cody shared the changes to the 2016 Standard in a PPT presentation (Attachment B). These are all the non-editorial changes.

   Question: Why not indicate accredited and not just certified?
   V1M5 1.7.3.1. The Committee did not make this change. It is legacy language. May take a look at it and see if a change is warranted. Ilona reminded people that if this is important to the commenter, be sure to comment on the Voting Draft Standard that is now up on the TNI website.

   The link to Implementation Guidance Documents was shared: https://nelac-institute.org/content/NELAP/interpret.php

   The DRAFT Standard has been posted on the TNI website for comment over the next 90 days.

   BREAK

4. Upcoming Projects: Implementation Guidance for Equilibrium Testing V1M5: 1.7.3.7.b.v.a

   Cody pulled up a copy of the new DRAFT Standard and read the language – Section 1.7.3.6.b.v.a:

   > The laboratory shall establish the uniformity of temperature distribution and equilibrium conditions in incubators and water baths prior to first use after installation or service. The equilibrium check shall include time required after test sample

addition to re-establish equilibrium conditions under full capacity load appropriate for the intended use.

The Committee had a lot of questions about this in the 2016 Standard and are planning to prepare Implementation Guidance. They have not gotten started on this but would like to hear any comments.

Paul noted there is a lot that goes into this, but it comes down to their being a volume of water at a specific temperature and it is going to take a certain amount of time to get to the correct incubation period. He is concerned there is going to be a lot of "tail chasing" in trying to address this.

Cody noted that some labs do it only at installation and service, but others do it annually to see how well their incubators are doing (not a requirement). Needs to be full capacity load because that is the worst-case scenario. Not planning to be overly proscriptive.

Committee members have offered examples of what they do in hopes that this will help write this implementation guidance.

A comment was provided that they think this equilibration requirement should be removed from the next Standard. Others on the call agreed. Too many variables and more stringent than the DW Manual. Cody noted that the requirements in the 2016 Standard are more specific than the 2009 Standard. Elisa noted this came up in an audit and the assessor had trouble with this language.

A comment was made to verify what is in the DW Manual. Paul reviewed what is in the DW Manual – page v-17, Section5.3.1.5. There is a discussion about bringing samples to room temperature and full loads. The TNI Standard has a lot more detail.

Cody suggested that people comment on this part of the Standard.

A comment was made that this was going to be deleted in a previous Standard update, but it was put back in because they were told it is a DW requirement. It was suggested that the Committee talk to Jennifer Best to confirm the requirement.

Paul compared this discussion to temperature loggers in coolers. Do you really want all that data?

There is a lot of confusion about whether samples should be brought to room temperature. Cody noted that some PT providers have this in their instructions, and another does not. Her lab tries to be consistent with all samples. This helps with incubators coming up to temperature too.

5. Current SIRs: SIR 414 Regarding DOCs and Variability/Reproducibility Testing

SIR 414 to Microbiology, July 21, 2021

Deals with Module 2 and 5. Cody read the request:

Describe the problem:
For ongoing DOC e.g. for HPC SimPlate, the lab performs a blind PT sample or a Quality Control sample with results meeting the manufacturer's acceptance criteria. However, we would like to be able to use section 1.6.3.2.e) "A documented process of reviewing QC samples performed by an analyst, or groups of analysts, relative to the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard. This review can be used to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary."

SM/TNI requires repeat counts performed monthly with criteria of 5% RPD for a single analyst or 10% for more than one analyst counting. Can this process be applicable or acceptable to meet section 1.6.3.2.e and be applied for continuing DOC for other analyst who did not actually perform the PT or QCS? If not, please expand on exactly what this section mean with a clear example.

From Lynn Bradley - To the Micro Committee:

Before determining this was a valid SIR, the Chairs asked the submitter “When you refer to an “analyst who did not actually perform the PT or QCS”, are you referring to a group member who did not contribute results to the group for the analysis in question, or did you have something else in mind?” and received the following response:

> Yes, I am specifically referring to the correct interpretation of 1.6.3.2.e) "A documented process of reviewing QC samples performed by an analyst, or groups of analysts, relative to the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard. This review can be used to identify patterns for individuals or groups of analysts and determine if corrective action or retraining is necessary."
>
> Let us assume there are at least 2 analyst but only one performed the QC this year. Both had done the initial DOC and had been performing the particular analysis throughout the year. Repeat counting is required to be done at least once a month with a given acceptance criteria. If the repeat count is done by the second analyst for this QC, can this be considered a continuing DOC for the second analyst who did not analyze the QC?
>
> If not, can you please provide a particular example as to when this can be applied.
>
> Thanks a lot for your clarification.

Cody commented that she and Robin took a brief look at this. Regarding the other analysts that did not perform the PT itself, if the analyst runs the method in full, it could not be applicable. If you only read results, it might be applicable. She asked for additional thought. Paul agreed.

Elisa needed more clarification on what type of sample they were analyzing. Not clear if it is a PT sample or some other blind sample.

It was commented that the IDOC/DOC applies to the analyst. There was agreement.

Paul noted again that the Draft Standard has been posted on the TNI website. It is open for 90 days for comment. There is also a copy of the Summary of Changes document.

Carl commented that the Chemistry Expert Committee is working on IDOC/DOC for the laboratory and segregating those requirements for each analyst. The Microbiology expert committee needs to do this too. Paul doesn't agree with this. The Standard talks about an analyst documentation of capability. Not a laboratory documentation of capability. Paul will share his comment with the Chemistry Expert Committee. Cody made a note and will check on it.

6. New Business

None.

7. Next Meeting and Close

The next regular teleconference will be on September 14, 2021 at 1:30pm Eastern.

The meeting was adjourned the meeting at 11am Eastern. (Motion: Elisa. Second: Jody)

Attachment A

Participants
Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information
Cody Danielson (Chair). (2022*) **Present**	Oklahoma	AB	Cody.Danielson@deq.ok.gov
Robin Cook (Vice-Chair) (2024*) **Absent**	City of Daytona Beach, EML	Lab	cookr@codb.us
Jessica Hoch (2022) **Absent**	TCEQ	Other	Jessica.Hoch@Tceq.Texas.Gov
Lily Giles (2022*) **Absent**	Louisiana	AB	Lily.Giles@LA.GOV
Mary Robinson (2022*) **Absent**	Indiana	AB	mrobinson@isdh.IN.gov
Ashley Larssen (2024*) **Absent**	KC Water	Lab	ashley.larssen@kcmo.org
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 (2024) **Absent**	NYCDEP	Other	eomoregie@health.nyc.gov
Christabel Monteiro (2024) **Present**	Pace National, Analytical	Lab	christabel.monteiro@pacelabs.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

Environmental Measurement Symposium

Summary of Proposed Changes to
2016 Standard Volume 1, Module 5
Quality Systems for Microbiological Testing

TNI Microbiology Expert Committee
8/10/2021 – 9am EST

8/10/21

1

Source of Changes

- All 2016 Standard Interpretation Requests (SIRs) were addressed in this revision
- Several non-SIRs were considered in this revision
- Parts of the standard that were known to cause confusion were considered in this revision
- Changes to other Modules were considered in this revision
- Improvement to the flow of the Standard was considered in this revision

2

Presentation Convention

ORIGINAL TEXT	SUGGESTED CHANGE
The item that was brought up as a potential concern.	What has been drafted for comment in the Working Draft Standard

JUSTIFICATION
The reason why the new language was drafted

3

V1M5 1.7.3.1
[Quality and Sterility of Standards, Reagents, Materials, and Media]

ORIGINAL TEXT	SUGGESTED CHANGE
1.7.3.1 Quality and Sterility of Standards, Reagents, Materials, and Media The laboratory shall demonstrate and document that the quality of the reagents and media used is appropriate for the test concerned including, but not limited to, test conditions and incubation times.	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 is appropriate for the analytical method.

JUSTIFICATION
SIR 331 was addressed to clarify QC checks in parent vs. sister laboratories

4

V1M5 1.7.3.1
[Quality and Sterility of Standards, Reagents, Materials, and Media]

JUSTIFICATION CONTINUED

Standard Interpretation

Standard: 2016
Section: V1M5. Section 1.7.3.1 (a)

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 understood that this means that the manufacturer'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: 10mL DEOX 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.

5

V1M5 1.7.3.1
[Quality and Sterility of Standards, Reagents, Materials, and Media]

JUSTIFICATION CONTINUED

- The SIR was specific to sterility testing, but the interpretation applies to all QC testing outlined in that Section of the Standard
- The exceptions cited are the requirements for reagent water testing. The Working Draft Standard continues to allow these tests to be done by another certified laboratory
- The updates to this part of the Standard include changes related to improved flow of language, and are outlined later in this presentation

6

V1M5 1.7.3.1.a.ii
[Quality and Sterility of Standards, Reagents, Materials, and Media]

ORIGINAL TEXT	SUGGESTED CHANGE
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 per batch of laboratory-sterilized funnels, using non-selective growth media.	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.

JUSTIFICATION

Language was updated to clarify the requirement regarding funnel sterility checks, and to create operational flexibility

7

V1M5 1.7.3.1.b.i
[Quality and Sterility of Standards, Reagents, Materials, and Media]

ORIGINAL TEXT	SUGGESTED CHANGE
1.7.3.1.b.i 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.	b.i All media shall be tested **prior to or at minimum in conjunction with first use for sterility following Section 1.7.3.1.** **b.ii All media shall be tested prior to or at minimum in conjunction with first use for selectivity to ensure the target organism(s) respond in an acceptable and predictable manner once per lot or batch. For selectivity the laboratory shall:**

JUSTIFICATION

SIR 406 was addressed to clarify timing of performance testing

8

V1M5 1.7.3.1.b.i
[Quality and Sterility of Standards, Reagents, Materials, and Media]

JUSTIFICATION CONTINUED

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.1.b

Requests:
"Para. 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?

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.

- ❑ The changes to this part of the Standard include changes related to improved flow of language, and are outlined later in this presentation

9

V1M5 1.7.3.6
Selectivity

SUMMARY OF CHANGES

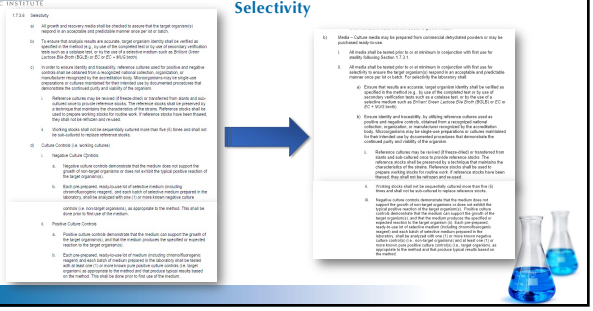
- ❑ The Section of the Standard regarding selectivity testing of media was moved to Section 1.7.3.1.b.ii
- ❑ The title of Section 1.7.3.1 was changed from Quality and Sterility of Standards, Reagents, Materials, and Media to Quality, Selectivity, and Sterility of Standards, Reagents, Materials, and Media
- ❑ Language previously in 1.7.3.6.a was updated when SIR 331 was addressed
- ❑ Subsections previously in 1.7.3.6 regarding positive and negative culture controls were combined

JUSTIFICATION

Language was moved to improve the flow of the Standard

10

V1M5 1.7.3.6
Selectivity



11

V1M5 1.7.3.1.d.ii
[Quality and Sterility of Standards, Reagents, Materials, and Media]

ORIGINAL TEXT	SUGGESTED CHANGE
1.7.3.1.d.ii The laboratory shall monitor the quality of the water for disinfectant residual, specific conductance, total organic carbon, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month. Analysis may be performed by another certified laboratory.	1.7.3.1.d.ii The laboratory shall monitor the quality of the water for disinfectant residual, conductivity, total organic carbon, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month. Analysis may be performed by another certified laboratory.

JUSTIFICATION

Language was updated to harmonize with other standards regarding specific conductance versus conductivity

12

V1M5 1.7.3.2.a [Method Blanks]

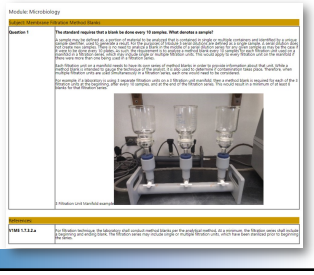
ORIGINAL TEXT	SUGGESTED CHANGE
1.7.3.2.a For filtration technique, the laboratory shall conduct method blanks per the analytical method. At a minimum, the filtration series shall include a beginning and ending blank. The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series.	1.7.3.2.a For filtration technique, the laboratory shall conduct method blanks per the analytical method. **The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series. At a minimum, the filtration series shall include a beginning and ending blank for each filtration unit.**

JUSTIFICATION

Language updated to clarify the requirement for beginning and ending blanks per filtration unit

13

V1M5 1.7.3.2.a [Method Blanks]



14

V1M5 1.7.3.3 Test Variability/Reproducibility

ORIGINAL TEXT	SUGGESTED CHANGE
1.7.3.3 For methods that specify counts (i.e. cfu/100mL or MPN/100mL), such as membrane filter, plated media, or other methods which specify a quantitative result, duplicate counts shall be performed monthly on one (1) positive sample for each month that the test is performed. If the laboratory has two (2) or more analysts, each analyst shall count typical results on the same sample. Counts shall be within ten percent (10%) difference to be acceptable. In a laboratory with only one (1) microbiology analyst, the same sample shall be counted twice by the analyst, with no more than a five percent (5%) difference between the counts.	1.7.3.3 For all methods that specify a quantitative result, duplicate counts must be performed monthly on one (1) positive sample for each month that the test is performed. These counts may be performed on environmental samples or quality control samples. If the laboratory has multiple analysts, all analysts must count results on the same sample, when possible, with no more than ten percent (10%) difference between the counts. In a laboratory with only one (1) analyst, the same sample shall be counted twice by the analyst, with no more than a five percent (5%) difference between the counts.

JUSTIFICATION

SIR 379 was addressed to clarify test variability/reproducibility requirements for all methods that specify a quantitative result, and to create flexibility

15

V1M5 1.7.3.3 Test Variability/Reproducibility

JUSTIFICATION CONTINUED

Standard Interpretation

Standard: 2016
Section: V1M5, Section 1.7.3.3

REQUEST:

My question is regarding the Test Variability/Reproducibility section in the new 2016 standard. The verbiage essentially states to perform for methods that specify counts (i.e. cfu/100mL or MPN/100mL)... " or other methods which specify a quantitative result." My question is, was the intent to hold labs accountable for performing this for IDEXX Quanti-trays as well? It is an MPN method; however, I did not feel the intent was to perform for this method but rather other MPN methods (e.g., multiple tube fermentation). Furthermore, if a laboratory is not obtaining any positive samples over the course of a month using this method, would they still be required to perform one? Standard methods instructs to perform this for plate counting methods, so I wanted to make sure the intent as to what methods to hold labs accountable for.

TNI FINAL RESPONSE:

The standard is clear on the inclusion MPN methods and this does not exclude Quanti-tray. Furthermore, the STD states 'duplicate counts shall be performed monthly'. It would be up to the lab to determine how they obtain the positive sample with which to perform the counts.

16

V1M5 1.7.3.7.b.i Laboratory Equipment

ORIGINAL TEXT	SUGGESTED CHANGE
1.7.3.7.b.i The laboratory shall use temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum-resistance thermometers to assess and document equipment temperatures. The temperature measuring devices shall be appropriate quality to meet specification(s) in the method. The graduation and range of the temperature measuring devices shall be appropriate for the required accuracy of the measurement. Temperature measuring devices shall be verified to national or international standards for temperature. Verification shall be performed at least annually (see TNI Volume 1, Module 2, Section 5.5.13.1). This verification may be accomplished by a single point provided that it represents the method mandated temperature and use conditions.	1.7.3.7.b.i The laboratory shall use temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum-resistance thermometers to assess and document equipment temperatures. The temperature measuring devices shall be appropriate quality to meet specification(s) in the method. The graduation and range of the temperature measuring devices shall be appropriate for the required accuracy of the measurement. Verification shall be performed as per TNI Volume 1, Module 2, Section 5.5.13.1.

JUSTIFICATION

Language updated because Module 2 now includes some of this language, and restating that language was redundant

17

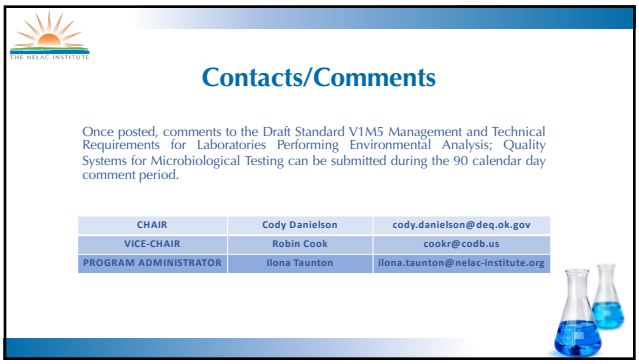
V1M5 1.7.5.2 Sample Handling

ORIGINAL TEXT	SUGGESTED CHANGE
1.7.5.2 Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where disinfectant (e.g. chlorine) usage is suspected (such as a new client or a new source), and all potable water supplies (including source water) shall be checked for absence of disinfectant residual in the laboratory unless all of the following conditions are met:	1.7.5.2 Microbiological samples from known chlorinated sources (such as wastewater effluent), unknown sources where disinfectant (e.g. chlorine) usage is suspected (such as a new client or a new source), and all potable water supplies (including source water) shall be checked for absence of disinfectant residual in the laboratory. Alternatively, the laboratory does not need to test as above if all the below exemptions are met:

JUSTIFICATION

Language updated to clarify the requirement and the allowed exemptions

18


THE NELAC INSTITUTE
Contacts/Comments
Once posted, comments to the Draft Standard V1M5 Management and Technical Requirements for Laboratories Performing Environmental Analysis; Quality Systems for Microbiological Testing can be submitted during the 90 calendar day comment period.
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19