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

**June 14, 2022**

1. Roll Call:

   Cody, Chair, called the meeting to order at 1:30pm Eastern on June 14, 2022, by teleconference. Attendance is recorded in Attachment A – there were 10 voting members present. Associates present: Stacey Chamura, Sviatlana Haubner, Joe Guzman, Tina Buttermore. and Debbie Bond.

2. Crystal City, VA – Summer Meeting

   Who will be attending: Robin, Cody

   Maybe: Jody, Matt

   Not: Amy, Elisa, Ashley

   Cody will be checking in with the Training Work Group to see who will be available in person to help with the training.

3. SIRs

   SIRs 423 and 425 have been returned for another response. This is the original email from Lynn on May 11, 2023:

   *The SIR subcommittee has reviewed the Microbiology Expert committee's responses to SIRs #423 and #425. Upon review, the subcommittee is concerned that the responses to these SIRs reflect the 'wants' or 'intentions' of the expert committee that are not fully supported by the text of the 2016 TNI Standard. Specifically, the expectation that the media performance checks (positive and negative controls - #423; selectivity, sensitivity, sterility, growth promotion, and growth inhibition - #425) must be performed by each individual laboratory location that is using the media.*

   *<u>Regarding response to SIR #423: (V1M5: 1.7.3.6.d):</u>*

   *The SIR sub-committee has reviewed the Microbiology Expert Committee's response to SIR #423 and have the following concerns, questions, and/or comments:*

   *1. The response includes the statement, "Using the example provided, each sister laboratory is required to perform their own testing with positive and negative culture controls." The question posed in SIR #423 does not provide an example nor*

*does it refer to 'sister laboratories'. The sub-committee suspects that this terminology is a copy-paste error from the response to SIR #425. The sub-committee requests that the expert committee review the submitters comments and questions and re-draft a response limited to the question asked in SIR #423.*

*<u>Regarding response to SIR #425 (V1M5: 1.7.3.6.b.i):</u>*

*The SIR sub-committee has reviewed the Microbiology Expert Committee's response to SIR #425 and have the following concerns, questions, and/or comments:*

*1. The subcommittee suggests that the expert committee utilize terminology that is supported within the TNI Standard instead referencing language outside the defined terms because the text of the response needs to be supported with the text of the Standard.*

*<u>Regarding both responses to SIR #423 and #425:</u>*

*1. The expert committee's responses include phrasing that the sub-committee finds unsupported by the text of the standard. The responses include reference to the statements/sections of V1M5: 1.7.3.1.d.ii and iii, which are included under the "Reagent Water" subsection and the specific text from ii and iii states, in part, "Analysis may be performed by another certified laboratory." The expert committee seems to be referencing an allowance in the reagent water subsection to infer a requirement in the rest of the standard module. The subcommittee requests that the expert committee provide additional details and standard citations that support this statement/expectation as it relates to the requirements of V1M5: 1.7.3.6.d and 1.7.3.6.b.*

*2. The expert committee also states "This quality control check must be performed at each location of use" in response to SIR #423 and "All quality control checks, except where specified …, must be performed in the laboratory of use" in response to SIR #425. The sub-committee is concerned that these statements are not supported by the text of the 2016 Standard. The sub-committee requests that the expert committee provide additional details and standard citations that support these statements/expectations as they relate to the requirements of V1M5 1.7.3.6.d. and V1M5 1.7.3.6.b.*

Cody followed up with a message to help prepare for today's meeting:

*As anticipated, our SIRs 423 and 425 have been returned. The reasoning for them being returned is more than what we had discussed at our MEC meeting.*
*I have highlighted the most pertinent comments below (green for 423, yellow for 425, and magenta for comments that apply to both 423 and 425). To summarize: in addition to having issues with the "sister lab" language (which is not in the Standard but did make it through with our SIR 313 response), the committee took issue with the MEC stating that the 2016 Standard supports the requirement that performance and control testing be done at the lab of use.*

*So what is the difference between SIR 313 and SIRs 423/425 where we are getting pushback, you ask?*
*For SIR 313, V1M5, Section 1.7.3.1 (a) does state that sterility checks must be done by the lab and that CoAs shall be verified by the lab. However, 1.7.3.6.d (SIR 423) and 1.7.3.1.b.i (SIR 425) do not include this language. The preamble to 1.7.3.1 does state that "the laboratory shall demonstrate and document that the quality of the reagents and media used…".*

*As a result, below may be the best we can do for these SIRs, since the parent lab/sister lab requirement is in the new DS but not supported by all subsections of the 2016 Standard:*

***SIR 423:** "The language in V1M5 1.7.3.6.d of the 2016 TNI Standard does not prohibit the use of Manufacturer's Certificates of Analysis. Refer to the program, client and AB requirements as appropriate for acceptance guidelines."*

***SIR 425:** "The language in V1M5 1.7.3.1.b.i of the 2016 TNI Standard does not require each laboratory location of use to perform such testing. However, 1.7.3.1 states "The laboratory shall demonstrate and document that the quality of the reagents and media used is appropriate for the test concerned…". Program, client and/or AB requirements may dictate that each location to perform these checks.*

We cannot use language from our current DRAFT Standard, so Cody and Robin worked on the responses above.

SIR 423 discusses CoA's, so this is why Robin is using CoA in the response. She thinks this is the best answer based solely on the 2016 Standard. The Committee discussed this and looked for other solutions within the Standard language and came up with:

The language in V1M5 1.7.3.6.d of the 2016 TNI Standard does not prohibit the use of positive and negative culture controls performed by the manufacturer, however the laboratory must prove that the testing meets the requirements of Section 1.7.3.6.d.i.b and 1.7.3.6.d.ii.b . These Sections of the Standard do explicitly state that lab-prepared media shall be analyzed with control cultures. Refer to the program, client and AB requirements as appropriate for acceptance guidelines.

SIR 425
The Committee considered their response to SIR 423 and discussed different options. The final response recommendation is:

The preamble, Section 1.7.3.1 states "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". Program, client and/or AB requirements may dictate that each location to perform these checks.

Cody will send these revised responses out to the rest of the Committee for comment and then request a vote.

*(Addition: Cody sent the final language to the Committee on 6/14/22 and requested a vote:*

*423:*
*The language in V1M5 1.7.3.6.d of the 2016 TNI Standard does not prohibit the use of positive and negative culture controls performed by the manufacturer, however the laboratory must prove that the testing meets the requirements of Section 1.7.3.6.d.i.b and 1.7.3.6.d.ii.b . These Sections of the Standard do explicitly state that lab-prepared media shall be analyzed with control cultures. Refer to the program, client and AB requirements as appropriate for acceptance guidelines.*

*425:*
*The preamble, Section 1.7.3.1 states "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". Program, client and/or AB requirements may dictate that each location to perform these checks."*

A motion was made by Jody by email on 6/15/23 to approve the responses for SIRs 423 and 425 as sent by Cody on 6/14/23. The motion was seconded by Elisa on 6/15/23. . Vote: on 6/15/23: Robin, Enoma, Cody, For, Elisa, Jody, Christabel, Maria Friedman, Matt, Jessica Hoch. On 6/16: Hunter.

4. Comments to Posted DRAFT Standard - Vote

The Committee will look at Comment 5. This was further discussed by email and Cody sent out revised language last Saturday. Cody pulled up the spreadsheet:

| Quality Systems for Microbiological Testing V1M5 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Disclaimer: The NELAC Institute (TNI) accepts no liability for the content of any comment on a standard. | | | | | | | |
| Any views or opinions on a standard are solely those of the commenter and do not necessarily reflect those of TNI | | | | | | | |
| Comment Number | Vote & Justification Persuasive/Non-Persuasive | Editorial (Y/N) | Section/Clause | Comment | Committee Action | Date Addressed | Committee Comment |
| # | P | Y | 1.2.3.4 | Whatever they said | What was done | When | Related info/justification for decision |
| 5 | P | | 1.7.3.3 | Section 1.7.3.3 The third sentence reads that all analysts must count results on the same sample, when possible. As worded, claims can be made that it may not ever be possible. Suggestion for improvement: If it really should be required that all analysts count the same sample monthly, then delete the phrase "when possible." | 1.7.3.3: For all methods that specify a quantitative result, duplicate counts must be performed monthly on at least 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 each analyst ~~s~~ must count a sample that has also been counted by another analyst. ~~results on the same sample, when possible, with~~ The difference between the counts shall be no more than ten percent (10%) or corrective action shall be taken ~~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. | | Updated to clarify requirement for all analysts to complete this requirement monthly. |

Jody thought that corrective action was added to the end of the final sentence. The last sentence now reads:

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 or corrective action shall be taken.

See Committee Comments above for justification.

A motion was made by Robin that comment #5 is persuasive and to approve the language changes in column F (Committee Action) that are in blue with the correction to the final sentence to add: or corrective action shall be taken. The motion was seconded by Enoma and there was no further discussion.

Roll Call vote:
Cody – For
Matt - For
Amy - For
Robin – For
Ashley - For
Jody – For
Jessica – For
Elisa – For
Enoma – For
Cristabel - For

The motion passed unanimously (10 votes).

Comment #6:

| Quality Systems for Microbiological Testing V1M5 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Disclaimer: The NELAC Institute (TNI) accepts no liability for the content of any comment on a standard. | | | | | | | |
| Any views or opinions on a standard are solely those of the commenter and do not necessarily reflect those of TNI | | | | | | | |
| Comment Number | Vote & Justification Persuasive/Non-Persuasive | Editorial (Y/N) | Section/Clause | Comment | Committee Action | Date Addressed | Committee Comment |
| # | P | Y | 1.2.3.4 | Whatever they said | What was done | When | Related info/justification for decision |
| 6 | NP | | 1.7.3.6.b.i and 1.7.3.6.b.ii.a.4 | Sections 1.7.3.6(b)(i) and 1.7.3.6(b)(ii)(a)(4) The specified requirements for "verification" are somewhat vague in both instances. It could be interpreted as "yes, this is indeed a thermometer" for verification purposes. Suggestion for improvement: Replace all instances of the word "verification" with "calibration verification" in both places. | | | Section 1.7.3.6 cites V1M2 5.5.13.1, which outlines requirements for verifications |

Cody reminded the Committee of the previous discussion. Robin noted that there was a discussion in the last CSDP EC meeting that the things consistent between modules will be pulled up and collected in Module 2 since that module applies to all Modules. Something like this would probably wind up there.

See Committee Comments above for justification.

A motion was made by Robin that Comment #6 is non-persuasive. The motion was seconded by Cristabel and there was no further discussion.

Roll Call vote:
Cody – For
Matt - For
Amy - For
Robin – For
Ashley - For
Jody – For
Jessica – For
Elisa – For
Enoma – For
Cristabel - For

The motion passed unanimously (10 votes).

Comments #1, #4 and #11 should be voted on together. The language between them is consistent. There was a lot of discussion surrounding the word "certified". The change was to "performed by another laboratory that is in compliance with these standards". Cody reviewed the Committee Comment where the justification for the change is.

| Quality Systems for Microbiological Testing V1M5 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Disclaimer: The NELAC Institute (TNI) accepts no liability for the content of any comment on a standard. | | | | | | | |
| Any views or opinions on a standard are solely those of the commenter and do not necessarily reflect those of TNI | | | | | | | |
| Comment Number | Vote & Justification Persuasive/Non-Persuasive | Editorial (Y/N) | Section/Clause | Comment | Committee Action | Date Addressed | Committee Comment |
| # | P | Y | 1.2.3.4 | Whatever they said | What was done | When | Related info/justification for decision |
| 1 | P | | 1.7.3.1.d.ii and 1.7.3.1.d.iii | Please add the word accredited either before or after the word certified lab in the Micro Module Also I have been more specific that the certified/accredited lab be certified/accredited for the specific tests being performed by the laboratory. This statement is not a requirement.(Why is this statement made in the standard if it is not a requirement?) 1.7.3.1.d.ii and iii "Analysis may be performed by another certified laboratory." I suggest the following: Suggested change: "Analysis must be performed by a certified/accredited laboratory for the tests being measured or requested from another laboratory." | 1.7.3.1.d.ii: … Analysis may be performed by another ~~certified~~ laboratory that is in compliance with these standards. 1.7.3.1.d.iii: … Analysis may be performed by another ~~certified~~ laboratory that is in compliance with these standards. | | "Certified laboratory" is not used anywhere else in the Standard. Changed language incorporated into new language for Comment #4 and Comment #11 |
| 4 | P | | 1.7.3.1.d.ii and 1.7.3.1.d.iii | Section 1.7.3.1(d) Subsections (ii) and (iii) mention that if the specified water quality tests are performed by an outside laboratory, that laboratory has to be "certified" (accredited?) for the tests in question. What if the laboratory performs the tests in-house? Does it have to be certified for the water quality analytes tested? Suggestion for improvement: Add a NOTE or additional requirements to Subsections (ii) and (iii) to read as follows: "NOTE: If the laboratory performs these tests itself internally, the laboratory does not need to be accredited for these tests when performed for the purpose of reagent water quality monitoring." | 1.7.3.1.d.ii: … Analysis may be performed by another ~~certified~~ laboratory that is in compliance with these standards. If laboratory only performs these tests for the purpose of reagent water quality monitoring, the laboratory does not need to be accredited for these tests. 1.7.3.1.d.iii: … Analysis may be performed by another ~~certified~~ laboratory that is in compliance with these standards. If laboratory only performs these tests for the purpose of reagent water quality monitoring, the laboratory does not need to be accredited for these tests. | | The intent is not for the laboratory to be accredited for these tests when performing internal testing. Includes language changes from Comment #1. |
| 11 | P | | 1.7.3.1.d.iii | There is not an accredited method that can meet the silica criteria for type I or type II water. | 1.7.3.1.d.iii: The laboratory shall monitor the quality of the water for metals (Cd, Cr, Cu, Ni, Pb, and Zn) and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) annually. ~~An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for High Quality (Type I) or Medium Quality (Type II) reagent water.~~ Analysis may be performed by another laboratory that is in compliance with these standards. An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for High Quality (Type I) or Medium Quality (Type II) reagent water. ~~Analysis may be performed by another certified laboratory.~~ | | Moved the last sentence to immediately after the metals and bacteriological water quality test to clarify that the monitoring applies to those tests only (not silica). Includes language changes from Comment #1. There is an ASTM method for silica, and also some states certify to an SOP. |

Cody would like to start by looking at Comment #1. Amy asked how would you determine if another lab is in compliance? Robin said you can look at their Scope of accreditation. Pennsylvania would not accept this if it doesn't say accredited. Robin noted that there are labs that adopt the TNI Standard, but they are not accredited and it is not required.

What about using "another certified or accredited laboratory"?

Why not use the recommended language in the comment? Maybe the word "must"?

Robin does not think the lab needs to be certified if they are doing it for themselves. Amy doesn't understand why it is OK to not be certified yourself, if you send it out … they have to be certified.

This module is the only one using the term "certified".

Need to be careful how this is approached because different states have different requirements.

This will need to be further discussed by email and at the next meeting.

5. Technical Specialist

Debbie from QMS Expert Committee is asking for comments on educational requirements and how new technologies are added. She would appreciate any feedback.

Amy commented that she does not need diplomas, she needs transcripts.

Look at courses instead of credit hours.

*(Addition: Cody provided the following comments in green on 6/24/23:*
*If you can focus your review on 5.2.6.1.c) and 5.2.6.2 and keep the following in mind, it should address comments received after San Antonio:*

- *Is the grouping of tests/technologies in the second paragraph of 5.2.6.1.c) appropriate? Any test types to add/remove? Is education appropriate?* ***The grouping makes a lot of sense for a lot of Micro labs. I think that it covers all the typical technologies that are not overly complex.***
- *What would be a good experience option for a TM in a lab that would like to add a new or emerging technology to their scope? Education?* ***I think that asking for experience for an emerging technology will get us nowhere. I think it could be covered in the first paragraph of c.***
  ***I also think that we could also that, without a bachelor's degree, if they do have experience in that technology or experience as a TE, they could oversee emerging technologies. For example, you can't come in as a new TE without a bachelor's degree and with no method or TE experience and bring up an emerging technology method, but if you have been a TE for XXX years or have XXX years of experience in that technology, you can be a TE. If we require a bachelor's degree, someone who is currently a TE without that degree who does all other methods won't be allowed to bring on new methods at all, even if they have staff with tons of experience in that method.***
- *Is there a clearer way to say "representative technologies"?* ***What do we mean by that? I suggest changing "experience in the analysis of representative technologies" to "experience in analysis using the technologies"***
- *Quality people missing education—is there a path available to them to be eligible to become TM?*
  - *What do you think of 5.2.6.2(Exceptions)?* ***I am not sure the ABs will like this, but I don't mind it. I think it is a risk based approach and that there could be people who fall into that area that would be great TEs.)***

6. New Business

None

7. Next Meeting and Close

The next meeting will be by teleconference on July 12, 2022, at 1:30pm Eastern.

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

Cody adjourned the meeting at 3:06 pm Eastern.

**Attachment A**

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

| Members | Affiliation | Balance | Contact Information |
|---|---|---|---|
| Cody Danielson (Chair) (2025) **Present** | Oklahoma | Lab | Cody.Danielson@deq.ok.gov |
| Matt Graves (2025*) **Present** | ERA | Other | Matt_graves@waters.com |
| Lily Giles (2025) **Absent** | Louisiana | AB | Lily.Giles@LA.GOV |
| Amy Hackman (2025*) **Present** | Indiana | AB | mrobinson@isdh.IN.gov |
| Robin Cook (Vice Chair) (2024*) **Present** | City of Daytona Beach, EML | Lab | cookr@codb.us |
| Ashley Larssen (2024*) **Present** | KC Water | Lab | ashley.larssen@kcmo.org |
| Jody Frymire (2025) **Present** | IDEXX | Other | Jody-Frymire@idexx.com |
| Jessica Hoch (2025) **Present** | TCEQ | Other | Jessica.hoch@tceq.texas.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) **Present – Added 2pm** | xxx | Lab | eomoregie@health.nyc.gov |
| Christabel Monteiro (2024) **Present** | Pace National, Analytical | Lab | christabel.monteiro@pacelabs.com |
| Robert Royce (2025*) **Absent** | New Jersey | AB | Robert.royce@dep.nj.gov |
| Maria Friedman (2025*) **Absent** | California | AB | qamfriedman@gmail.com |
| Ilona Taunton (Program Administrator) **Absent - Recording** | The NELAC Institute | n/a | Ilona.taunton@nelac-institute.org |

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

| | Action Item | Who | Expected Completion | Actual Completion |
|---|---|---|---|---|
| 104 | Implementation Guidance for Equilibrium. | Committee | TBD | See note in 5/11/21 minutes. |
| 105 | Discuss definition of Lot with Chair of CSDP EC. | Kasey<br>Paul Junio | 2/11/21 | Started, but ongoing.<br>7/13/21: Remove |
| 112 | Develop Understanding Microbiology Course | Cody<br>Committee | TBD | |
| 113 | Complete Response to Draft Comments Process | All | Ongoing | 5/10/22: Voted on Comments: 2, 3, 7, 8, 9 and 10<br>6/14/22: Voted on Comments 5 and 6. |
| 114 | Provide Technical Specialist Feedback to QMS – Debbie Bond | All | 7/14/22 | |
| 115 | Finish request to update response to SIRs 423 and 425 | All | 6/30/22 | |
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**Attachment C**

**Backburner / Reminders – MEC**

| | Item | Meeting Reference | Comments |
|---|---|---|---|
| 1 | Update charter (if needed) every 5 years. | n/a | Ongoing |
| 2 | Review Method codes and send comments to Robin for Dan Hickman. | | Moved to back-burner on 6/9/20. |
| 3 | Provide an update on what has been done with the method codes and database after Jennifer's review and internal EPA meetings. | | This was moved from the Action Items table.<br><br>Notes: 6/9/20: Ask Jennifer for a follow-up.<br>11/9/20 – Not available for a follow-up. |
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