Microbiology Expert Committee (MEC)
Meeting Summary

September 14, 2021

1. Roll Call:

Cody, Chair, called the meeting to order at 1:30pm Eastern on September 14, 2021 by teleconference. Attendance is recorded in Attachment A – there were 10 members present. Associates present: Antoine Chamsi, Chris Fuller, Debbie Bond, Joe Guzman, Nigel Allison, Robert Royce, Thekkekalathil Chandrasekhar, Carl Kircher and Paul Junio.

A correction needs to be made to the vote that happened during the July 13th meeting. The Committee needs to re-vote. Christabel made a motion for Cody to be Chair and Robin to be Vice-Chair. The motion was seconded by Enoma. There was no further discussion and it was unanimously approved.

Robin asked if the summary of changes document that is currently on the TNI website needs to change if more changes are made to the Standard. It will need to be updated if the Standard is re-posted.

Robin made a motion to approve the summary document as posted on the TNI website. Ashley seconded the motion and it was unanimously approved.

The July and August minutes were reviewed on Webex. A motion was made by Robin to approve the July 13, 2021 and August 10, 2021 minutes as written. The motion was seconded by Jessica and unanimously approved.

2. Committee Training

The Expert Committee Training that Paul Junio did is now available for everyone to watch. All voting members must watch it and let Cody know once it has been reviewed. She will report to CSDP when all members have watched it. Associate members are welcome to view also.

3. BSR-8

Bob Wyeth requested information from the Committee to prepare a project abstract for ANSI:

"Abstract of Project: Provide a one paragraph description of the standard. The information should clearly indicate what is covered by the standard in order to differentiate it from similar standards or projects on file at ANSI. As required, please note in the scope if this standard is intended to be submitted for consideration as an ISO, IEC or ISO/IEC JTC-1 standard.

He provided an example of what the Asbestos Expert Committee wrote. The Committee looked at the example to see what they needed to change and Cody made the changes on screen. There was agreement and Cody sent this summary to Bob Wyeth:

Volume 1 of the TNI Environmental Lab Sector Standard is titled Management and Technical Requirements For Laboratories Performing Environmental Analysis. Module 5 refers to laboratory requirements for quality systems for microbiological testing. Several changes have been proposed for the Standard in Module 5 that were driven by the need to harmonize with changes to other Modules, a desire to provide clarity to parts of the Standard that have been known to cause confusion, and to improve the flow of the Standard.

4. Discussion from August's Conference Meeting

V1M5 1.7.3.1. Why not indicate accredited lab and not just certified?

Cody asked if there was any history of why this was written this way. Robin thinks it would be more confusing.

Carl noted certification is a regulatory activity by states. TNI uses the term accreditation so it makes more sense to keep language harmonized in all the standards. Use accredited instead.

The Committee is considering to make the change. It will be discussed further as we start reviewing written comments.

Implementation Guidance for Equilibrium Testing V1M5: 1.7.2.7.b.v.a.

Robin provided some background. Language was in the 2003 Standard and then it was removed in 2009 Standard by the Quality Systems Committee. There was not as separate Microbiology Expert Committee back then. When the Expert Committee was formed, they felt there was benefit and added language back in. It doesn't go where they wanted it to go … doesn't confirm there is no degradation of equipment.

The suggestion was to remove it all together. This can also be looked at next meeting when we have the actual comment.

Cody asked if there were any stronger opinions. Jessica is a data user and used to be assessor and she thinks there is a good reason to keep it. Need to do a heat distribution study.

Cody brought up the discussion from the Conference about bringing samples up to room temperature. This will be further discussed in an upcoming meeting.

5. SIR 414

Standard
Volume and Module (eg. V1M2)
Section (eg. C.4.1.7.4)

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.

Thank you.

Committee Comment:

Response:

Cody reviewed the SIR with the Committee. She asked if anyone on the call has used Section 1.6.3.2.e. Carl Kircher noted that sometimes city water plants have weekend people that come in to count the results. They don't set-up the test or put it in the incubator. Robin noted that might be a workgroup DOC. They work together to come up with a result. It is not an individual DOC. There might be some instances where a DOC could be used individually if all they do is readout results. It would only apply to reading results.

Cody will try to DRAFT some language and send it out by email for discussion.

(Addition: Discussion continued by email:

From Cody – Email 10/12/21: Okie dokie, we have three versions that say the same thing but are worded differently. Thanks for all the feedback! I like them all, but think maybe #3 is the most informational without being redundant. We can discuss at the meeting today or via email beforehand, makes no difference to me. Here they are in all their glory:

Response 1: Your example would apply to 1.6.3.2.e if the analyst using 1.7.3.3 only read out positive results for that method. Please note that 1.7.3.3 does not include determination of non-positive environmental or QC samples, and therefore a DOC following 1.6.3.2.e

using 1.7.3.3 would not prove an analyst competent in determining non-positive environmental or QC sample results or competent at performing any other parts of the method.
If the laboratory had a documented process for analyzing samples using the method, utilizing associated techniques (ex. aseptic technique) and meeting QC requirements, on a defined basis in a similar manner for all analysts (such as monthly positive and negative QC samples for each analyst), that could be used to determine patterns/trends and as documentation for an on-going DOC.

Response 2: Your example would apply to 1.6.3.2.e if the analyst using 1.7.3.3 only read out positive results for that method. Please note that 1.7.3.3 does not include determination of non-positive environmental or QC samples, and therefore a DOC following 1.6.3.2.e using 1.7.3.3 would not prove an analyst competent in determining non-positive environmental or QC sample results or competent at performing any other parts of the method. Therefore 1.7.3.3 cannot be used solely to meet the requirements for an ongoing DOC.
1.6.3.2.e refers to those instances where a lab may use other approaches to an on-going DOC, such as lab generated blind samples, replicate analysis, in-batch positives and negatives or other reasonable approaches. If the laboratory has a documented process for analyzing samples using the method, utilizing associated techniques (ex. aseptic technique) and meeting QC requirements, on a defined basis in a similar manner for all analysts (such as monthly positive and negative QC samples for each analyst), which could be used to determine patterns/trends, it could be used documentation for an on-going DOC.

Response 3: Your example would apply to 1.6.3.2.e if the analyst using 1.7.3.3 only read out positive results for that method. Please note that 1.7.3.3 does not include determination of non-positive environmental or QC samples, and therefore a DOC following 1.6.3.2.e using 1.7.3.3 would not prove an analyst competent in determining non-positive environmental or QC sample results or competent at performing any other parts of the method. Therefore 1.7.3.3 cannot be used solely to meet the requirements for an ongoing DOC.
1.6.3.2.e refers to those instances where a lab may use other approaches to an on-going DOC, such as lab generated blind samples, replicate analysis, in-batch positives and negatives or other reasonable approaches. If the laboratory has a documented process for analyzing samples using the method, utilizing associated techniques (ex. aseptic technique) and meeting QC requirements, on a defined basis in a similar manner for all analysts which could be used to determine patterns/trends, it could be used documentation for an on-going DOC.

From: Hunter Adams <hunter.adams@wichitafallstx.gov>
Sent: Tuesday, October 12, 2021 7:39 AM
To: Cody Danielson <Cody.Danielson@deq.ok.gov>
Cc: Paul Junio <paulj@nlslab.com>; Jessica Hoch, etc. **Subject:** [EXTERNAL] Re: SIR 414 Response Draft Language

I agree - cut the first sentence and the last sentence covers what was cut at the beginning.

J Hunter Adams, M.S.
Environmental Laboratory Supervisor
City of Wichita Falls - Cypress Environmental Laboratory
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Mailing Address: P.O. Box 1431, Wichita Falls, TX 76307
hunter.adams@wichitafallstx.gov I Phone: 940-691-1153

On Mon, Oct 11, 2021 at 1:16 PM Cody Danielson <Cody.Danielson@deq.ok.gov> wrote:
Thanks Paul. Perhaps we ax the whole first sentence then? I think the last sentence mostly covers the same into but in a different context.

From: Paul Junio <paulj@nlslab.com>
Sent: Monday, October 11, 2021 1:13 PM
To: Cody Danielson <Cody.Danielson@deq.ok.gov>; Jessica Hoch, etc. **Subject:** [EXTERNAL] Re: SIR 414 Response Draft Language

I would be careful with the first sentence of the response. While I agree with the sentiment, that doesn't appear in the Standard anywhere and could be seen as affing requirements.

Paul Junio
Northern Lake Service
sent from my phone

From: Cook, Robin <cookrobin@CODB.US>
Sent: Monday, October 11, 2021 1:04 PM
To: Cody Danielson <Cody.Danielson@deq.ok.gov>
Subject: [EXTERNAL] RE: SIR 414 Response Draft Language

Try this one.

From: Cody Danielson <Cody.Danielson@deq.ok.gov>
Sent: Monday, October 11, 2021 1:36 PM
To: Jessica Hoch, etc.
Subject: RE: SIR 414 Response Draft Language

[EXTERNAL EMAIL. EXERCISE CAUTION.]
Thank you Jessica. How do we feel about Take 2 (below)? I added Jessica's suggestions:

Response: An Ongoing DOC is intended to capture the entire process, per individual, to show competency in not only the method but also associated techniques (ex. aseptic technique) and QC requirements. Your example would apply to 1.6.3.2.e if the analyst using 1.7.3.3 only read out positive results for that method. Please note that 1.7.3.3 does not include determination of non-positive environmental or QC samples, and therefore a DOC following 1.6.3.2.e using 1.7.3.3 would not prove an analyst competent in determining non-positive environmental or QC sample results or competent at performing any other parts of the method. Therefore 1.7.3.3 cannot be used solely to meet the requirements for an ongoing DOC.
1.6.3.2.e refers to those instances where a lab may use other approaches to an on-going DOC, such as lab generated blind samples, replicate analysis, in-batch positives and negatives or other reasonable approaches. If the laboratory has a documented process for analyzing samples using the method, utilizing associated techniques (ex. aseptic technique) and meeting QC requirements, on a defined basis in a similar manner for all analysts (such as monthly positive

and negative QC samples for each analyst), which could be used to determine patterns/trends, it could be used documentation for an on-going DOC.

From: Jessica Hoch <Jessica.Hoch@Tceq.Texas.Gov>
Sent: Monday, October 11, 2021 11:06 AM
To: Cody Danielson, etc
Subject: [EXTERNAL] RE: SIR 414 Response Draft Language

The proposed response addresses the SIR and reiterates the intent of the DOC. The only thing I would bring up for consideration/discussion is whether we should provide an example for how the lab could apply 1.6.3.2.e in the way they are looking to. The example provided in the response addresses the info/situation they provided, but I don't think it is hitting their intent in the question to us. For example, if the lab had a regular process for running QC samples, on a defined basis in a similar manner for all analysts (Monthly pos/neg QC samples for each analyst), *that* could be used to determine patterns/trends and as documentation for an on-going DOC.

Let me know if I am misunderstanding or overlooking anything here. Just wanted to get the conversation started ahead of our meeting this week 😊

Have a good day!
Jessica

From: Cody Danielson <Cody.Danielson@deq.ok.gov>
Sent: Tuesday, October 5, 2021 3:20 PM
Subject: SIR 414 Response Draft Language

Good morning all,

As promised, here is the drafted language for MEC's response to SIR 414 is in yellow below.
Please Reply All if you have any comments.
If possible, it would be nice to vote on this in advance of our next MEC meeting, but I'll see what we have for comments first.

Thank you!
Cody

SIR 414 to Microbiology, July 21, 2021

	Standard
	Volume and Module (eg. V1M2)
	Section (eg. C.4.1.7.4)

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."

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Thank you.

Committee Comment:

Response: An Ongoing DOC is intended to capture the entire process, per individual, to show competency in not only the method but also associated techniques (ex. aseptic technique) and QC requirements. Your example would apply to 1.6.3.2.e if the analyst using 1.7.3.3 only read out positive results for that method. Please note that 1.7.3.3 does not include determination of non-positive environmental or QC samples, and therefore a DOC following 1.6.3.2.e using 1.7.3.3 would not prove an analyst competent in determining non-positive environmental or QC sample results or competent at performing any other parts of the method.

To the Micro Committee (from Lynn Bradley):
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.*)*

6. Membership

Cody will look through application and plan to discuss possible new members next month. We can still add 2 members to get to 15. Cody's job change may affect her stakeholder status.

7. Next Meeting and Close

The next meeting is scheduled for October 12, 2021 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 3:01 pm Eastern.

Attachment A

Participants
Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information
Cody Danielson (Chair) (2022*) **Present**	Oklahoma	AB	Cody.Danielson@deq.ok.gov
Jessica Hoch (2022) **Present – Phone**	TCEQ	Other	Jessica.Hoch@Tceq.Texas.Gov
Lily Giles (2022*) **Present**	Louisiana	AB	Lily.Giles@LA.GOV
Mary Robinson (2022*) **Absent**	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 (2022*) **Absent**	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**	Pace National, Analytical	Lab	christabel.monteiro@pacelabs.com
Patrick Roundhill (2023*) **Present**	New Leaf Management, LLC	Lab	patrickroundhill@gmail.com
Ilona Taunton (Program Administrator) **Present at 2:09 Eastern**	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 Paul Junio	2/11/21	Started, but ongoing. 7/13/21: Remove
110	Complete Summary of Changes of document for posting on the website.	Cody	7/26/21	
111	Send final copy of DRAFT Standard and Summary of Changes to Ilona for posting.	Cody	7/30/21	
112				

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter (if needed) in November 2019. 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. Notes: 6/9/20: Ask Jennifer for a follow-up. 11/9/20 – Not available for a follow-up.