

**Quality System Expert Committee (QS)
Meeting Summary**

March 8, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on March 8, 2021. Attendance is recorded in Attachment A – there were 11 members present. Associate Members present: Karna Holquist, Lisa Parks, Robin Cook, Ty Atkins, Cindy Redmond, Jack Denby, Jeanette Hernandez, Cody Danielson, Jessica Jensen, Renee Jernigan, Tiffany Shaw, Scott Siders, Eric Denman, Valerie Slaven, Ashley Larssen, Kasey Raley, Kristin Brown, Patty Carvajal, Rachel Van Exel, Carol Barrick, Chris Gunning, Paul Junio, Carl Kircher and Douglas Kablik.

The February minutes were sent by email and shared on Webex. Earl made a motion to approve the February 8, 2021 minutes as written. The motion was seconded by Amy. There was no further discussion, and they were unanimously approved.

2. New Workgroup to Help with Standard Rewrite

Debbie let people know there is a new workgroup being developed to work on the non-controversial sections of the Standard rewrite. She encouraged everyone to consider joining this workgroup. If someone is interested, they should contact Debbie and Kathi.

Kathi noted that people will get a section of the Standard to look at. Does the section need any language changed? Each section should not take more than a few hours of effort.

Iлона described the format of the Standard template that people will be working on. It is a copy of ISO/IEC 17025:2017 with TNI language from the 2016 Standard inserted and some ISO/IEC 17025:2005 language inserted that is not part of the new 2017 version. When sections are reviewed there may be duplicate language that needs to be removed, TNI language that may need to be placed in a different spot or re-worded to work better with ISO/IEC 17025:2017, etc. It is important to keep track-changes on so it is clear what changes were made when the Committee reviews the Standard. Debbie and Kathi will provide instruction in an upcoming workgroup meeting.

3. Technical Manager Discussion

Debbie asked if the expectation is to still to have different requirements based on a Module. There was agreement.

Starting with Microbiology:

Robin Cook pointed out that the goal was to give people credit for experience. Whatever language is used has to be auditable. The Microbiology Committee did get push back on using experience and on the option to contact the state. Robin commented that the option to contact the state should be stricken. It was commented that some states have made some allowances in extreme situations, but if you leave it in, they will all say “no”. It becomes a legal issue. What criteria should they use to decide when it is OK and not? They don’t want to get into this.

Robin also highlighted that the current exemptions are assumed to stay in place.

Chris Gunning (NGAB) thinks (vi) does need to be taken out. It is an invitation for consistency. Jenna (NJ) also agrees. There was general agreement to remove this. Debbie crossed through the language.

Debbie asked about the note on recent experience. Robin and others asked about the timing. There are people that take leave and are still competent when they come back. It was noted that labs could use a DOC to show competency. Kathi pointed out that this is not a current requirement.

Kasey (Chair, Microbiology) noted that this is something the lab should determine. There were concerns about whether the person would be up to date on new technologies.

Given this discussion, this will be sent back to Microbiology for an update (Attachment D). Debbie will send it back today so they can possibly look at it during their meeting tomorrow.

Section (v.a.): The last line should probably be a note.

Simplify first sentence in (v.a.)? Kathi thinks it may need to stay as is to make it very clear what is being looked for.

Earl commented that a Technical Manager can learn new technologies. That isn’t addressed in this. It does not recognize the capability to learn a new technique and exercise sound technical judgement in the use of that technique.

Carl noted that Florida applies this to assessors. They apply the technical training part of the 2003 Standard. They write it into their assessor contracts. Carl will send this to Ilona and Debbie.

Earl thinks the competencies for assessors should be similar to technical managers.

(Addition: Jerry Parr let Ilona know the end of the week that the Competency Task Force is planning to work on the Technical Manager issue. Debbie Bond (Chair, QS) and Kasey Raley (Chair, Microbiology) will be invited to their meetings as they develop language. The Quality Systems Committee will stop work on this topic until they receive an update from the Task Force.)

4. SIR #392

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.5.8

Describe the problem:

The section of the Standard states "Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due."

Most labs have interpreted that this requirement applies to support equipment such as balances and pipettors. Does this section apply to analytical equipment such as turbidimeters, spectrophotometers, pH meters, ICP-MS, etc?

Committee Comments: Because of the complexity associated with labeling analytical instruments with calibration and calibration due dates, many labs take advantage of the "otherwise identified" piece of the requirement to create other mechanisms to identify the calibration status, when durable labeling is not practicable.

Response: The term "all equipment" includes both support and analytical equipment. When practicable, all equipment must be "labeled, coded or otherwise identified" so the calibration status of the equipment is readily available to avoid the use of out-of-calibration equipment.

The Committee reviewed SIR 392 and reviewed proposed response language developed by Debbie. A few changes were suggested by Amber and they were incorporated into the language above. Earl made a motion to accept the Response to SIR 392 as written above. The motion was seconded by Kathi and it was unanimously approved.

5. Action Items

A summary of action items can be found in Attachment B.

6. New Business

None.

7. Next Meeting and Close

The next regular meeting will be on April 12, 2021 at 1pm Eastern by teleconference.

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

Debbie adjourned the meeting at 2:20pm Eastern (Motion – Earl, Second – Amy Unanimous Approval).

Attachment A

Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) Present	Alabama Power	2023*	Lab	dbond@southernco.com
Kathi Gumpfer (Vice-Chair) Present	ChemVal Consulting	2024	Other	kgumpfer@chemval.com
Nicole Cairns Absent	NYSDOH	2024*	Lab	nicole.cairns@health.ny.gov
Michael Demarais Present	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis Present	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Lizbeth Garcia Present	Oregon Dept. of Environmental Quality	2022	Accrediting Body	LIZBETH.GARCIA@dhsosha.state.or.us
Stephanie Atkins Absent	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson Present	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen Present	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak Present	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
William Ray Present 1:30pm	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross Present	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Amy Schreader Present	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Michelle Wade Absent	A2LA Workplace Training	2024	Other	mwade@a2lawpt.org
Alyssa Wingard Absent	NAVSEA LQAO	2024	Other	alyssa.wingard@navy.mil
Ilona Taunton (Program Admin) Present	The NELAC Institute	n/a	(828)712-9242	ilona.taunton@nelac-institute.org

Attachment B

Action Items – QS Expert Committee

	Action Item	Who	Expected Completion	Actual Completion
63	Consider starting a list of items to add to the small laboratory handbook.	All	TBD	
65	Add ISO/IEC 17025:2017 language from the 2016 TNI Standard into the DRAFT Combined Standard.	TBD	TBD	
73	Change black text in combined Standard to italics in preparation of starting to work on updating language in the Standard.	Jessica	2/2/20	<i>4/15: Needs to be started.</i>
77	Prepare summary document of comments received during the 9/25/20 Public Webinar.	Jessica, Kathi, Paul Junio	11/9/20	
78	Send SIR 393 back to LASEC.	Jessica	11/16/20	1/11/21 – will be resent.
79	Send Public Webinar responses to attendees of the webinar.	Ilona	2/15/21	
80	Send SIR 401 Response to Lynn and LASEC.	Debbie	2/15/21	
81	Send QSM info they included on electronic records. Send to Debbie and Ilona.	Kathi	3/5/21	
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Microbiology

Any technical manager of an accredited environmental laboratory engaged in microbiological/biological analysis shall be a person:

- i. with a bachelor's degree; and
- ii. with sixteen (16) college semester credit hours of biological science to include at least one 4 credit hour course in general microbiology; and
- iii. with two (2) or more years of experience in the analysis of microbiological environmental samples representative of the analyses for which the lab seeks and maintains accreditation,
- iv. A master's or doctoral degree may be substituted for one (1) year experience.
- v. 1 year experience working in an ~~environmental~~ **microbiological** laboratory may be substituted for 4 credit hours.
 - a. **Multiple years of substitution may be utilized, but each year substituted must be related to the learning of and proficiency across the scope of accreditation for analytical method/technique or instrumentation type. NOTE: This will help ensure an increasing level of knowledge in environmental analyses (preparation and/or instrumentation) during that time period.**
 - b. The 4 credit hour general microbiology **and a 4 credit hour biological science** course cannot be substituted with experience