

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

June 14, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on June 14, 2021. Attendance is recorded in Attachment A – there were 10 members present. Associate Members present: Ashley Larssen, Brian Lamarsh, Christopher Fuller, Cindy Redmond, Douglas Kablik, Eric Davis, Eric Denman, Jeanette Hernandez, Jessica Jensen, Joe Manzella, Karna Holquist, Kadey Raley, Katie Strothman, Kelvin Yuen, Kristin Brown, Linda O’Donnell, Lisa Parks, Meera Neb, Michelle Wade, Paul Junio, Rachel Van Exel, Renee Jernigan, Tiffany Shaw, Tom Widera, and Ty Atkins. Guests: Aaren Alger and Jerry Parr.

(Addition: The May minutes were sent by email and shared on Webex. On July 12, 2021, Tony made a motion to approve the May 10, 2021 minutes as written. The motion was seconded by Jenna. There was no further discussion, and it was unanimously approved.)

2. Action Items

Debbie reviewed the Committee action items. Changes were made directly into the table in Attachment B.

3. Technical Manager

Aaren Alger and Jerry Parr joined the meeting today to talk about work being done by the Competency Task Force. They started talking about Technical Managers. They talked about current language in the Standard and understanding the lab and AB struggles in meeting the Standard. The person responsible for different laboratory activities varies between laboratories. They went through the Standard to find things that needed to be done and they took a look at who is responsible for the different activities.

The Competency Task Force is working on a DRAFT proposal that Debbie shared on Webex and by email with the Committee. This is only a DRAFT and they are looking for comments. The DRAFT included a summary of the proposal, pros and cons, examples and a look at the future with this type of change.

Summary (from DRAFT):

Remove the Technical Manager duties, qualifications, and exemptions from VIM2 §§4.1.7.2.f and 5.2.6 and allow laboratories to determine the personnel needed (including their qualifications and experience) to meet both the requirements of the standard and the organizational needs of the laboratory. There is no inherent need to establish minimum qualifications for personnel performing tasks defined in the standard.

*If any required tasks are not being performed satisfactorily, assessors may use VIM2 §5.2 to determine that laboratory management has not assured the competence of the staff assigned to perform any of the requirements of the standard, based on clusters of findings around that particular requirement. This is currently done for other personnel (QA Manager, for example) and can be done for the tasks associated with the Technical Manager position, as well. Every assessor has a list of tasks or duties required by the standard, and needs only to determine that **some individual** within the lab is satisfactorily performing each of those duties, regardless of what title that person might have.*

The idea is not to tell the labs how to do it ... just what needs to be done.

The focus has been changed to how to determine the technical expertise needed. They got away from the management aspect. Often times the Technical Manager is not the manager.

They (Competency Task Force) have had different suggestions to remove more language and they have also looked at Drinking Water language. At this point they really want comments so they can prepare another DRAFT before they meet with the NELAP AC.

Kathi is good with the direction this is headed if it can be made achievable for labs. There was general agreement with this statement.

Jenna noted this would be difficult because of state requirements. They grant secondary to 200 labs. If other states did not have requirements that were as stringent, they would have to review all this. This would be difficult to implement, and they would prefer not to go in this direction.

There was also a lot of support for the DRAFT. A comment was made that labs will really like this, but ABs may have a difficult time supporting it.

Aaren noted that they are meeting with all the Expert Committees and CSDEC. The feedback will be reviewed and then another DRAFT will be prepared for NELAP AC review and comment. Labs in smaller communities are struggling to find people to fit the current standard requirements and unions in some labs have also complicated things. This is a first attempt and everyone is encouraged to send comments to Aaren, Jerry and/or Lynn Bradley (Program Administrator for the Task Force).

Aaren still sees the value in education but realizes now that there are other avenues to meet the capabilities since education is not the only important aspect.

Could it be that someone in the laboratory has to have the education, but maybe someone else has the experience? It was commented that this could be confusing. Which one trumps in solving issues ... education or experience?

Jerry emphasized that ISO/IEC 17025: 2017 clearly states that management needs to ensure the competency of persons in their labs. Each lab does this differently based on size and scope.

Michael wanted to hear about how this will improve small laboratories technically. Jerry noted the change makes it easier to find competent people without the constraints of meeting some specific criteria. There are competent people that don't currently meet the requirements of the Standard.

Labs are struggling. There are labs that only have a technical manager in name only and they are not doing the job in the lab. Someone else is actually doing the job.

The other issue for small labs is that they can't promote within. They have to hire outside. This allows people to start in a lab and work their way up.

It was commented that they need people to troubleshoot issues and people without a degree would have a tougher time trouble shooting. There was some disagreement with this statement. It depends on the situation. Some people do become a technical expert through experience.

Aaren will be doing a talk on this topic during the August meeting.

4. Internal Audits

Debbie shared an email with the voting members to find out if they preferred option 1 or 2. The support was for Option 1.

OPTION 1

1. In addition to the requirements listed in 8.8.1 and 8.8.2, the internal audit program shall include:
 - a. a pre-defined schedule covering a 2-year period
 2. The planned interval for each audit shall be determined by the lab and shall not exceed:
 - a. 24 months methods/technologies on the scope of accreditation
 - b. 12 months for the elements in Module 2 of this standard

OPTION 2

1. In addition to the requirements listed in 8.8.1 and 8.8.2, the internal audit program shall include:
 - a. An evaluation and determination of risk level associated with each element of the quality management system and laboratory activities that conforms to this standard,
 - b. defined criteria for each risk level (high, moderate, and low), and
 - c. a pre-defined schedule.
2. The pre-defined schedule shall ensure internal audits are conducted at a frequency not to exceed:

- a. 12 months for elements or activities deemed high or of greatest risk,
- b. 18 months for elements of activities deemed moderate or of medium risk or
- c. 24 months for elements or activities deemed low or of minor risk.

It was commented that Drinking Water has a 1 year “should” language. Jessica noted that they were told in training that a “should” is a “must” in the Drinking Water Certification manual.

Iлона commented that the committee might consider adding language that the timing requirements must be the most stringent since this is a major change. There was agreement by many to do this. Note: Follow the most stringent requirements.

Amber sent some language suggestions: 24 months for labs with ten or more technologies and 12 months for labs with less than 10 technologies.

Debbie asked Amber if substituting months instead of technologies would be OK. She will check back with her State. Jessica Jensen thought this could be discriminating to a small lab.

Debbie may want to explore sharing this with a bigger audience for more feedback. Maybe a public webinar?

Jessica commented the issue the public had before was with the +/- months. Iлона noted that there are many labs and states that do use 24 months already. The goal is to have a system that is in control. Even if you have the ability to set things to 24 months, you should shorten this to put it back in control if there are issues. Minimize risk when you know there is a problem.

Is there better wording for “technologies”. It needs to be clear what it means. Kristin Brown commented there is a technology table that most of the ABs use. Kathi looked at it in LAMS and noted that it is a fairly detailed table. Earl thinks the table should be referenced if that is what is meant.

There will be further discussion in July.

5. SIR 378

There are 3 SIRs that Debbie distributed to the Committee – 1 new and 2 repeats. Debbie will review the repeat SIRs (378 and 392) and send proposed language by email for comment and hopefully finalize them by email. The Committee will look at 412 in July.

6. Conference in August

The Committee will meet Monday August 9th at 9am Eastern.

7. Membership

The associate members were asked to step off at 2:22pm Eastern.

Debbie pulled up the applications on Webex to fill the vacant position on the Committee.
Applicants were:

Ashley Larsen
Meera Neb
Katie Strothman

A motion was made by Earl to add Ashley Larssen to the Quality Systems Expert Committee. The motion was seconded by Lizbeth and unanimously approved. (For – 9, Against – 0, Abstain – 0.)

8. New Business

None.

9. Next Meeting and Close

The next regular meeting will be on June 14, 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 2:37pm Eastern.

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 Gumper (Vice-Chair) Present	ChemVal Consulting	2024	Other	kgumper@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 Present	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson Absent	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 Absent	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
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	
83	Determine Goal for Completing Volume 1 Module 2 Standard Update.	All	TBD	
84	Add a definition for “method validation” to the definitions section of Module 2.	All	TBD	
85	Continue working on controversial Standard updates within Committee meetings. Examples: Internal Audits, Technical Manager, Document/Record Retention, QC, need for Quality Manual and Quality Policy, and Equipment Calibration tags.	All	TBD	Ongoing
86	Send Internal Audit language options by email to committee for comment.	Debbie	6/7/21	Complete

