Quality System Expert Committee (QS)
Meeting Summary

May 10, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on May 10, 2021. Attendance is recorded in Attachment A – there were 11 members present. Associate Members present: Carol Barrick, Rachel Van Exel, Douglas Kublik, Ty Atkins, Christopher Fuller, Paul Junio, Eric Denman, Jessica Jensen, Tom Widera, Karna Holquist, Renee Jernigan, Lisa Parks, Cindy Redmond, Joe Manzella, Jack Denby, Linda ODonnell, Chris Gunning, Kelvin Yuen, Debra Zeller, and Brian Lamarsh.

The April minutes were sent by email and shared on Webex. Nicole made a motion to approve the April 12, 2021 minutes as written with a change to the quote on page 2 (should be Jenna instead of Jennifer) and correction of the number of members on the call. The motion was seconded by Tony. There was no further discussion, and it was unanimously approved.

There is a new Committee member training required for Chairs and voting committee members. A link will be sent out soon. Associates are also welcome to take it. Let Debbie know when you take the training.

There is a new opening for a voting member on the Committee. Michelle Wade will be resigning as a voting member but will stay involved as an associate member. Associate members are being encouraged to contact Debbie and Ilona if they are interested in becoming a voting member.

2. Action Items

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

3. Internal Audits

Debbie shared the language that Nicole and Nick worked on to incorporate risk into the procedures:

1. *The internal audit program shall include:*

    a. *all elements of the quality management system and all laboratory activities,*
    b. *an evaluation and determination of risk level (high, moderate, or low) associated with each element of the quality management system and each laboratory activity,*
    c. *defined criteria for each risk level (high, moderate, and low), and*

d. *a pre-defined schedule.*

2. *Items 1 a-d. above shall be reviewed and updated, as applicable, at least every 12 months.*

3. *Internal audits shall be completed:*

    a. *every 12 months for high-risk elements or activities,*
    b. *every 18 months for moderate-risk elements or activities, or*
    c. *every 24 months for low-risk elements or activities.*

It was commented that 12 months for high-risk is a very short window of time for a small lab that has many competing priorities. Jessica Jensen noted that she thinks small labs have less high-risk items because they have less turnover, etc. There was some disagreement with this statement. Nicole commented that the requirement is currently annual for everything. This changes it to 12 months only for high-risk items. It was commented that many labs don't do it within 12 months, and they are given some lenience.

There was quite a bit of discussion about whether this timing is correct, can the lab assess risk and how does the AB decide if it is appropriate, and the new concept might be difficult for people to implement (excessive training needed).

Language in #2 needs to emphasize that the audits need to be completed - not just planned.

Language in #3 – Can add something along the lines of: The pre-defined schedule shall ensure internal audits are conducted at a frequency not to exceed …

If the definition of risk changes, a lab would have to re-determine their internal audit schedule.

Chris Gunning commented that you have to look at Section 8.7 that says each time you do a corrective action you have to update your risk and opportunities. Every time a lab has a corrective action, they have to look at how the item was originally categorized and how it has now possibly changed. This could affect the schedule. For this reason, #2 is not needed. The schedule is fluid with continuous updates. Jenna was concerned this could be a nightmare for a lab to track. It might also be difficult for the assessors and other assessors on the call agreed.

Perhaps keep language similar to what it is currently in the Standard but extend the time frame? Jessica Jensen noted that this got negative feedback in the public webinar.

Chris commented that the only spots an assessor would point to a deficiency related to risk assessment would be in 4.15 (Impartiality) or in determining risk during management review. Risk is talked about in Section 8.5, but there is not really anything auditable. The language being looked at today is too detailed. The concept is good, but the detail would be difficult to manage. It would be better to just give them a time frame.

The language presented above was an attempt to offer labs more flexibility than the annual schedule for all currently in place. Maybe there is another way to do this?

Debbie asked: Is it better to not let a lab define their own risk? A number of labs disagreed with this comment.

Paul commented that the criteria is along different risk levels. If a lab cannot define these levels, they will have a problem.

Ilona noted that the Committee can reach out for public feedback anytime if it is needed.

Chris Gunning suggested removing the need for the lab to determine risk and instead note that all technical items need to be reviewed every 18 months. All QMS items need to be reviewed every 24 months. The lab can do it more frequently if there are problems.

The labs still need a predefined schedule.

Debbie would like to send out the options for some solid feedback by email and then finish the discussion next month and decide next steps. Chris Gunning will put suggested language together and send to Debbie and Ilona.

4. Charter

Debbie presented the Charter the Committee worked on during the last meeting. She reviewed all the changes.

A motion was made by Nicole to approve the Charter as distributed with the Agenda for today's meeting. Michael seconded the motion, and it was unanimously approved.

Debbie will send the final copy to Paul Junio and Ilona.

5. SIR 378

Lynn Bradley (LASEC) sent back SIR 378 for a possible language change. The alternative language needs to be approved by the Committee or different language needs to be sent.

Nicole made a motion to approve the new language, but a second was not forthcoming. Michael commented that he would need to remove a line in order to second.

Work on this agenda item will continue by email or be completed during the June meeting.

6. New Business

None.

7. 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 2:30pm Eastern. (Motion – Michael. Second – Lizbeth. Unanimous.)

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 Gumpper (Vice-Chair) **Absent**	ChemVal Consulting	2021*	Other	kgumpper@chemval.com
Nicole Cairns **Present**	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	2019*	Accrediting Body	LIZBETH.GARCIA@dhsoha.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 **Absent**	Retired	2021*	Other	papaearl41@hotmail.com
Jenna Majchrzak **Present**	NJ DEP	2021*	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	2021*	Other	mwade@a2lawpt.org
Alyssa Wingard **Present**	NAVSEA LQAO	2021*	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	
82	Write internal audit requirements to incorporate risk within certain time frames	Nicole	5/7/21	Complete 5/10/21
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	

Attachment C

Backburner / Reminders – QS Expert Committee

	Item	Meeting Reference	Comments
1	Review charter in November 2021	Ongoing	Ongoing