

Quality System Expert Committee (QS)
Meeting Summary

April 12, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on April 12, 2021. Attendance is recorded in Attachment A – there were 11 members present. Associate Members present: Cindy Redmond, Cody Danielson, Debra Zeller, Douglas Kablik, Eric Denman, Carl Kircher, Jessica Jensen, Joe Manzella, Karna Holquist, Kasey Raley, Kelvin Yuen, Linda O'Donnel, Paul Junio, Stephanie Atkins, Tiffany Shaw, Tom Widera, Ty Atkins and Valerie Slaven.

The March minutes were sent by email and shared on Webex. Tony made a motion to approve the March 8, 2021 minutes as written. The motion was seconded by Nicole. There was no further discussion, and they were 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.

2. New Workgroup to Help with Standard Rewrite

The Workgroup had their first meeting and are starting to assign sections. The first sections are due this Friday.

3. Internal Audits Discussion

What is an acceptable time frame for annual audits?

Debbie displayed the section in the Module 2 template – Section 8.8.

Marlene Moore sent an email on this topic on 1/26/21:

"Internal audits shall normally be performed at least once every 12 months, or completed within a 12- month time frame for segmented (or rolling) internal audits. A documented decision-making process shall be followed to change (reduce or restore) the frequency of internal audits or the time frame in which internal audits shall be completed. Such changes shall be based on the relative stability and ongoing effectiveness of the management system. Records of decisions to change the frequency of internal audits, or the time frame in which they will be completed, including the rationale for the change, shall be maintained."

I do not think method or technology audit should be stated but the lab just provide the justification for ensure that all activities are covered in the internal audit.

Debbie asked the ABs how much over 12 months is OK? Tony noted that sometimes he sees 14 months. His biggest concern is how the corrective action is being handled.

Paul Junio noted that the internal audit schedule doesn't have to be at the level of "VOCs need to be done in January". The entire internal audit needs to be done annually. Karna raised similar concerns.

Carl Kircher thinks 12 months is 12 months. He sees labs break up the audit quarterly. Jessica Jensen asked Carl if Florida defines annually as 12 months in their regulations. He could not confirm. Need to define what annually means.

What is the problem? Jessica noted that annually needs to be defined. Ilona noted that ISO is looking at internal audits as risk based? You need a schedule what works for your lab and ensures the labs stays in control.

Kasey thinks the labs should be able to determine their own schedule.

Ilona noted that the new Standard says the internal audits need to be planned.

Ty Atkins noted that maybe the annual schedule is what needs to be reviewed annually.

Nicole is in agreement with the previous comments. Everyone sets a schedule and real world happens. They hurry through the audit when they get behind and it defeats the purpose. Labs should have more flexibility.

There have been comments on making this more risk based. Jennifer in New Jersey thinks a time frame does need to be defined, but she does think we need to define what annually means. Need to specify. They are OK if it is a little off, but waiting 11 months would be too far off.

Carl is asking if a time frame will be specified? Everyone agrees it needs to be more specific than annually. Nicole commented that maybe high risk items need to be looked at every 12 months and less risky areas can be spread out over 24 months.

Nick emphasized again that labs he works with have planned intervals based on risk. He noted that more labs haven't changed their internal audit policies. Most labs have moved to doing portions of the audits over time. Gives them a little more flexibility when they need it. They don't feel like they are up against the wall on deadlines.

Jessica thinks no date requirements would not be accepted by many of the ABs.

Ilona reminded people about Nicole's suggestion – determine risk and set-up a schedule. It moves the lab in the right direction? Jessica reminded people that assessors also need to know how to do this.

Internal Audits have to include method audits too. Should guidance be given to make sure that all methods are looked at within a window of time? It is probably not OK to do all organics one year and then nothing the next year. At some point everything needs to be looked at.

Nick – if the lab has had no non-conforming work, passes all PTs, etc ... Why force labs to do audits for things where there is evidence it is under control. Why give labs more work? High turn-over, failing PTs, etc ... could be reasons to look at methods.

Paul thought a time frame needs to be set.

Debbie asked Nicole if she could write internal audit requirements to incorporate risk within certain time frames. She will try to merge the risk with a time frame.

Section 8.5 is the risk section. Nick will review Nicole's DRAFT before it is submitted to the Committee for review. It will be reviewed during the May meeting.

4. Charter

Ilona noted that an approval date needs to be in the header and the Decision Making section can be eliminated.

Debbie started at the top – see Attachment D for update.

Debbie will send out the document to the Committee to make any further changes. It will be voted on during the May meeting. Let Debbie know about needed changes.

5. Action Items

Debbie reviewed and updated action items. See Attachment B.

6. New Business

None.

7. Next Meeting and Close

The next regular meeting will be on May 10, 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 2:28pm 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 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@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	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 Absent	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	
65	Add ISO/IEC 17025:2017 language from the 2016 TNI Standard into the DRAFT Combined Standard.	TBD	TBD	Paul completed #65 and 73. Completed: 2/21/21
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	Completed: 2/21/21
77	Prepare summary document of comments received during the 9/25/20 Public Webinar.	Jessica, Kathi, Paul Junio	11/9/20	Complete (Voted on in December)
78	Send SIR 393 back to LASEC.	Jessica	11/16/20	1/11/21 – will be resent. Completed 1/12/21
79	Send Public Webinar responses to attendees of the webinar.	Ilona	2/15/21	Complete
80	Send SIR 401 Response to Lynn and LASEC.	Debbie	2/15/21	Complete 2/8/21
81	Send QSM info they included on electronic records. Send to Debbie and Ilona.	Kathi	3/5/21	Complete 2/8/21
82	Write internal audit requirements to incorporate risk within certain time frames	Nicole	5/7/21	Complete 5/10/2021

Attachment C

Backburner / Reminders – QS Expert Committee

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Laboratory Quality Systems Expert Committee Charter

(Revised ~~xx/xx/xxxx~~)

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Mission

To maintain environmental laboratory quality management systems standards (TNI Volume 1, Module 2) based on public input, to provide technical assistance on issues related to adopted standards, and to develop tools that facilitate the implementation of the standard.

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Composition of the Committee

The Committee is composed of balanced membership of no more than 15 members from among the following TNI stakeholder groups: Accrediting Bodies, Laboratories, and Other;
Associate members are not limited in number, and are not required to demonstrate balance in their numbers;
Members serve three year terms, and are eligible to serve two consecutive three year terms

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Objectives:

1. Review and revise standards based on input from all stakeholder groups

Success Measure:

- a. Timely development of standards based on a 5 year review per ANSI requirements
- b. Improving the Standard, such as by increasing the clarity of the intent of the Standard and incorporating advances in technology

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2. Ensure that the Standard will produce data of known and documented quality

Success Measure:

Adoption of the Standard by relevant stakeholder groups

3. Provide technical assistance such as responding to Standard Interpretation Requests (SIRs)

Success Measure:

Responses to SIRs within the 45 days as per SOP 3-105.

4. Provide technical assistance in developing tools to facilitate the implementation of the standard

Success Measure:

Provide requested checklists, training materials, and the Small Lab Handbook

5. Ensure continuity with TNI Volume 1 Modules 3 through 7

Success Measure:

Reviews performed by the CSDEC find no conflicts between Modules when such review is made.

Available Resources:

- Volunteer committee members
- Participating stakeholders and their organizations
- Existing national and international consensus-based standards
- TNI Infrastructure
- Environmental technical community
- TNI Website and TNI support services (administrative, technical editing, etc.)
- Teleconference and web-based services
- Limited Travel Funding

Anticipated Meeting Schedule:

- Monthly Committee virtual meetings open to all Full and Associate Members (default time on TNI Website);
- Additional committee meetings as needed
- Committee meetings during semiannual TNI Forums (Winter and Summer) open to all forum registrants

Deleted: Decision Making:

Decisions of the Quality Systems Expert Committee can be made by electronic ballot or by the respective votes of the committee member in teleconference or face-to-face sessions. In any case a quorum, representing more than 50% of the committee members must be represented in the voting process. Decisions will be made, consistent with the requirements set down in the current revisions of SOP-2-100 and SOP-2-101 as follows:

Type of Decision

... [1]

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