Quality Management System Expert Committee (QMS)
Meeting Summary

November 5, 2024

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on November 5, 2024. Attendance is recorded in Attachment A – there were 6 voting members present. Associate members present: Carl Kircher – Phone only (until 2pm Eastern), Cindy Redmond, Dan Jackosn, Debra Zellar, Fida Kased, Kelvin Yuen, Nicole Van Aken, Tammy Kreutzer, and Bill Reeves.

A quorum for doing business was not met, but Debbie decided to proceed with a meeting for sharing and working on information that would not be final.

The agenda was distributed by email to the Committee. There were no changes made to the agenda. The agenda was approved by unanimous consent.

2. Work on DRAFT Standard

The Committee restarted the review of the Standard at Section 8.4.

Section 8.4.2:

After extensive discussion on now "record" and "document" should be used, the Committee recommended the following language.

8.4.2.1 The laboratory must retain all records for a minimum of five (5) years from generation of the last entry in the records.

8.4.2.2 Records that are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

8.4.2.3 Access to archived information must be recorded.

Sections 8.5:

No changes recommended to 8.5.1 through 8.5.3.

Recommended that 8.5.4 and 8.5.5 be added. There was consideration of adding language about acting in a timely fashion. After further discussion the Committee decided that 8.5.2 amd 8.5.5 take care of it and it was not added.

8.5.4 Records of the identification and mitigation of risk shall be maintained.

8.5.5 Identified risks and any mitigation plans shall be reviewed annually and updated as applicable.

No changes recommended to Section 8.6.

Section 8.7.1:

Section 7.7 covers "Ensuring the validty of results". This covers information added to this section. Labs have to have a procedure for monitoring results. See 7.7.1.i – review of reported results.

Remove language in 8.7.1.a. The new language in ISO 17025:2017 is sufficient. The lab has to correct it, so having to require that labs designate individuals to assess QC data types doesn't seem as useful. Also could not find what the data types are.

Remove language in 8.7.1.b: Designating which individual(s) or positions are responsible for initiating and/or recommending corrective action.

The language added from the ISO/IEC 17025:2017 Standard about a cause analysis was considered to be added as a NOTE. Two voting members had to step off, so this discussion will continue at the next meeting.

A workgroup meeting will be held on November 18, 2024 at 2 or 3pm Eastern. These meetings are used to continue work on the review of the Standard, but no final decisions can be made. *(Addition: See Attachment B for workgroup meeting summary.)*

3. New Business

None.

4. Action Items

A summary of Action Items can be found in Attachment C.

5. Next Meeting and Close

The next meeting will be by teleconference/webinar on December 9, 2024 at 1pm Eastern. A Standard Review Workgroup meeting will be held November 18, 2024 at 2 or 3pm Eastern. Debbie will follow-up with time.

Debbie adjourned the meeting at 2:04 pm Eastern.

Attachment A
Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) **Present**	Alabama Power	2026	Lab	dbond@southernco.com
Carla McCord **Absent**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Nicole Cairns **Present**	NYSDOH	2027	Lab	nicole.cairns@health.ny.gov
Michael Demarais **Present**	SVL Analytical	2026	Lab	michael@svl.net
Tony Francis **Present**	SAW Environmental	2026	Other	tfrancis@sawenviro.com
Carol Gebhart **Absent**	ALS Global	2027*	Lab	Carol.gebhart@alsglobal.com
Stephanie Atkins **Absent**	Pace Analytical	2027	Lab	stephanie.atkins@pacelabs.com
Jordan Adelson **Present**	DoD - Navy	2024*	Other	jordan.m.adelson.civ@us.navy.mil
Nicholas Slawson **Absent**	A2LA	2026	Accrediting Body	nslawson@a2la.org
Joann Slavin **Absent**	Wadsworth Center/Environmental Laboratory Approval Program	2027*	Accrediting Body	joann.slavin@health.ny.gov
Caitie Van Sciver **Absent**	NJDEP	2027*	Accrediting Body	Caitie.vansciver@dep.nj.gov
Zaneta Popovska **Absent**	ANAB	2025*	AB	zpopovska@anab.org
Sean Hayes **Present**	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov
Amy Schreader **Absent**	UC Laboratory	2027	Lab	amy@uclaboratory.net
Ashley Larssen **Absent**	KC Water	2027	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	n/a	Ilona.taunton@nelac-institute.org

Attachment B – November 18, 2024 Workgroup Summary

(Addition:

The following Voting members attended the workgroup meeting: Carla McCord, Carol Gebhart, Debbie Bond, Joann Slavin, Jordan Adelson, Michael Desmarais, Nicole Cairns (3:10pm Eastern), Sean Hayes, Stephanie Atkins, Zaneta Popovska – 10 voting members.

The following Associate Members attended the workgroup meeting: Cindy Redmond, Debra Zeller, Fida Kased, Kristin Brown, Lisa Parks, Paul Junio, Rebecca Pierrot, Bob Wyeth, Sushmitha Reddy, Stephanie Drier, Tammy Kreutzer, Ty Atkins, and Bill Reeves.

Summary

The Committee is continuing to hold a Standard review workgroup meeting on the 3rd or 4th Monday of the month to review language that will be reviewed and discussed at the following Committee meeting on the second Monday of the Month. No official business is done at these meetings and all language suggestions are discussed at the Committee Meetings.

The meeting started at 3pm and concluded at 4:32pm Eastern.

Ilona described the process of what happens to the Standard before the Committee does its final review and voting. The definitions, introductions, Sections 1 and 2 and the Annex A,B and C need to still be reviewed.

Debbie reviewed the changes made at the last meeting (see November 5, 2024 notes).

The review continued in Section 8.7.1. –

There was language from ISO/IEC 17025:2005 added in Section 8.7.1.b:
The cause of a nonconformity may not be obvious and therefore the cause analysis must include a review of any areas that could be the cause. Cause analysis applies to failures that indicate a systemic error.

The Committee discussed whether this language is still needed. Carol noted that Section 7.10.1.c discusses this. It appears informational. There was general agreement to recommend this language be removed. The new Standard covers this well already.

Section 8.7.1.d: Corrective action. Leave as is. Lab determines when more work needs to be done on a corrective action to ensure it does not happen again. When this is done the lab would want to check effectiveness.

8.8 Internal Audits

The goal is to spread the internal audit over 3 years – not to do it all in one year every 3 years. Need to be sure this is clear.

Lisa said the workgroup that worked on this language intended that i) was to cover the concern Ilona raised where technology should be covered each year. It is not just Organic one year, Inorganic one year, etc …

Section 8.8.3.c.i: Is there a need to define representative? Leave it. Consider adding examples to Annex C of "how" this can be done. "Representative" is a fundamental concept that people should understand.
Updated flow of language from c) to (i) and (ii).

Section 8.9 Management Reviews:

Section 8.9.2.1:
Added: b) a review of the effectiveness of the data integrity system.

This system is discussed in the standard and does not need anymore detail.

Attachment C: QSM Action Item Summary – 2024

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
1	Update V1M2	V1M2		Ongoing	Ongoing	Ongoing		See #6 – Review SIRs See #2 – Workgroups See #3 – Technical Specialist 12/10/23: Reviewing the DRAFT Standard and working on finalizing language that was inserted from work done by the various language workgroups and making sure language is properly placed in the new format. Additional language editing is being done through this review. The Summary of Changes/Justification document will be updated through this review process. The Committee is looking at changing the Quality Manager title to Quality Specialist. 1/8/24: Edited Data Integrity Section. 5/13/24: Started review of language again.
2	Develop Workgroups to work on language in specific section of the Standard.	V1M2		Ongoing	Ongoing	Ongoing		Language Workgroup tasks: – Internal Audits – Document/Record Retention – Quality Manual – Define “Appropriate QC” in Section 7.7 (ISO/IEC 17025:2017) – Consistent use of Procedure and Policy - Clarification of unique ID

								2/6**/23**: Working on defining Technology. Will work with PTPEC, Chemistry and LAMS to further this work. 3/6/23: Working on records retention language. 4/11/23: Committee sending ideas for records retention language to Workgroup for consideration. 7/10/23: Language formulated is now being added to the DRAFT Standard. 8/11/23: The Definitions Workgroup presented information on definitions and there was a lot of discussion surrounding duplicate, replicate, records, policies and procedures (written). 9/11/23: A number of new workgroups have been formed to continue work on the standard. Workgroups now include: - Definitions (presenting 9/11/23) - Language (present Oct) – on Oct agenda - Data Integrity (present Oct) – delayed to Nov - Subcontracted Work (present Dec) - Measurement Traceability (present Dec) - Calibration Requirements (not started) - Handling Test Items (not started) 9/13/23: The Definitions WG has completed their task to evaluate ~12 terms and compose definitions, if needed, and review full V1M2 Draft for correct use of the term 'Procedure.' The update included the final items that no definitions for duplicate or replicate will make it into V1M2, and defining

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								Procedure as “written” is not in conflict with any ISO 17025:2017 usage of procedure. 11/15/23: The WG for Subcontracting Work (V1M2 4.5.5) completed its task and the draft language is incorporated into Draft V1M2. Data Integrity WG (V1M2 4.2.8.1 & 5.2.7) is almost done but will need to review the most recently proposed additions to match up with QSM 6.0 V1M2. Workgroups Measurement Traceability (5.6), Calibration Requirements (5.5), and Handling Test Items (5.8) just launched this month and will begin tackling suggested edits to these sections. 12/11: Continued updates can be found above in the work for the Standard update since the Committee is now focused on reviewing language in the DRAFT Standard.

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3	Technical Specialist Language	V1M2		Ongoing	Ongoing	Ongoing		1/11/23: Worked on Exceptions. 2/13/23: Made updates based on conference comments. Working on language to make it clear current technical managers may continue as technical specialists for same areas of responsibility. 8/7/23: Technical Specialist status was reviewed at the Conference and comments ranged from concern that it still won't work for smaller labs to concern that the differing requirements between the Expert Committees makes it confusing. 12/10/23: Received a batch of recommended changes from NELAP AC. Debbie plans to talk to the NELAP AC about the changes. 2/12/24: The Committee started going through the table of recommended changes from the NELAP AC and included Committee Decisions that will be voted on after the table review is complete. 5/13/24: The table was completed in April and the results were presented in the minutes. The minutes and the decisions included were approved 5/13/24. Debbie will send out the comments relevant to the Expert Committees so they can start thinking about whether they need to update their Standard to include more Technical Specialist language.

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4	Defining Technology	Various TNI Standards	Paul Junio Tony Francis Debbie Bond	January 2023	12/11/23			1/11/23: Will work with Paul Junio's group to define Technology. PT, AB, QSM, etc. 12/11/23: Paul has started email communication on this topic, but the Workgroup has not met yet. 5/13/24: Need an update. Group has not met formally.
5	Respond to SIRs	SIR 453 SIR 465		Ongoing	Ongoing	Ongoing	Lynn Bradley – LASEC PA	**3/13/23**: Responded to SIR 453 regarding quarterly calibration verification of manual repeating pipettes. 8/14/23: Responded to SIR 465 regarding Class A glassware.
8	Address NEFAP request for recommended language in Section 7.3.	V1M2 – Section 7.3	Tracy Szerszen-NEFAP Chair	7/10/23	7/10/23			7/10/23: Alternate language recommended to NEFAP. 12/10/23: Debbie will meet with NEFAP at the conference to look at the language. 1/24/24: Language was reviewed during the conference and placed into the DRAFT Standard.
10	Internal Audit		Ilona Debbie	12/10/23	12/10/23			12/10/23: Checklists were added to Internal Audit Database to internal audit can be performed. Scheduled for 1/4/23. 1/4/24: Audit performed by Debbie and Ilona. 2/12/24: Internal Audit shared with the Committee and Corrective Action was completed. Ilona will send to CSDP EC for final review . *(Addition: 2/13/24: Sent to Paul Junio and Bob Wyeth on 2/13/24.)*

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
11	Implementation Tool: Prepare a crosswalk for old vs new Standard.				TBD			6/20/24: Ilona noted that there is a crosswalk for the ISO language, but TNI language would need to be added.
12	Respond to SIR 489	SIR 489		7/8/24	7/8/24	7/8/24		7/8: Committee approved response.