Quality Management System Expert Committee (QMS)
Meeting Summary

March 10, 2024

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on March 10, 2024. Attendance is recorded in Attachment A – there were 6 voting members present. Associate members present: Michelle Berrett-Muir, Cindy Redmond, Linda ODonnell, Amy Lovelace, Brian Eichelberger, Nicholas Evans, Jeanette Hernandez, Windsor Molnar, Kelvin Yuen, Ryan McMullin, Ty Atkins, Carl Kircher (phone), Bill Reeves, Tammy Kreutzer, Lynn Boysen, Nicole Van Aken, Anagha Chitre, Kim Fielder, Stephanie Drier, Lisa Parks . Guest: Bob Wyeth.

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

There was no quorum today so final decisions and voting could not be done.

2. Definitions

The Committee continued to work on review of the definitions in the DRAFT Standard. A survey has been prepared to get input from all the Expert Committees to see what definitions they are using in their Standard and to get feed back on what definitions should be in Module 2. Ilona brought up the survey so the Committee can see how it works. The deadline for completion is April 1, 2025.

<u>Lot</u>

The term is used in the Support Equipment section. The term will be left in and will be looked at again.

<u>Matrix</u>

Ilona noted that this definition in the glossary looks a lot like the definition we currently have called Quality System Matrix. Field decided to just call it Matrix. When we met previously, we suggested also just calling it Matrix and deleting Quality System Matrix that is on the Survey. Use the definition in the Glossary.

<u>Mobile Laboratory</u>

Changed to Mobile Facility as used in ISO/IEC 17025:2017. The definition is different than what is in the glossary. Stephanie asked if someone put up a tent, would that be acceptable. Would the tent be considered enclosed? What if you take the pH at the at the source and its not measured in the Mobile Facility. That is field testing. The question will be raised with the Field Activities Expert Committee to see if this definition needs more

work. FAC has already finished their Volume 1, so “enclosed” is part of their final definition. Ilona suggested looking at the definition for field activities that says testing, calibration, measurements, observations or sampling performed outside of the confines of the FSMOs permanent control. This would fit with what Stephanie is asking. Need to talk to FAC.

Precision

Stephanie noted that Standard Methods, says a measure of the degree of agreement among replicate analysis of a sample.

Nicole found a definition in another ISO/IEC Standard: closeness of agreement between independent test measurement results obtained under stipulated conditions.

Lynn shared what is in the Drinking Water Manual: The measure of mutual agreement among individual measurements.

After extensive discussion, the proposed definition is: The measure of agreement between independent observations or measurement sof a given property obtained under specified conditions. Precision is susally expressed as standard deviation, variance or range, and other absolute or relative terms.

Procedure

The definition was placed by the Definitions Workgroup a couple of years ago. Nicole thinks it should be updated a bit to written instructions for performing a task, process or other laboratory activity.

Quality Assurance

A question was raised about the need to include the term “client” in the definition as stated now. Another concern raised was about context of the definition. How well does it relate to a lab verses someone managing government contracts.

Another definition option: A definitive plan for laboratory operations that specifies the measures used to produce data with known precision and bias.

After further discussion, Debbie proposed: The system of documented activities implemented at a laboratory that supports the laboratory's quality objectives.

Work will continue on definitions at the Workgroup meeting beling planned for March 24, 2025 at 1pm Eastern.

3. Crosswalk Workgroup

Debbie suggested that the Committee form a workgoup to develop a crosswalk between the 2016 Standard and this new Standard being worked on. She expects that the language is likely in its final location so work on this can begin. Debbie would like to complete this by the summer face-to-face meeting. The following Committee members volunteered: Ashley, Carl, and Stephanie.

4. New Business

None.

5. Action Items

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

6. Next Meeting and Close

The next meeting will be a workgroup meeting to continue work on the Standard on March 24, 2025 at 1pm Eastern by teleconference. The next Committee meeting will be on April 14, 2025 at 1pm Eastern by teleconference.

Debbie adjourned the meeting at 2:31 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 **Absent.**	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 **Absent**	DoD - Navy	2024*	Other	jordan.m.adelson.civ@us.navy.mil
Nicholas Slawson **Present**	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 **Present**	NJDEP	2027*	Accrediting Body	Caitie.vansciver@dep.nj.gov
Zaneta Popovska **Absent**	ANAB	2025*	AB	zpopovska@anab.org
Sean Hayes **Absent**	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov
Amy Schreader **Absent**	UC Laboratory	2027	Lab	amy@uclaboratory.net
Ashley Larssen **Present**	KC Water	2027	Lab	XXXX
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	n/a	Ilona.taunton@nelac-institute.org

Attachment B: QSM Action Item Summary – 2024/2025

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. Continued review of language June, July, August, September, October, November. 12/9/24: Finished up review of language and started review of Definitions. Considering how to handle extensive list – are all definitions needed? Work with Ilona and Paul before next meeting.
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)

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								– 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

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								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 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.

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. 9/9/24: Workgroup in August reviewed and Committee discussed during regular meeting. Experience requirement going to 1 year. QMS will set a minimum requirement and the Expert Committees

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								can add more to their Standard if more is needed. 12/9/24: There will be a session in Jacksonville that will discuss concept of Analytical Disciplines and Technical Specialists.
4	Defining Technology (Analytical Disciplines)	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. September Update: CSDP EC is developing an Analytical Disciplines Workgroup. October: Workgroup began meeting. There will be a session in Jacksonville devoted to this topic. Will impact Training, Credentialing, and Technical Specialist.
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.

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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	1/24/24		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	2/13/24		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.)*
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.
13	Respond to SIR 504	SIR 504		12/9/24	12/9/24			12/9/24: Complete SIR by email because no quorum on call.