Quality Management System Expert Committee (QMS)
Meeting Summary

May 12, 2025

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on May 12, 2025. Attendance is recorded in Attachment A – there were 9 voting members present. Associate members present: Bill Reeves, Lynn Boysen, Kim Fielder, Nicholas Johnson, Lee Ann Kline, Jeanette Hernandez, Ty Atkins, Linda Odonnell, Amy Lovelace, Brian Eichelberger, Debra Zeller, Cindy Redmond, Michelle Berrett-Muir, Nicole Van Aken, Tammy Kreutzer, Paul Junio, Kathleen Lloyd, Homer Youngblood, Douglas Kablik, Windsor Molnar, Jasmina Kuljanac, Kristin Brown, Sumy Cherukara, Nicholas Evans, Annmarie Beach, Anagha Chitre, and Carl Kircher (by phone only).

Lee Ann Kline is a new Associate Member of the Committee. She introduced herself.

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

The April meeting minutes were reviewed. A motion was made by Nicole to approve the April 14, 2025 minutes with editorial changes to correct the dates from the previous meeting. The motion was seconded by Joann. Vote: Unanimous.

2. Definitions

The Committee resumed review of the Definition Survey table starting with Certified Reference Material.

<u>Certified Reference Material</u>
Keep this definition, but review it against the Volume 3 definition from ISO Guide 30.

<u>Confirmation</u>
Delete. Ask Module 7 to include it in their Module if still needed.

<u>Contract</u>
Delete

<u>Correction</u>
Keep definition in Module 2 and update as needed.

<u>Corrective Action</u>
Keep definition in Module 2 and update as needed.

<u>Data Integrity</u>
Delete. This is well defined in the language in the Standard.

Document
Keep definition in Module 2 and update as needed.

In-depth Data Monitoring
Delete

Legal Chain of Custody
Delete

Limit of Detection (LOD)
Delete. Ask Module 4 to include it in their Module and share their definition with Module 3.

Matrix Spike
Delete. Ask Module 4 to include it in their Module. Notify Module 7 to look at Module 4 before defining in their Module.

Method
Discuss with Module 3 and 7 to decide whether to drop it. Committee would like to drop it from Module 2, but the term is used in Modules 3 and 7.

NIST
Delete. Notify Module 3 about deletion. They can define in their Module if they think they need it.

Preservation
Keep definition in Module 2 and update as needed.

Quality Manual
Delete

Record
Keep definition in Module 2 and update as needed. Need to make sure it is being used consistently throughout the Standard.

Reference Material
Keep definition in Module 2 and update as needed. Review against Volume 3 definitions that are from ISO Guide 30.

Reference
Keep definition in Module 2 and update as needed. See VIM definition to incorporate language (change "used" to"designated").

The Committee discussed how defintions are used and found. Consideration should be givent to adding a note at the top of the definitions to explain where defintions can be found. Some may be in the Modules where the terms is used.

3. New Business

   None.

4. Action Items

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

5. Next Meeting and Close

   The next Committee meeting will be on June 9, 2025 at 1pm Eastern by teleconference. There will not be an optional Workgroup meeting in May.

   Debbie adjourned the meeting at 2:43 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 **Present**	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 **Present**	ALS Global	2027*	Lab	Carol.gebhart@alsglobal.com
Stephanie Atkins **Absent**	Pace Analytical	2027	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Absent**	A2LA	2026	Accrediting Body	nslawson@a2la.org
Joann Slavin **Present**	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 **Present**	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 **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

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

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

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

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