Quality Management System Expert Committee (QMS)
Meeting Summary

June 9, 2025

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on June 9, 2025. Attendance is recorded in Attachment A – there were 7 voting members present. Associate members present: Kim Fielder, Linda O'Donnell, Annmarie Beach, Homer Youngblood, Meera Neb, Kelvin Yuen, Bill Reeves, Debra Zeller, Paul Junio, Lynn Boysen, Kathleen Lloyd, Jasmina Kuljanac, Lee Ann Kline, Jeanette Hernandez, Lien Nguyen, Windsor Molnar, Brian Eichelberger, Kristin Brown, Amy Lovelace, Nicholas Evans, and Marlene Moore.

There is not a quorum, so no formal business can be done and the minutes cannot be approved. Minutes will be approved next month.

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

2. Technical Specialist

Debbie provided an update on Technical Specialist language. After a meeting with the NELAP AC, Debbie, Paul Junio and Ilona met to work on the Technical Specialist language. It looks like the language may go back into Module 2 with some simplification and not into the Technical Modules. The language will include the level of degree along with an amount of required experience to with each degree level. There may be room for some Technical Module specification but this will be minimal if any.

Ilona noted that during the NELAP AC meeting a number of comments were that they liked the concept of what was originally presented (tiered approach with degree and education), but didn't like all the complicated additions from the Technical Modules. A course could be mentioned, but perhaps Annex C could be used to note course examples since Annex C can be used to help with implementation. Module 2 could say a related course must be taken for specific analytical disciplines with a reference to Annex C where examples would be given.

Paul noted that we are not asking the NELAP AC to write the Standard for us … just provide feedback that can be used to develop the Standard.

Ilona noted that if you look at the original language that came form the Techinical Modules, you will see that there are specific Modules that requested specific course work or training. Make it more generic in the text and refer to Annex C. There may be some instances where a minimum of a Bachelor's degree is required and this can be summarized as a sentence – A minimum of a Bachelor's degree is required for x, y and z. This might reduce the complexity that the NELAP AC was concerned about.

Another thing discussed was that the NELAP AC is OK with exceptions like Bob Shannon in Radiochemistry, and the example Robin Cook often gives. These don't happen often, but they are open to them when they do. Needs to be less than 10% or the language does not work.

2. Definitions

The Committee resumed review of the Definition Survey table starting with "selectivity". The Committee also reviewed Sensitivity, Standard, Technology, and Traceability.

Technology needs to be defined. Need to take a look at the LAB Standard also.

The last definition considered was Traceability. The Committee will continue working on definitions at the Workgroup meeting on June 23, 2025 at 1pm Eastern.

(Addition: Summary of June 23, 2025 Workgroup Meeting

The Committee continued the review of the Definition Survey Summary that Ilona prepared. The Committee looked for definitions that could be deleted because no Expert Committee used it in their Module or needed it for the current DRAFT they were working on. Where only one Expert Committee still needed a definition, the Expert Committee will be notified that the definition should be added to the Expert Committee's module. Where multiple Expert Committees used or needed the definition, the definition will be left in Module 2. The Summary Table was used to document this information and will be available after the review is complete.

The definitions looked at included: Verification,Batch, Lot, Measurement, and Moble Facility. This completed the initial review of the definitions. Debbie will prepare a DRAFT letter to each Expert Committee Module with the results. The Committee than began reviewing defintions that are to be kept in Module 2.)

3. New Membership

Debbie closed the meeting at 1:23pm Eastern for associate members since new membership was being discussed.

Debbie received 2 applications for consideration: Brian Eichelberger and Katie Strothman. After review of the Committee make-up it was determined that a new Committee member could not be a laboratory. It would put the Committee out of balance.

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 Committee meeting will be on July 14, 2025 at 1pm Eastern by teleconference. There will be an optional Workgroup meeting on June 23, 2025 at 1pm Eastern by teleconference.

   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 **Absent**	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
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

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	Complete	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	2/11/25		12/9/24: Complete SIR by email because no quorum on call.