Quality Management System Expert Committee (QMS)
Meeting Summary

April 14, 2025

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on April 14, 2025. Attendance is recorded in Attachment A – there were 13 voting members present. Associate members present: Alexander Chieh, Bill Reeves, Lynn Boysen, Brian Eichelberger,

There were no changes made to the agenda. Change – add review of the minutes. The agenda was approved by unanimous consent.

The March meeting minutes were reviewed. A motion was made by Tony to approve the March 10, 2025 minutes as written. The motion was seconded by Nicole. Vote: For – 12, Against – 0, Abstain – 1 (Carol). The minutes were approved.

2. Review of SIRs

The following SIRs were submitted, but were found to not be valid SIRs. These SIRs are reviewed by the Expert Committees to determine if anything needs to be considered for a Standard update.

SIR-507
This was already addressed in the DRAFT Standard. The lab must ensure that items are verified.

SIR-508
This SIR looks similar. It just asks about Module 2 and SIR-507 asked about Module 2 and Module 5.

SIR-510
No change needed to the DRAFT Standard. The Standard is clear that monitoring the temperature of a water bath is required.

SIR-512
This SIR is actually a Chemistry Expert Committee SIR. Debbie will send it back to Lynn.

SIR-514
No change needed to DRAFT Standard.

3. Technical Specialist

Debbie went through notes from the Jacksonville meeting and shared the table she sent with the Agenda - Existing Regulations in NELAP States about Technical Manager Qualifications – March 2025.

Key Personnel is not defined so it should be removed or defined. Instead of using the term Key Personnel – Use Technical Specialist. Tony suggested Key Personnel and notifications might be AB specific.

The language in DRAFT Section 5.5.1 was removed and moved to Draft Section 5.6.5. This includes assignment of a deputy here, so it is covered already.

There were some suggestions to consider providing a competency record for the deputy technical specialist to the AB. There was not support for this susggestion given that the deputy does not need to meet any specific qualifications.

The Committee then discussed options for developing a plan to replace the Technical Specialist. Specific calendar days for replacement may difficult to meet. There was also some continued discussion the need for some experience regarding the deputy, but it was pointed out that the AB an ask additional questions once they get the plan. After further discussion DRAFT setion 5.6.5 was split into 5.6.5 and 5.6.6. and the following language was agreed upon:

5.6.5 The laboratory must have a deputy(ies) for the Technical Specialist(s).
a) The deputy is not required to meet the qualification requirements of a Technical Specialist.

5.6.6 The deputy must assume the responsibilities of the Technical Specialist when the Technical Specialist is unable to fulfill the duties specified in sections 5.6.3 a) and b) for fifteen (15) consecutive calendar days.
a) When the deputy has assumed the responsibilities of the Technical Specialist for more than sixty (60) consecutive calendar days, the laboratory must notify the accreditation body in writing and include a plan with a timeline for appointing a qualified Technical Specialist.

The Committee then moved on to looking at Section 6.2 Personnel.

Section 6.2.2.2.a: The Committee disussed need for appropriate records that must be maintained to show previous reognition as a Technical Specialist. Caitie and Lynn Boysen mentioned that their states require the lab to submit the paperwork again. The concept of grandfathering was discussed. Is submitting a resume that states you were a Technical Specialist elsewhere sufficient? Might need transripts and other records. Language should not be specific. The following language was agreed upon:

a) Any person who was formally recognized as a Technical Specialist (however named) based on requirements or exceptions in previous revisions of this Standard will continue to be eligible as Technical Specialist for the same analytical disciplines at any accredited laboratory. Appropriate records must be available to show previous recognition as a Technical Specialist.

Commented [DB1]: From Jacksonville '25: Add that appropriate records must be maintained to show previous recognition as TS."

Section 6.2.2.2.b: The question asked was: Is this lab experience or experience as an operator, or does it matter? There was general agreement that is should be laboratory experience. It was also asked if we should add analytical discipline to this experience. This needs to be looked at further.

Section 6.2.2.2.c: This needs further discussion. TNI will not require it, but if the ABs accept it, it will be another option. There was also discussion in Jacksonville that Bob Wyeth is supposed

to look into. There was concern that a TNI standard was pointing to another TNI program. The NGABs noted that this could be an ANSI concern.

Section 6.2.2.2.d: It was questioned if this section should be removed. Further discussion is needed and an update is needed from Paul Junio (CSDP EC, Chair) regarding analytical disciplines.

There was also discussion in Jacksonville regarding multiple Technical Specialists. Is that OK or are ABs expecting this to be limited to one or two.

4. New Business

None.

5. Action Items

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

6. Next Meeting and Close

The next meeting will be a workgroup meeting to continue work on the Standard on April 28, 2025 at 1pm Eastern by teleconference *(Addition: See Attachment B for a Summary of this meeting).* The next Committee meeting will be on May 12, 2025 at 1pm Eastern by teleconference.

Debbie adjourned the meeting at 2:32 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 **Present**	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
Jordan Adelson **Present**	DoD - Navy	2024*	Other	jordan.m.adelson.civ@us.navy.mil
Nicholas Slawson **Present**	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 **Present**	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 **Present**	UC Laboratory	2027	Lab	amy@uclaboratory.net
Ashley Larssen **Absent**	KC Water	2027	Lab	XXXX
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	n/a	Ilona.taunton@nelac-institute.org

Addition: Attachment B: Summary of April 28, 2025 Workgroup Meeting

The Committee reviewed 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:
Calibration Curve, Chain of Custody Form, Critical Supples and Services, Data Redution, Field of Accreditation, Finding, Internal Standard, Laboratory Control Sample, Matrix Spike Duplicate, Measurement System, Mobile Laboratory (new name now Mobile Facility), Physical Parameter, Proficiency Test Sample, Quality Management System Matrix (now using only Matrix), SOP, Blank, and Method Blank.

Attachment C: 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

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.

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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.