

**Quality Management System Expert Committee (QMS)
Meeting Summary**

December 11, 2023

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on December 11, 2023. Attendance is recorded in Attachment A – there were 11 voting members present. Associate members present: Rebecca Pierrot, Brian Eichelberger, Paul Junio, Kelvin Yuen, Patty Carvajal, Amanda Grande, Fida Kased, Debra Zeller, Eric Denman, Joann Slavin, Kim Fielder, Matt Sica, Megan Rothgerber, Ty Atkins, Sushmitha Reddy, Carol Gebhart, Sumy Cherukara, and Annmarie Beach.

Debbie shared the November meeting minutes on screen. Kathi raised an issue about using “must” instead of “shall”. She noted that ISO/IEC uses “shall”. This issue was brought to TNI and the Policy Committee decided to make this change. Paul Junio will research this and bring information back to the next meeting, but no change will be made to the November meeting minutes. Ilona shared information from CSDP requiring the use of “must”.

A motion was made by Earl to approve the November 13, 2023 minutes as written with a correction to Kathi’s attendance at the last meeting. The motion was seconded by Kathi and unanimously approved. Ilona will request that the minutes be posted.

2. Winter Meeting

Debbie shared the DRAFT agenda for the meeting in Columbus, NC.

The Committee update will be since the last meeting in Minneapolis since she will also share the 2023 Accomplishments and 2024 Plans slides.

Debbie will reach out to people for help presenting the various updates for Workgroup activity.

Debbie asked if an update should be done on the Field Activities/NEFAP request. She will be meeting with Tracy Szerszen (NEFAP, Chair), Ilona, Paul Junio and Katie Strothman (FAC/NEFAP) at lunch to discuss this language prior to the QMS meeting on Wednesday. There was agreement to provide an update.

Most of the afternoon will be used to continue to work on the language in the actual DRAFT Standard.

Debbie will not be presenting anything on Technical Specialist. She received a batch of recommended changes from the NELAP AC. If the Committee is good with what they

are recommending, this should finish up this section of the Standard. Debbie wants to talk to the NELAP AC about the changes and has not had time to do this yet.

(Addition: Email from Lynn Bradley on 9/23/23:

QMS Request for Feedback on Technical Specialist Language

*Shortly after conference, Debbie Bond (Chair of Quality Management Systems [QMS] Expert Committee) requested feedback from the Council about the near-final version of language for the Technical Specialist (TS) qualifications. This position was formerly called the Technical Manager or Technical Director, but after review by the Competency Task Force last year, has been re-defined to clarify that supervisory or managerial responsibilities are not necessarily part of the role, and additional adjustments made to allow for experience to count while not diminishing the expertise of the person. The following comments were made during the meeting, and **Kristin asked that everyone read through the draft and provide any additional comments directly to her for communication back to Debbie and QMS.***

- *Overall – this is very close to being finished. Some explanation of how to account for the difference in course hours between quarter and semester terms must be included.*
- *§4.1.7.2 – use only one title for the position of Technical Specialist (for purposes of completing accreditation applications) while clarifying that the job title used in the laboratory need not match the title used in the application itself*
- *§4.1.7.2 – states that a TS (not necessarily the same person) must be responsible for every “field of accreditation” in the lab, but later (in 5.2.6.1 and 5.2.6.2) the phrase “representative technologies” is used – consistent nomenclature is important for clarity. Additionally, if used, the term “representative technologies” needs to be defined, as without clear definition, its use may vary with different ABs.*
- *§4.1.7.2 – the requirement to appoint a replacement upon a fifteen day absence is not enforceable and needs to be omitted; it is not possible to hire a replacement within two weeks*
- *§5.2.6.1.b.ii – could you clarify that 1 year of experience is needed for the “earned” associate’s degree while only 6 months is needed for bachelor’s/master’s/doctoral degrees? This is confusing as written.*
- *§5.3.6.2.1.c – microbiology is now more specific than chemistry – was this the committee’s intent?*
- *§5.2.6.1.c.i – please clarify “appropriate field” as associate’s degrees are typically not specialized, and clarify whether 2 years of a 4-year program is acceptable. Remove the comma after education. Also, clarify same issue as 5.2.6.1.b.ii*
- *§5.2.6.1.d – this radiochemistry section is far too prescriptive, with eight college courses (or equivalent) and an additional course for each technology (up to 4) is excessive. It’s not clear why the requirement that one year of experience must be devoted to a single technology is imposed – again this seems overly prescriptive*
- *§5.2.6.2 – the “new technology” was confusing, people did not consistently read this as an “emerging technology” and instead thought that the person overseeing the area where the new technology was added should be assigned. Probably should clarify that this section is about more than just adding a different detector to an existing GC, for example.*

- §5.2.6.2 – *which waiver would substitute for the college level microbiology course? There are other ways to learn micro. It is important to keep the “experience in lieu of education” exception, as qualified people are scarce.*)

3. Internal Audit

Debbie and Ilona will meet the first week of January to work through the Internal Audit and wrap up end of year housekeeping items.

The agendas for the conference are due January 8th and the Annual Report slides are due January 16th. The Committee will be able to review the slides before they are submitted.

4. SIR

Lynn periodically sends copies of SIRs to the Expert Committees that were found to not be a valid SIR. These are for information only in case there is something in it that might be helpful when updating the Standard. Lynn forwarded SIR #463 that had a question about the relationship between ISO/IEC 17025 and the TNI Standard. Ilona looked back through Lynn’s responses and found that she responded to this submittal with the following comment: *However, I will answer your question by explaining that the TNI Standard, Volume 1 Module 2, includes all of the ISO/IEC 17025 language PLUS specific requirements designed to address environmental laboratories.*

5. DRAFT Standard Review

The data integrity workgroup wrapped up and the language has been inserted in the DRAFT for review.

The continued review of the DRAFT Standard will restart at Quality Specialist where the Committee ended last month. Section 5.6.2 - Restarted at “e.”

f. go ahead and delete annually.

Old 4.2.8.2 – Change name to specialist instead of manager. Could this be moved to “i” above. This will be moved. Change wording to “be responsible for maintaining the quality manual.

Update a- coordinate ...

Change line leading to this – add be responsible.

This section will now read:

5.6.1 In addition, the laboratory shall have a quality specialist who:

- a) functions independently from technical operations for which they have quality assurance oversight;
- b) has training and/or experience in the laboratory's quality management system; and
- c) has a general knowledge of the analytical methods for which data review is performed.

5.6.2 The laboratory quality specialist shall be responsible for:

- a) coordinating quality activities;
- b) evaluating data objectively and performing assessments without outside influence;
- c) maintaining the quality manual;
- d) arranging for or conducting internal audits as per Section 4.14;
- e) notifying laboratory management of deficiencies in the quality management system; and
- f) monitoring corrective actions.

The Committee will begin the next review with data integrity (Section 4).

6. Committee Membership

Associate members were asked to end the call. The following Voting Members were present: Ashley, Earl, Jenna, Debbie, Kathi, Carla, Sean, Nicole, Amy, Michael and Zaneta.

Kathi, Earl and Jenna will be rotating off of the Committee. Earl will continue as an Associate member. Looking at the application, this means that two ABs and 1 lab can be added to the Committee. The Committee reviewed all resumes and discussed options. All candidates were excellent.

The Committee decided to vote on the only two AB candidates and to handle the vote for a lab by having Committee members type into Chat their vote and whoever had the most votes would be included in the vote for new voting membership of the Committee. Carol Gebhart had the most votes.

A motion was made by Ashley to approve Joann Slavin (AB, NY), Caitie van Sciver (AB, NJ) and Carol Gebhart (Lab, ALS) as new voting members of the Committee with terms effective after the winter meeting. The motion was seconded by Jenna and unanimously approved.

(Addition: Paul Junio (Chair, CSDP) approved the new members by email on 12/11/23.)

Vice-Chair

Kathi nominated Carla for Vice-Chair of the Committee. There were no other nominations.

Kathi made a motion to approve Carla as Vice-Chair of the Committee. The motion was seconded by Earl and there was no further discussion. The motion was unanimously approved.

Chair

Debbie is willing to continue to Chair and there were no other nominations.

Kathi made a motion to approve Debbie as Chair of the Committee. The motion was seconded by Amy and there was no further discussion. The motion was unanimously approved.

(Addition: Nicole, Stephanie, Amy and Ashley are interested in serving a second term. Their second term will need to be approved by the Committee.)

7. New Business

None.

8. Action Items

Iлона changed the format for tracking action items. A copy can be found in Attachment B.

9. Next Meeting and Close

The next meeting will be by teleconference on January 8, at 1pm Eastern. Jenna, Zaneta and Carla will not be able to make this meeting. Earl may also not be available.

Debbie adjourned the meeting at 2:35pm 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
Kathi Gumpper (Vice-Chair) Present	ChemVal Consulting	2024	Other	kgumpper@chemval.com
Nicole Cairns Present	NYSDOH	2024*	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
Carla McCord Present	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins Absent	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson Absent	A2LA	2026	Accrediting Body	nslawson@a2la.org
Earl Hansen Present	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak Present	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@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	2024*	Lab	amy@uclaboratory.net
Ashley Larssen Present	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Jordan Adelson Absent	Navy (DoD)	2027*	Other	jordan.m.adelson.civ@us.navy.mil
Ilona Taunton (Program Admin) Present	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B: QSM Action Item Summary – 2023

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.
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

								<p>2/6/23: Working on defining Technology. Will work with PTPEC, Chemistry and LAMS to further this work.</p> <p>3/6/23: Working on records retention language.</p> <p>4/11/23: Committee sending ideas for records retention language to Workgroup for consideration.</p> <p>7/10/23: Language formulated is now being added to the DRAFT Standard.</p> <p>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).</p> <p>9/11/23: A number of new workgroups have been formed to continue work on the standard. Workgroups now include:</p> <ul style="list-style-type: none">- 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) <p>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</p>
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Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								<p>Procedure as “written” is not in conflict with any ISO 17025:2017 usage of procedure.</p> <p>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.</p> <p>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.</p>

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
3	Technical Specialist Language	V1M2		Ongoing	Ongoing	Ongoing		<p>1/11/23: Worked on Exceptions.</p> <p>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 some areas of responsibility.</p> <p>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.</p> <p>12/10/23: Received a batch of recommended changes from NELAP AC. Debbie plans to talk to the NELAP AC about the changes.</p>
4	Defining Technology	Various TNI Standards	Paul Junio Tony Francis Debbie Bond	January 2023	12/11/23			<p>1/11/23: Will work with Paul Junio's group to define Technology. PT, AB, QSM, etc.</p> <p>12/11/23: Paul has started email communication on this topic, but the Workgroup has not met yet.</p>

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
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.
6	Review SIRs for need to modify the DRAFT Standard.	SIRs		Ongoing	3/13/23	10/9/23		9/11/23: halfway through a final review of SIRs. 10/9/23: Completed review of SIRs. Workgroups are continuing to meet to propose language for the DRAFT Standard. The Committee will now begin focus on reviewing all language in the DRAFT Standard. CLOSED
7	Review language received from Consumables Task Force for possible inclusion in DRAFT Standard.			7/10/23		8/11/23		7/10/23: A definition for “Critical Supplies and Services” is being added to the DRAFT Standard and the Committee is still working through recommended Chemical Certificate and Service Certificate contents. 8/11: Language from the Consumables Task Force was presented at the Conference and feedback was that it did not belong in the Module 2 Standard. CLOSED.
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.

