# Quality Management System Expert Committee (QMS) Meeting Summary

## June 10, 2024

### 1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on June 10, 2024. Attendance is recorded in Attachment A – there were 10 voting members present. Associate members present: Dan Cantu (Audio only), Alma McCammond, Annmarie Beach, Bill Reeves, Brian Eichelberger, Carol Barrick, Cindy Redmond, Dan Jackson, Debra Zeller, Fida Kased, Jeanette Hernandez, Kathleen Lloyd, Linda O'Donnell, Lynn Boysen, Nicole Van Aken, Rebecca Pierrot, Sumy, Tammy Kreutzer, and Ty Atkins.

There were two additions made to the agenda sent by email.

- Welcome new members. (Debbie)
- TNI Field Standard Update (Ilona)

There was no objection to the additions. The agenda was approved by unanimous consent.

Bill Reeves introduced himself. He was a QA manager and is now working at the national level for Eurofins.

The March and May minutes were distributed by email and reviewed on screen. There was not a quorum in April, so the March minutes were not voted on. A motion was made by Joann to approve the March 11, 2024 and May 13, 2024 minutes as written except for a meeting date correction in the May 13<sup>th</sup> minutes. The motion was seconded by Carla and unanimously approved.

## 2. Field Standard

The Field Standard is going through it's final committee review in preparation to have it posted as a DRAFT Standard for comment.

Paul Junio reviewed all the definitions and worked on them with Ilona and the Field Activities Committee (FAC). These definitions will be shared with QMS for inclusion as appropriate in the Module 2 Standard.

Ilona also noted that the FAC will be including an Informative Annex to include text that did not seem appropriate in the Standard. Information in this section includes implementation examples. For example, the list of prohibited actions in Section 4.1.6.1 of our Module 2 DRAFT is included in Annex C in the Field Standard.

## 3. NEMC Agenda

The Committee will be meeting from 9-12pm with a break from 10-10:30am. Debbie is hoping the DRAFT Standard will be getting close to finalization.

Agenda items:

- Technical Specialist might need to be a separate agenda item.
- Standard Review and Highlight changes.
   Are we losing anything? Adding things?
   Possibly use the change summary form to present this information.

Debbie reminded people to be sure sign-up for the hotel and registration.

## 4. Work on DRAFT Standard

Section 7.10.1: Change to a note instead of a requirement.

Section 6.4.6: The Committee will return to this section after Paul Junio finishes his review of the same section in the Field Standard. Ilona will forward this information to Debbie once complete. Some of the changes are intended to make it line up better with ISO/IEC language to make it easier for a user to use it.

Section 7.2: Ilona noted that reminders in the standard about how forms should be stored are not needed when the information is already stated in another part of the Standard. Move all this language to the appropriate section of Section 8.

Need to be careful about what should be a note and what is a requirement. Is it something you can assess to?

Debbie would like to meet again this month. The Committee agreed to a workgroup meeting on June 24, 2024 at 1pm Eastern to continue work on the Standard for review at the July meeting.

(Addition: A group met on June 24, 2024 at 1pm Eastern to continue looking at the Standard. This was not an official Committee meeting and all work will be reviewed by the full Committee during the July meeting.

In Attendance: Debbie, Carla, Jordan, Michael and Nicole Associate Members: Andy Freeman, Annmarie Beach, Bill Reeves, Carl Kircher, Carol Barrick, Cindy Redmond, Debra Zeller, Jeanette Hernandez, Kathleen Lloyd, Lisa Parks, Lynn Boysen, Nicole Van Aken, Ryan McMullin, and Sumy.

*Discussion:* <u>Section 7.4.1.2</u>: Updated the language regarding ink on records.

<u>Section 7.4.4</u>: Is 7.4.4.1 a note or is it really needed. Ilona does not think it is a requirement to assess. Change "I" to 7.4.4.1.

<u>Section 7.5</u> - Technical Records

Carl Kircher thinks any record keeping that EPA deems should be present, should be included. For example, MDLs should be available.

Remove c).

Remove a) - covered in 7.3 sampling section.

Ilona noted that the FAC included records retention in Section 8.4.

Debbie moved much of the language to Section 8.4 - Covers all records and not just Technical.

Keep the historical reconstruction list together in this section of the Standard. Carl would like to keep this too.

Action Item: Need a crosswalk during implementation. This implementation tool should be added to the action table. Ilona noted that there is a crosswalk for the ISO language, but TNI language would need to be added.

<u>Section 7.5.1.1</u>: Remove note about memos, etc ... and simplify to "all records" received.

The next meeting will be July 8, 2024 1pm Eastern.)

## 5. New Business

None.

## 6. Action Items

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

#### 7. Next Meeting and Close

The next meeting will be by teleconference/webinar on July 8, 2024 at 1pm Eastern. A workgroup meeting to continue working on the Standard will be on June 24, 2024 at 1pm Eastern.

Debbie adjourned the meeting at 2:27 pm Eastern.

## Attachment A Participants Quality Systems Expert Committee (QS)

		1	Committee (QS)		
Member	Organization	Expiration	Representation	Email	
Debbie Bond	Alabama Power	2026	Lab	dbond@southernco.com	
(Chair)					
Present		0005*			
Carla McCord	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov	
Present					
Nicole Cairns	NYSDOH	2027	Lab	nicole.cairns@health.ny.gov	
Present					
Michael Demarais	SVL Analytical	2026	Lab	michael@svl.net	
Present					
Tony Francis	SAW Environmental	2026	Other	tfrancis@sawenviro.com	
Absent					
Carol Gebhart	ALS Global	2027*	Lab	Carol.gebhart@alsglobal.com	
Absent					
Stephanie Atkins	Pace Analytical	2027	Lab	stephanie.atkins@pacelabs.com	
Present					
Jordan Adelson	DoD - Navy	2024*	Other	jordan.m.adelson.civ@us.navy.	
Present				mil	
Nicholas Slawson	A2LA	2026	Accrediting	nslawson@a2la.org	
			Body		
Absent					
Joann Slavin	Wadsworth Center/Environmental	2027*	Accrediting	joann.slavin@health.ny.gov	
Present	Laboratory Approval		Body		
Fiesent	Program				
Caitie Van Sciver	NJDEP	2027*	Accrediting	Caitie.vansciver@dep.nj.gov	
			Body		
Absent		0005*	4.5		
Zaneta Popovska	ANAB	2025*	AB	zpopovska@anab.org	
Absent					
Sean Hayes	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov	
Dreeset					
Present Amy Schreader	UC Laboratory	2027	Lab	amy@uclaboratory.net	
		2021			
Present					
Ashley Larssen	KC Water	2027	Lab	ashley.larssen@kcmo.org	
Present					
Ilona Taunton	The NELAC Institute	n/a	n/a	Ilona.taunton@nelac-	
(Program Admin)				institute.org	
Present					

Attachment B: QSM Action Item Summary – 2024

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.
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

				<ul> <li>2/6/23: Working on defining Technology.</li> <li>Will work with PTPEC, Chemistry and LAMS to further this work.</li> <li>3/6/23: Working on records retention language.</li> <li>4/11/23: Committee sending ideas for records retention language to</li> <li>Workgroup for consideration.</li> <li>7/10/23: Language formulated is now being added to the DRAFT Standard.</li> <li>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).</li> <li>9/11/23: A number of new workgroups have been formed to continue work on the standard. Workgroups now include: <ul> <li>Definitions (presenting 9/11/23)</li> <li>Language (present Oct) – on Oct agenda</li> </ul> </li> </ul>
				<ul> <li>Data Integrity (present Oct) – delayed to Nov</li> <li>Subcontracted Work (present Dec)</li> <li>Measurement Traceability (present Dec)</li> </ul>
				<ul> <li>Calibration Requirements (not started)</li> <li>Handling Test Items (not started)</li> </ul>
				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

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

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
3	Technical Specialist Language	V1M2		Ongoing	Ongoing	Ongoing		<ul> <li>1/11/23: Worked on Exceptions.</li> <li>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.</li> <li>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.</li> <li>12/10/23: Received a batch of recommended changes from NELAP AC.</li> <li>Debbie plans to talk to the NELAP AC about the changes.</li> <li>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.</li> <li>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.</li> </ul>

Item	Task Description	Document	Contact	Task	Start Date	Complete	External	Comments
		Number		Added		Date	Communications	
4	Defining Technology	Various TNI Standards	Paul Junio Tony Francis Debbie Bond	January 2023	12/11/23			<ul> <li>1/11/23: Will work with Paul Junio's group to define Technology. PT, AB, QSM, etc.</li> <li>12/11/23: Paul has started email communication on this topic, but the Workgroup has not met yet.</li> <li>5/13/24: Need an update. Group has not met formally.</li> </ul>
5	Respond to SIRs	SIR 453 SIR 465		Ongoing	Ongoing	Ongoing	Lynn Bradley – LASEC PA	<b>3/13/23</b> : Responded to SIR 453 regarding quarterly calibration verification of manual repeating pipettes. 8/14/23: Responded to SIR 465 regarding Class A glassware.
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. 1/24/24: Language was reviewed during the conference and placed into the DRAFT Standard.
10	Internal Audit		llona Debbie	12/10/23	12/10/23			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.)

Item	Task Description	Document	Contact	Task	Start Date	Complete	External	Comments
		Number		Added		Date	Communications	
11	Implementation Tool:				TBD			6/20/24: Ilona noted that there is a
	Prepare a crosswalk							crosswalk for the ISO language, but TNI
	for old vs new							language would need to be added.
	Standard.							