Quality Management System Expert Committee (QMS)
Meeting Summary

October 8, 2024

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on October 8, 2024. Attendance is recorded in Attachment A – there were 9 voting members present. Associate members present: Alma McCammond, Brian Eichelberger, Debra Zeller, Kim Fielder, Lynn Boysen, Nicole Van Aken, and Paul Junio.

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

Minutes will be reviewed by email as Ilona catches up due to an injury and storm recovery.

2. Work on DRAFT Standard

The Committee continued it's review of the DRAFT Standard beginning with Section 8.2. The Committee started looking at the Quality Manual. Carol continued to work on this after our last meeting and reviewed the Standard to look for all procedures in the DRAFT Standard to help the Committee with this section. This was sent to everyone by email. Perhaps this list is a better direction for how to note what is required in the Quality Manual.

Ilona looked back into the 2016 Standard and shared what was written previously for Section 8.2.4.2 e). "Commitment" does not seem appropriate. Perhaps used the term "define" or "mechanism". Need indication for how management is doing it. "Mechanism" confuses some of the work done on definitions.

Need to look at Standard format SOP to see if it should be "section", "Section" or "Clause". Paul confirmed it should be capitalized – Section. Ilona noted that ISO language is Clause instead of Section, but TNI's SOP uses "Section". The Committee will review this later and possibly remove the word all together.

Does laboratory approved signatories need to be included. This may be included in Section 7.8.2.1.o where it discusses persons who are authorized to report results. Clause 5.5.b is also relevant. Change language to point to Sections 5.5, 5.6 and 6.2.

The Committee may take one more look at Section 8.2.4.1.

Summary of DRAFT changes made:

8.2.4.1 The laboratory must have a quality manual and the quality manual must contain:

a) document title;

b) laboratory's full name and address;

c) name, title, location (if different from 8.2.4.2b), and contact information for the individual(s) responsible for the laboratory;

d) identification of all major organizational units which are to be covered by this quality manual and the effective date of the revision;

8.2.4.2 The quality manual must contain or make reference to the following at a minimum:

a) procedure(s) for addressing impartiality and confidentiality requirements defined in 4.1 and 4.2;

b) identify management that has overall responsibility for the laboratory, as per 5.2,

c) define the range of laboratory activities for which it conforms with this document as per 5.3 and 5.4, including the identification of any activities not performed at its permanent facilities;

d) define the organization and management structural requirements, including its place in any parent organization, as per 5.5a) and include relevant organization chart(s);

e) define how the laboratory management communicates management system effectiveness as per 5.7a);

f) define how the laboratory management ensures the integrity of the management system when changes are made as per 5.7b);

g) define roles and authorities for personnel performing laboratory activities per 5.5, 5.6, and 6.2;

h) have procedure(s) for personnel requirements as per 6.2.5;

i) define the measures used to control facilities and environmental conditions per 6.3;

j) procedures for meeting the equipment requirements of 6.4;

k) procedures for meeting metrological traceability requirements of 6.5;

l) procedures for meeting the externally provided products and services requirements of 6.6;

m) procedures for the review of requests, tenders and contracts as per 7.1;

n) procedures for the selection, verification, and validation of methods as per 7.2;

o) when the laboratory is responsible for sampling, procedures for meeting requirements as per 7.3;

p) procedures for handling the test or calibration items, and for subsampling when not defined by the reference test method, as per 7.4;

q) procedures for technical records as per 7.5;

r) procedures for evaluating measurement uncertainty as per 7.6;

s) procedures for ensuring the validity of results as per 7.7, including defining which strategies are used by the laboratory and frequency of monitoring activities;

t) procedures for reporting results to clients and, where appropriate, internal calibration reports, that meet the requirements of 7.8;

u) procedures for handling and resolving complaints as per 7.9 and addressing nonconforming work as per 7.10;

v) procedures for the control of data and information management system as per 7.11;

w) define how the laboratory meets the management system requirements of 8.1.2;

x) procedures for document control (8.3), non-technical record control (8.4), risk management (8.5), improvement (8.6), corrective action (8.7), internal auditing (8.8), and management review (8.9).

A Teams invite was sent out for a Standard Review Work Group meeting on October 28, 2024.

The Committee started reviewing Section 8.3 with the limited time left in the meeting.

Need to clarify that forms are documents in the definition of "document" in Section 3.

(Addition: Standard Review Workgroup Meeting – October 28, 2024

Voting members in attendance: Jordan Adelson, Nicholaus Slawson, Ashley Larsen, Amy, Carol Gebhart, Michael Desmarais, Katie VanSciver, Carla McCord, Sean Hayes, Debbie Bond
Associate members in attendance: Paul Junio, Ryan McMullin, Alma McCammond, Stephanie Drier, Kelvin Yuen, Meera Neb, Jeanette Hernandez, Ty Atkins Sumy Cherukara, Kim Fielder, Kathleen Lloyd, Tammy Kreuter, Nicole Van Aken, Carl Kircher (by phone), Bill Reeves, Cindy Redmond, Debra Zeller, Matthew Sica, Lynn Boysen, Carol Barrick, Kristin Brown

Summary

The Committee is continuing to hold a Standard review workgroup meeting on the 3rd or 4th Monday of the month to review language that will be reviewed and discussed at the following Committee meeting on the second Monday of the Month. No official business is done at these meetings and all language suggestions are discussed at the Committee Meetings.

The meeting started at 1pm and concluded at 2:30pm Eastern.

The group considered adding a Section 8.2.4.1 e):

The group spent extensive time discussing whether they should continue to require page numbers and total number of pages in documents.

It was noted that technology is changing and some laboratories have systems that report data on one continuous page online. There are no page numbers. This requirement limits future technology. Some labs report data online but it is in a pdf format that still includes pages.

This requirement is to look for a method to identify that a document is complete and that "pages" are not missing.

The group recommended place holder language until a better description can be formulated. Ilona will help with this as needed after the Committee finishes reviewing Section 8. Need a term for a document that does not have page numbers because the document flows as one page online.

The group will look at Section 8.2.4.2 w) after it reviews Sections 8.3-8.9.

The group continued with the review of language in Section 8.3:

Re-worded and added g) to 8.3.2:

g) it has authorized editions of external documents that provide instruction to the analyst. Authorized editions of the TNI standard revision and reference methods to which the laboratory is accredited must be available within the laboratory's controlled document system.

Section 8.3.3:
Need to clarify that forms are documents in the definition of "document".)

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 meeting will be by teleconference/webinar on November 5, 2024 at 1pm Eastern due to the holiday on the November 11, 2024. Debbie will determine after this meeting whether a Standard Review Work Group meeting will be held later that month continue work on the Standard that will be brought back to the December meeting.

Debbie adjourned the meeting at 2:26 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
Jordan Adelson **Present**	DoD - Navy	2024*	Other	jordan.m.adelson.civ@us.navy.mil
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 **Absent**	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	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	n/a	Ilona.taunton@nelac-institute.org

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

								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 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 Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								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		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.

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
4	Defining Technology	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.
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.
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		Ilona 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 Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
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.