Quality Management System Expert Committee (QMS)
Meeting Summary

January 8, 2024

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on January 8, 2024. Attendance is recorded in Attachment A – there were 14 voting members present. Associate members present: Anagha Chitre, Amanda Grande, Alexander Chieh, Brian Eichelberger, Carol Barrick, Carol Gebhart, Sumy Cherukara, Cindy Redmond, Fida Kassed, Kim Fielder, Kristin Brown, Kelvin Yuen, Linda O'Donnell, Lisa Parks, Megan Rothgerber, Matt Sica, Paul Junio, Patty Carvajal, Ryan McMullin, Sushmitha Reddy, Tammy Kreutzer, and Ty Atkins.

Debbie shared the December meeting minutes on screen. The meeting date should have been December 11th, the winter meeting is in Columbus, OH – not NC, and in Section 6 the date for the approval of new members needed to be added.

A motion was made by Earl to approve the December 11, 2023 minutes as written with the corrections above. The motion was seconded by Michael and unanimously approved. Ilona will request that the minutes be posted.

Jordan introduced himself as a new member of the Committee.

Ilona noted the voting members that are finishing their first term need to be approved for a second term. This will be done be email vote.

(Addition: Four voting members are finishing their first 3 year term on the Committee and want to serve a second term. Earl made a motion to approve a second term as a voting member for Stephanie Atkins, Nicole Cairns and Ashley Larssen. The motion was sconded by Carla McCord. Amy Schreader commented that she would also like to serve a second term. Earl and Carla amended the motion and second to include Amy Schreader.
Email Vote:
Jenna – For (1/11/24)
Michel – For (1/11/24)
Zaneta – For (1/11/24)
Nicholas – For (1/11/24)
Earl – For (1/11/24)
Amy – For (1/11/24)
Nicole – For (1/12/24)
Kathi – For (1/15/24)

The motion was approved.)

2. Winter Meeting – Columbus, OH

Debbie reviewed the slides she and Ilona worked on for the Annual presentation that covered the Committee's 2023 Accomplishments and 2024 Plans (Attachment B).

3. DRAFT Standard Review

The Committee started work in Section 4 – Impartiality.

Debbie reviewed the new Data Integrity language added. There was a question about numbering. All ISO/IEC language numbering needs to be left as is. TNI language should follow the format without changing ISO/IEC numbering.

Section 4.1.6. – It was questioned why this doesn't read a lab will not do these things instead of requiring procedures. Jordan noted this came from QSM and they thought that a procedure helps with training and they have not had any problems enforcing it.

Section 4.1.6 now reads:

Data Integrity System

The laboratory shall establish and maintain a data integrity system to detect and deter improper, inappropriate, or prohibited actions. The system shall address 1) data Integrity procedures, 2) data integrity training, 3) periodic in-depth data monitoring, and 4) data integrity investigation.

The laboratory shall not engage in any prohibited actions including, but not limited to the following:

This list was edited and now reads:

i. fabricating, falsifying, or misrepresenting data, including creating data for an analysis that was not performed or for a sample that was not collected (dry lab);
ii. using external analysts, equipment, and/or laboratories to perform analyses when not allowed by contract, or intentionally concealing such use;
iii. recording improper date/time, including resetting the internal clock on an instrument to make it appear that a sample was analyzed within a compliant time frame, or recording a false date/time or changing a date/time to make it appear that required times were met;
iv. unwarranted manipulation of samples or analytical conditions, including unjustified dilution of samples, or changing the instrument conditions for sample analysis from the conditions used for standard analysis;

v. unwarranted manipulation of software, including forcing calibration or QC data to meet acceptance criteria, removing software operational codes indicating analyst manipulation of results, changing LIMS parameters to avoid displaying appropriate qualifiers, inappropriately subtracting background, or improperly manipulating the baseline (e.g., chromatographic or spectrophotometric baselines);
vi. turning off, or otherwise disabling, electronic instrument audit/tracking functions;
vii. misrepresenting or misreporting QC samples, including representing spiked samples as being digested or extracted when a digestion or extraction was not performed;
viii. substituting previously generated analyses for a non-compliant calibration or QC analysis to make it appear that an acceptable analysis was performed;
ix. failing to prepare or analyze method blanks, the laboratory control sample (LCS), and when required matrix spikes, in the same manner that samples were prepared or analyzed; e.g., using dedicated labware, instrumentation, or laboratory space for the preparation or analysis of QC samples, analyzing QC samples outside of required analytical time frames, using additional instrument blanks or increased rinse times before or after QC sample analysis when not similarly applied to field samples;
x. tampering with QC samples and results, including over/under spiking and adding surrogates after sample extraction;
xi. deleting or failing to record QC data outside acceptance criteria to conceal the fact that calibration or other QC analyses were outside acceptance criteria;
xii. performing improper manual integrations, including peak shaving, peak enhancing, or baseline manipulation to meet QC acceptance criteria or to avoid nonconforming work;
xiii. concealing a known analytical or sample problem;
xiv. removing failed QC analyses from the record of an analytical sequence;
xv. purposely excluding known QC failures from the case narrative;
xvi. observing out-of-compliance equipment conditions, then adjusting the equipment into compliance and recording only the compliant observation;
xvii. recording the temperature of the surface of an ice pack rather than the temperature of a representative sample container;
xviii. failing to report a known improper action to the appropriate laboratory or client, or to an appropriate government official; or
xix. reporting data for regulatory purposes from a modified method that fails to adhere to all regulatory and statutory requirements.

Add a Section 4.1.6.1 after this list. Add:

4.1.6.1 Data Integrity Procedures

The data integrity procedures shall, at a minimum, address the following:

b) requirements to act impartially and to refrain from inappropriate practices.

c) frequency of data integrity training;

d) topics to cover in data integrity training including the prohibited actions in 4.1.6.x;

e) frequency and a schedule of items to be reviewed for conducting periodic in-depth data monitoring;

f) process for confidential reporting of data integrity concerns within the laboratory and a process whereby laboratory management is informed of the issues;

g) requirements that management ensures no retaliation, coercion or intimidation of employees reporting concerns or potential issues;

h) information on performing a detailed data integrity investigation; and

i) records required for training, in-depth data monitoring, reported data integrity concerns, and data integrity investigations.

The Committee then looked at 4.1.6.2 and made edits. The section now reads:

4.1.6.2 Data Integrity Training

Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees. The laboratory shall have records demonstrating when staff participate in data integrity training and that they understand their obligations related to data integrity. A record of the topics covered in the data integrity training shall be provided to all attendees. Data integrity training shall include the following:

a) organizational mission and its relationship to the critical need for honesty;

b) the relationship of laboratory-generated data to public health concerns and the need for known and documented quality;

c) review of data integrity procedures;

d) how and when to report data integrity issues;

e) requirements for keeping analytical records;

f) requirements for reporting qualified data;

g) requirements to refrain from improper, inappropriate, and prohibited actions; and

h) potential consequences of engaging in improper, inappropriate or prohibited actions:

i. Immediate termination
ii. Debarment
iii. Civil or criminal prosecution

The next Section to review will be Section 4.1.6.3.

4. New Business

None.

5. Action Items

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

6. Next Meeting and Close

The next meeting will be in person in Columbus, OH on Janary 24, 2024, at 8am Eastern.

Debbie adjourned the meeting at 2:33pm 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) **Absent**	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 **Present**	SAW Environmental	2026	Other	tfrancis@sawenviro.com
Carla McCord **Present**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins **Present**	Pace Analytical	2024*	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
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
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B – Slides for Annual Meeting in Columbus, OH

Quality Management Systems Expert Committee

- **2023 Accomplishments**
  - Reviewed the terms Procedure and Policy and standardized use throughout the V1M2 Draft Standard by defining that procedures must be written.
  - Worked on Technical Specialist, Quality Specialist and Quality Manual language.
  - Workgroups completed:
    - Definitions
    - Language - Internal Audits, Document/Record Retention, SOP Sections, Sample IDs, Define Undue Delay
    - Data Integrity
    - Handling Test Items
    - Subcontracted Work
  - Completed 2 SIRs.
  - Performed TNI Internal Audit

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- **2024 Plans**
  - Finalize Technical Specialist and "Appropriate QC" (Section 7.7) language
  - Workgroups complete work:
    - Measurement and Traceability
    - Calibration Requirements

    Wednesday, 8:00 – 4:00
  - Participate on Technology Definition Workgroup
  - Prepare Draft Standard presentation as Webinar or at Summer Conference to gain comments prior to finalization.
  - Complete V1M2 Draft Standard.
  - Consider need for implementation documents and tools - Module 2 Assessment Checklist, Summary of changes between 2016 and new Standard, etc.
  - Continue to respond to Standard Interpretation Requests.
  - Complete Internal Audit Corrective Action
  - Develop training to support credential initiative

Attachment C: 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. 1/8/23: Edited Data Integrity Section.
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.
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.

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.
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.
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.
11								