Quality Management System Expert Committee (QMS)
Meeting Summary

December 9, 2024

1. Roll Call/Minutes Approval:

Carla McCord, Vice-Chair, called the meeting to order at 1pm Eastern by teleconference on December 9, 2024. Attendance is recorded in Attachment A – there were 5 voting members present. Associate members present: Alma McCammond, Brian Eichelberger, Debra Zeller, Kim Fielder, Lynn Boysen, Nicole Van Aken, and Paul Junio. Guest: Bob Wyeth.

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

There was not a quorum at the meeting, so no voting could be done.

2. SIR 504

SIR 504 to QMS, December 1, 2024

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.5.13.1 e ii
Describe the problem: This section requires that disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with first use. Is it acceptable to perform this verification at one location of a network laboratory, and share that verification documentation among its laboratories, providing the required documentation of verification to any network laboratory that uses the lot in question?	

SIR 504 was received for the Committee to review and respond to. Carla reviewed Section 5.5.13.1.3.ii in the 2016 Standard.

Carol noted that it should be acceptable because regular QC will be run with the lots. This is not the same as the issue with media and solvents where storage conditions could have an affect so transportation could be an issue.

Lynn Boysen (AB, Minnesota) would require the actual lab to check it. Virginia would also require the lab to check it. It was noted that "the Laboratory" is used, so this should mean that it is the lab that is using it that should verify it.

This check could be done prior to or in conjunction with first use – shouldn't need to do anything extra.

Bob Wyeth is concerned this is to big a risk.

Ilona asked if the Committee could think of any instances where it would be OK to have a "sister" or third party lab analyze something? Should we review the Standard for these opportunities?

The Standard does state "the" laboratory shall verify volumetric devices once per lot, prior to or in conjunction with its first use. Therefore, the laboratory performing the work must perform the verification.

Carla proposed language for the Committee to consider based on the discussion. This will be distributed by email for further discussion.

DRAFT Response:
The Standard does state "the" laboratory shall verify volumetric devices once per lot, prior to or in conjunction with its first use. Therefore, the individual laboratory performing the work must perform the verification.

(Addition: The DRAFT Response was distributed by email and received the following comments:

- *I feel, the lot verification from one laboratory is sufficient for sharing across network labs, similar to Certificates of Analysis (CoAs). The purpose is to confirm accuracy of each lot. As the Standard specifies, "the laboratory shall verify volumetric devices once per lot, prior to or in conjunction with its first use,". Once completed, this verification can be shared with other network labs in the same manner as CoAs, ensuring consistency and alignment across the network.*

- *I agree with the initial response that the laboratory performing the work must do the verification. While we assume the lot is the same across all network labs, we cannot guarantee that transport was the same to all locations and that storage and climate is the same at all locations.*

  The laboratory that is going to use that lot of equipment needs to verify that the equipment is capable and was received as intended. I think the response that was given is great.

- *Why is it acceptable to contract out to an ISO-certified vendor for:*
  - *Balance calibrations*
  - *Thermometer calibrations*
  - *Equipment calibrations*

  But it is not acceptable to use a TNI-certified laboratory to verify the volume of a volumetric device?

  Does the TNI standard define "the laboratory" as a single physical location?

- *I agree with statement that the labs must conduct the individual verification since there is no guarantee that the in-network labs are using the same equipment and/or testing conditions (and for the other reasons mentioned).*

  Even when items are purchased with COAs, aren't labs required to verify that the use by the lab aligns with the COA information? Similarly for calibrations, all calibrated equipment must be verified internally prior to use with client samples.

- *A good point was raised regarding transport, weather, and storage conditions. However, the standard in question is focused on the supplies themselves, not the individual lab processes. How do we then interpret calibrations to NIST standard, which are always shipped out and returned back to individual labs? Or Class A glassware, which dont require verification?*

- *These are great points and really show the confusing levels of verification/calibration in equipment and items.*

  Personally, for calibrated equipment and Class A glassware I would still verify both upon receipt. The standard sort of alludes to this, for equipment that is shipped out and returned it leans on 5.5.8 which discusses when equipment leaves the labs control (which it does when shipped out for a calibration) it should be checked and verified upon return before being placed into service. The check is to ensure that nothing was messed up in transit or during the receipt.

  For Class A glassware, I would look more towards 4.6.2 since it is a purchased item and not something that was calibrated. 4.6.2 says that purchased items must be verified before use to ensure that the purchased item complies with the labs specifications for it (in the case of Class A glassware, that it is indeed class A and reads as intended.)

  These are also where my notion comes from that the volumetric equipment should be verified by the laboratory that is going to do the work, they need to be sure it is reading as it should even after transit and storage at their location.

  Again, weird that there is not a great singular point for these things, but the standard does have some notes for these things just in very different areas!

- *Is the risk acceptable to these multi-location laboratories to put their faith into interpretations and readings from individuals and equipment at a single location and time to verify anything. I would not.*

- *My concern is that we may be making this more complicated than it needs to be, and it raises the question of where we draw the line. I'm in favor of checks, but at what point do we rely on the actual process instead of redoing everything at each facility.*

- *This language is simplified in the working Draft. Unfortunately, for the SIR we have to interpret only the language that is in V1M2 2016, 5.5.13.1 e ii. It says, "**the laboratory shall verify** volumetric measuring devices as follows…"*

Personally, I would trust another lab or vendor to verify the lot if I know their process is sufficiently robust or per a published method. If the lab is using these for their LCSs and/or other QC they are also being verified with each batch. BUT, for SIR 504, we need to interpret the language in V1M2 2016.

- *What if a corporate lab purchased 10,000 units of a single lot, then dispersed 1,000 units to each of its 10 labs. What if one of the labs within the 10 does not confirm the volumetric marks. Does this make the 1,000 units at that lab unusable, or does it mean all 10,000 units are unusable?*

  Second this does not allow the lab to assess and deal with the risk associated with accepting the vendor's validation alone or with a single assessment on receipt. If I were to set up a procedure, I would purchase the 10,000-unit lot, verify a fraction of the 10,000 – such as testing 100 randomly selected units (1% of the total) – then if verified, send each lab their 1,000-unit allotment (possibly minus the 10 per lab used to test the lot).

  The hard part in this is this need to tell labs what to do. Allow them to assess their own risk and determine procedures to deal with the risk. This is the heart of 17025-2017.

- *The Standard states "the" laboratory shall verify volumetric devices once per lot, prior to or in conjunction with its first use. Why is only "the" quoted? I understand that the draft takes that one word and draws a conclusion that isn't supported by anything in the Standard, i.e., that "the" laboratory is a single entity at a single location.*

  Further, there's an unstated assumption that 'verify' seems to have taken on in this response, i.e., to perform a test of some sort. Related to the discussion about Class A glassware and microliter syringes which must be verified according to 4.6.2, where are we getting a different definition of 'verify' that takes on more than comparing a part ordered against the manufacturer's description and tolerances?

  To address the shipping concerns and risk element, I'd be inclined to ask if any of these volumetric devices have ever failed this verification?

  I've got an opinion on how this should be handled based on what the Standard actually says. I don't think that there is a clearly stated requirement in the Standard, and would propose an answer of 'yes' to the SIR. Regardless of the answer provided, I think the next revision of Module 2 needs to consider what we actually mean when we say 'verify' if in one case (4.6.2) it seems to indicate that a review of paperwork is sufficient, but in another case (5.5.13.1) it seems to indicate that active testing of a consumable must occur.

- *I agree with statement above that "verified" has not been defined as "tested analytically" which means currently the lab can define the verification process based*

on their own evaluation of any risk. If we intend for it to include an analytical measurement method, (and i think it was intended in the current revision, though not clearly stated) we should define it more clearly in the next revision. I also agree that risk of failure is low, but has happened occasionally, and based on training I've gotten at Cincinnati, I think the drinking water folks at EPA do expect this to be performed by each laboratory as a test method using calibrated volumetric/gravimetric equipment.)

3. Work on DRAFT Standard

The Committee began it review at Section 8.9.4 where it left off.

Bob Wyeth suggested using the term "without undue delay". The Committee felt that is too vague. The goal is to have a plan and that the lab is following the plan.

The Committee updated the language to:

8.9.4 When any changes are identified, management must have a plan for implementation.

The Committee then focused their review on Definitions:

Acceptance Criteria – Make sure there is not an issue with this definition and PTPEC defintiions.

Analyst – Do we need to consider field?

Assessment – Remove "evaluation" to eliminate confusion with evaluations that are peformed on ABs.

Batch – EMC is working on batch sizes – so don't use specific numbers here. Reference methods for batch size. Revisit this – check with Jerry if he has some suggestions.

Blank: May need other blank definition?
Trip blank
Temperature blank
Field blank
Equipment blank
Matrix Blank
Method Blank
Instrument Blank

The term "Form" may need a definition.

Do we really need to define all of these terms that are currently in the Definitions section?

Ilona volunteered to talk to Paul Junio about the definitions in general since he chaired the Defitions Workgroup. Should all of these definitions be in the Definitions section? Are some terms already clear or "defined" in the Standard itself and not needed here? Are all of these terms used in the Module 2 Standard?

4. New Business

Remember to register for the Winter Forum and book your hotel room. Feb 3-6, 2024. Early bird ends early January.

5. Action Items

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

6. Next Meeting and Close

The next meeting will be by teleconference/webinar on January 13, 2024 at 1pm Eastern.

Carla adjourned the meeting at 2:31 pm Eastern.

Attachment A
Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) **Absent**	Alabama Power	2026	Lab	dbond@southernco.com
Carla McCord **Present**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Nicole Cairns **Absent**	NYSDOH	2027	Lab	nicole.cairns@health.ny.gov
Michael Demarais **Absent**	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 **Present**	Pace Analytical	2027	Lab	stephanie.atkins@pacelabs.com
Jordan Adelson **Absent**	DoD - Navy	2024*	Other	jordan.m.adelson.civ@us.navy.mil
Nicholas Slawson **Absent**	A2LA	2026	Accrediting Body	nslawson@a2la.org
Joann Slavin **Absent**	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 – off at 2pm Eastern**	ANAB	2025*	AB	zpopovska@anab.org
Sean Hayes **Absent**	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov
Amy Schreader **Absent**	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

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. 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

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

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