

Quality Management System Expert Committee (QMS) Meeting Summary

May 13, 2024

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on May 13, 2024. Attendance is recorded in Attachment A – there were 12 voting members present. Associate members present: Anagha Chitre, Alma McCammond, Brian Eichelberger, Carol Barrick, Debra Zeller, Doug Kablik, Fida Kased, Jeanette Hernandez, Joe Manzella, Kim Fielder, Linda O'Donnell, Matt Sica, Nicole Van Aken, Earl Hansen, Sarah Brown, Sushmitha Reddy, Tammy Kreutzer and Ty Atkins.

There were no changes to the agenda and it was approved by unanimous consent.

The April minutes were distributed by email and reviewed on screen. The attached table was reviewed to ensure that there were no objections to the content. A motion was made by Caitie to approve the April 8, 2024 minutes as written. The motion was seconded by Tony and unanimously approved.

2. Technical Specialist Comments

Debbie talked to the NELAP AC last Monday (5-6-24). She discussed the change in thought to keep the general elements in Module 2, but put any additions that are module specific into the modules.

See Attachment B for Debbies questions (peach) and the final column for comments from the NELAP AC (green).

Debbie shared the text she prepared on 5/1/24 for comment and shared the general feedback she received:

Technical Specialist – idea for moving forward (from QMS Committee 5/1/24):

We'll decide on a general set of minimum requirements to be a technical specialist for any analytical methods. Once we have those, we can ask technical modules if they would like to add a little more on top.

For example (this is an example ONLY; we won't discuss these details right now): We may decide a technical specialist must have one of the following to qualify:

- *a Bachelor of Science degree in any discipline and 2 years of experience in the analytical disciplines for which he/she is technical specialist*
- *an associates and 4 years' experience*
- *4 college level science courses and 5 years' experience*
- *plant operator's certificate appropriate for the facility*

- *TNI credentials*
THEN technical modules can add something extra within those modules, like Asbestos may want to add the NIOSH training and Micro may want to add a microbiology course.

FEEDBACK:

- *If additional requirements are in technical modules, VIM2 will have to state, “and other requirements in technical modules.”*
- *When we state 4 years, 2 years, etc., be clear on whether we mean x years in each analytical discipline or x years total in combined analytical disciplines.*
- *Consider having experience in a laboratory instead of analytical disciplines.*
- *TNI TS credentials are moving in the direction of having a credential for TS for each analytical discipline.*
- *From Lynn: see if there’s anyone in the QMS committee who can join the credentialing committee as an associate.*
- *A short bulleted list of how to qualify is the right way to go.*

Comments/Discussion:

General Feedback:

- seemed simpler and a better way to go.
- Some concern about what will show-up in the module additions.
- Concern about the term “relevant”. It is too vague.

A comment was made that it this seems like it is harder for someone applying for 1 discipline instead of 2. If 1 year is OK for someone seeking more than one discipline, why isn’t it OK for a person seeking 1 discipline. Need to continue to think this through.

Move towards lab experience instead of specific discipline.

Iлона agrees that it makes sense for someone to join the Credentialing committee since they are working on Technical Specialist credentialing. She had talked to Jerry and he thinks the overlap is there. He said the group will be seeking specific feedback from QMS when needed.

Debbie asked how the Committee would like to move forward. Should the entire Committee continue to discuss or should a workgroup be developed to discuss this and then bring it back to the Committee with a recommendation. The preference was to develop a workgroup. Alma, Carol and Carla volunteered to join and Bryan Ech and Joann Slavin volunteered by email.

Debbie is hoping for more volunteers and will send out an email. The workgroup will work with the spreadsheet and propose changes to the working DRAFT. The workgroup will start with the Summary supplied with the meeting agenda for today’s meeting (see italic language above).

Iлона recommended that the Committee reach out to the Expert Committees to provide an update and share the relevant NELAP AC comments so they can begin thinking about whether they need to add anything to their modules. Radiochemistry has already finished up their Standard and this could require them to open it back up. Asbestos may be in the same position. Debbie will reach out.

3. Work on DRAFT Standard

Last time the document was reviewed was at the Columbus, OH meeting. Comments were inserted from the meeting and can be found the Columbus Meeting summary in the February 12, 2024 meeting minutes.

Definitions

Debbie sent out the definition for Test Item to Expert Committees and she got 3 comments back:

- Micro suggested adding concentrates.
- Simplify to original sample received.
- Radiochemistry introduced derivative sample.

The Committee will go back to definitions at the end of the review of the DRAFT Standard. This will make it easier to make sure they reflect the DRAFT Standard.

Section 4.1.6.1:

Columbus Comment: Do we need to keep this full list of examples? Yes, some procedures would be weak without this.

There was agreement with this response.

The Committee will continue review of the Standard at the next meeting in Section 5. Debbie is suggesting that the Committee meet twice in June and July in preparation for the in person meeting in early August. She reminded people to be sure to register and get a room for this meeting before June 15, 2024.

4. New Business

None.

5. Action Items

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

6. Next Meeting and Close

The next meeting will be by teleconference/webinar on June 10, 2024 at 1pm Eastern..

Debbie adjourned the meeting at 2:27 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 Present	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 Present	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 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 Present	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: Review of NELAP AC Comments on Technical Specialist Decisions by the QMS Expert Committee

Citation	Comment	Comment made by	Proposal	Committee Decision	Comment #	AC Comments 5/6/24
4.1.7.2 The technical specialist may be responsible for fields of accreditation at more than one location provided the laboratory submits a plan detailing availability at each location to the primary accrediting body. The accrediting body shall evaluate the plan to determine if approval is granted.	I feel a disclaimer should be listed here, that this is an exception, by no means the preferred process	ILELAP		It would not add value to include which method is preferred here. Regarding this clause, we need to know if Abs are ok with this clause and along with that find out what their requirements are for evaluating and if an evaluation could be expected in time to help small labs bridge the gap between losing a TS and hiring another one.	7	Timing has not been an issue in the past. This is a very helpful clause.
5.2.6.1 Technical Specialist Qualifications	Propose adding an overview paragraph/statement on how technical specialist qualifications can be met. From my review it seems they can be met by 1. Education/experience 2. Exception, 3. The NELAC Institute Credentialing 4. New Technology	MNELAP	Technical Specialist qualifications are based on the following options, education, experience, exception, TNI Credentialing, technology scope expansion and Accreditation Body (AB) approval (proposed in future comment).	Include an introductory statement that says something similar to what is proposed. NOTE: Check on the AB approval suggestion.	12	AB approval could be an option for temporary emergency situations as in Comment #24.

Citation	Comment	Comment made by	Proposal	Committee Decision	Comment #	AC Comments 5/6/24
5.2.6.2 Exceptions	The committee should consider allowing the Accreditation Body to make or allow an exception.	MNELAP	Minnesota would propose that an exception be added to allow for technical specialists be approved in response to Federal and State emergencies, in geographic areas where residents have few to no convenient options for securing laboratory testing or in laboratory responsibility areas operated by artificial intelligence. The AB would need to use risk based and knowledge driven qualification considerations.	CHECK WITH ABs: Could we add a statement that ABs may grant waivers in certain circumstances?	24	This should have a time limit. For example, labs can work or reapply with each AB individually each (year?) to review the waiver.

Citation	Comment	Comment made by	Proposal	Committee Decision	Comment #	AC Comments 5/6/24
<p>5.2.6.2 a) Any person who is approved as technical specialist (or however named) based on requirements or exceptions in previous revisions of this standard is considered to continue approved to be technical specialist for the same areas of responsibility for the current ABs. A person who is admitted as a technical specialist under these conditions, and leaves the laboratory, will be eligible for hire as a technical specialist for the same fields of accreditation in another accredited laboratory, pending approval from the AB.</p>	<p>Who is going to track or what system will be used to track those already approved under previous standards and how does an AB evaluate the current AB? Current as of when? Current ABs in which they hold this technical specialist designation or the current ABs in TNI system and currently functioning as NELAP recognized ABs? NGABs? The second sentence makes it seem like they will be admitted as a technical specialist for new/different ABs pending approval. So then would "current" in previous statement apply? Seems like they could add to the ABs they work for in this sentence and go beyond the "current" ABs.</p>	<p>MNELAP</p>	<p>Suggested Language: 5.2.6.2 Technical Specialist Qualification Exceptions, one criterion must be met in order to receive the waiver. a) Any person who is approved as technical specialist (or however named) based on requirements or exceptions in previous Standard revisions is considered approved to be technical specialist for the same areas of responsibility.</p>	<p>REVISE: The person who leaves the laboratory may have difficulty showing eligibility. Is the second sentence even possible or necessary? Can we revise the first sentence to make it a little more flexible (remove "for the current Abs")?</p>	<p>26</p>	<p>Leave second sentence as is.</p>
<p>Overall</p>	<p>Some explanation of how to account for the difference in course hours between quarter and semester terms must be included.</p>	<p>Comments from AC Minutes from 9/11/23</p>		<p>Course seems to be the best term we have to describe education without a degree. Not a significant difference between quarter and semester.</p>	<p>42</p>	<p>No comment.</p>

Attachment C: 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		<p>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.</p>
2	Develop Workgroups to work on language in specific section of the Standard.	V1M2		Ongoing	Ongoing	Ongoing		<p>Language Workgroup tasks:</p> <ul style="list-style-type: none"> – 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 same 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> <p>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.</p> <p>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.</p>

