Quality Management System Expert Committee (QMS)
Meeting Summary

February 12, 2024

1. Roll Call/Minutes Approval:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on February 12, 2024. Attendance is recorded in Attachment A – there were 13 voting members present. Associate members present: Carl Kircher, Anagha, John Gumpper, Kathi Gupper, Amanda Grande, Alexander Chieh, Alma McCammond, Annmarie Beach, Brian Eichelberger, Caitie, Carol Barrick, Sumy Cherukara, Cindy Redmond, Debra Zeller, Eric Davis, Fina Kased, Jeanette Hernandez, Rebecca Pierrot, Kathleen Lloyd, Kim Felder, Kristin Brown, Nic Johnson, Patty Carvajal, Sushmitha Reddy, Tiffany Shaw, Tammy Kreutzer, and Zaneta Popovska.

A motion was made by Michael to approve the January 8, 2024 minutes and Winter Forum Summary (Attachment B) as written with the following corrections: 1/8/24: Meeting date correction and spelling correction for Columbus. Summary: Add Nick to attendance and correct year to 2024. The motion was seconded by Amy and unanimously approved.

There was a change made to the agenda to include a discussion on the Internal Audit performed by Debbie Bond and Ilona Taunton early January. There were no further changes requested to the Agenda.

2. Internal Audit

The Committee reviewed the internal audit. There was one finding that related to the CSDP EC. The Committee discussed the issue and the recommended corrective action was prepared and documented in Attachment C.

A motion was made by Ashley to approve the internal audit and proposed corrective action in Attachment C. The motion was seconded by Jordan and it was unanimously approved. Ilona will send the corrective action response to the CSDP EC for their approval. Once they approve the internal audit and corrective action, the 2023 Internal Audit will be complete.

(Addition: Ilona sent the corrective action by email to Paul Junio (Chair, CSDP EC) and Bob Wyeth (Program Administrator) on February 13, 2023. Debbie Bond and Carla McCord were copied.)

3. Winter Forum – Columbus, OH

Debbie reviewed the Winter Forum Summary (Attachment B) in order to review what was discussed in Columbus, OH.

Carl Kircher commented that when laboratories want to make changes to their scopes, they note the changes as matrix, method and analyte. Recognition under NELAP is matrix and specific technology (e.g., Membrane Filtration, ICPMS, etc.)

4. Technical Specialist Comments

The Committee received comments from the NELAP AC in a table format. The remainder of the meeting was spent reviewing these comments and placing the Committee's decision in the last column of the table found in Attachment D.

What does the Committee really want the Technical Specialist to do? The current DRAFT may be too vague? This needs to be further discussed.

The Committee did not make as much progress as hoped, so Debbie may suggest an additional informal meeting to work on the table of comments later this month.

(Addition: Debbie scheduled an informal meeting on February 26, 2024 at 1pm Eastern to only make more progress on the Technical Specialist Comments table. All Committee members were invited to participate. The meeting ended at 1:55pm Eastern. Persons in attendance included:
Committee Voting Members (8): Amy Schreader, Caitie Van Sciver, Carla McCord, Debbie Bond, Joann Slavin, Jordan Adelson, Michael Desmarais, and Nicole Cairns (Ilona Taunton – Program Administrator).
Associate Members: Alma McCammond, Carol Barrick, Sumy Cherukara, Cindy Redmond, Debra Zeller, Doug Kablik, Fida Kased, Kim Felder, Kristin Brown, Kelvin Yuen, Linda O'Donnell, Matt Sica, and Patty Carvajal.

The results of this meeting can be found in Attachment E and have been shared with the entire Committee by email on March 6, 2024.)

5. New Business

None.

6. Action Items

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

7. Next Meeting and Close

The next meeting will be by teleconference/webinar on March 11, 2024 at 1pm Eastern.

Debbie adjourned the meeting at 2:30 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 **Present**	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 **Present**	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 – Summary of Winter Forum Meeting in Columbus, OH

January 24, 2024, 8am – 12pm Eastern and 1-4pm Eastern

Attendance: Debbie Bond, Michael Demarais, Amy Schreader, Nicole Cairns, Ashley Larssen Nick Slawson and Tony Francis.

Summary Prepared by Nicole Cairns and Ilona Taunton (Program Administrator)

8-12pm Eastern

Columbus Comments: (Definitions) Need to look at TNI definition vs ISO definition, perhaps cannot use reference material in measurement traceability section - go back to use of standards, reagents, reference materials. TNI also has a definition for reference standard. This was an old ISO term, but the committee could perhaps repurpose this term for use in the standard or get rid of it entirely. ISO differentiates between reference material and measurement standard.

Columbus Comment: (Section 4.1.6 – Data Integrity System) Do we need to keep this full list of examples? Yes, some procedures would be weak without this.

Columbus Comments: (Old Section 4.1.7.2 "Analytical Disciplines" table:

- MS is not a discipline; chemistry is.
- Chemistry discipline is probably too broad.
- Organic categories only address GC, didn't break out radiochemistry and asbestos technologies. Maybe limit to organics, inorganic metals, inorganic non-metals, radiochemistry, asbestos, etc….
- These specifications could be limiting if we go to level of ECD, PID, FID
- Maybe chromatography and then chromatography - mass spec.
- Focus on the separation technology and identification.
- Comment about moving towards a risk-based program.
- Could result in difficulty of hiring applicable staff that meet these criteria.
- Metals - How does flame AA vs ICP-MS fit into this. Would Flame AA be sufficient to cover ICP?
- Need to have manual integration experience - need to be solid in this area.
- AB comment- prefers blissfully vague language in current standard. The more specific we go, the more cumbersome this is going to be. What about new technologies?
- Gotten too specific, needs to be more vague. This should be on the lab to define who the right person is to fill the role.

Technical Specialist Discussion:

Educational system is weak; never going to satisfy everyone with education AND experience requirements. Need to get back to a performance base. Are they reporting appropriate data, no data integrity issues, etc…?

Should we re-survey the ABs to see if they would be willing to relax some of the education requirements. ABs don't have training to properly evaluate the information being sent to them, nor track it. Would prefer that TNI manage a database that says a person is qualified.

A DOC shows that you are technically capable of performing a method/technology. This could be done within a timeframe that is much less than the current experience required.

Columbus Comments: Section 6.2 – Personnel – Chemical Testing (Module 4)

- Experience always trumps education; could be a "should" instead of a "shall"?
- What is the purpose of a technical specialist? See 4.1.7.2 b) above. There will not always be "a" person within the lab that has the authority on all of this even in a specific area.
- Is goal accountability? We won't be able to use this standard the way that it is intended.
- Emphasis should be more on the laboratory to document this. Landscape has changed. COVID produced students with no in-person lab experience.
- Need to define who is responsible for the data and what are the minimum requirements for that person.
- Maybe re-insert technical manager who would hold the education experience and the oversight, but they don't need the technical experience. They would just have to make sure that they have technical staff to cover that. The technical person has the experience and that person knows what they are doing and that they are doing it correctly.

Columbus comment: Section 6.2.6.c.i through ii.
Changed to quality "specialist", fixed "roll" to "role" typo. Do we need to include the "however named" in this section.

1-3pm Eastern

The Committee continued to review language in the DRAFT Standard. Committee is starting to change the word “shall” in TNI language to “must”.

Section 6.2.6: Change Quality Manager to Quality Specialist

When technical specialist and quality specialist are used, should it always say “however named”?

Section 6.3 – OK

Section 6.4
Section 6.4.5.1: Went through this in calibration requirements update earlier today.

Section 6.4.6.1: Look for better definitions for Support Equipment and Analytical Equipment. Standard should stand on its own. Reworded for clarity.

Section 6.4.6.2:
Lots of questions/discussion about timers in the summary table. Also need to consider microbiology requirements. Discussion about whether to include the table in the standard, guidance, or implementation guidance. Consensus at meeting is to include both language and table in the standard. Need to make sure the table could be citable if don't include the language.

e. Need to make a table before deciding whether to present both or just one (table or text).

There is an SIR that deals with class A – plastic vs glassware
Maybe add a note for Class A-plastic: It does not conform to Class-A glassware specifications. Plasticware can't be considered Class A even if the vendor claims that is. It is mis-leading marketing. Need to include a Note on Class-A designated plasticware. Debbie added a note to that clause about this.

Discussion on what types of certificates would be acceptable; "in compliance with" vs "verified" or "checked" within a tolerance. Maybe provide some minimum guidance? ISO Guide 31 is being used by Consumables Task Force to determine an acceptable Certificate. How do we ensure the intent that labs can use "certificates"; ensure that an assessor can't say it's not a suitable certificate if lab believes it meets their needs? Have the labs define in a procedure?

Lab also has to have a procedure and specifications for selecting/evaluating vendors.

ii. Could it just be single point checks for non-adjustable pippetors? What about just points of use if only using two points. The mid-point is never actually used. Maybe just volumes of use for one or two points and bracketing for more than two points.

NEFAP Discussion:

NEFAP EC sent some language to Module 2 to consider for inclusion. The Committee reviewed it and had some concerns.

Section 6.2 might be a good place to put it too.

Conclusion was to keep in Section 7.3 and put in Section 6.2. This will be further discussed with the full Committee.

For Consideration:
Section 7.3.4 Laboratories performing field sampling activities shall define the competence requirements of personnel and authorize personnel to perform sampling. Where the laboratory arranges for an external sampling organization to be used, the laboratory shall have procedures to ensure that the experience and technical competence of the samplers are sufficient for sampling activities and that they comply with the relevant clauses of this document and other sampling documents (i.e. sampling plans, sampling methods, regulatory documents, etc.). Use of NEFAP Accredited Sampling Organizations meets these requirements.

Section 6.4.7
Section 6.4.7.1: Similar 2005 ISO language that was put back into Standard. If it was literal 2005 ISO/IEC language it would have to be referenced.

Section 7 – put additional language directly under c as “i”.

Section 7.2.1.2:
Document control of forms is important. Forms should be controlled. A form is a document, but once your write on it, it becomes a record.

Putting forms under document control helps because when SOPs are updated, the controlled forms can be updated as needed.

What about Video as documentation – It is a procedure.

Might have maintenance procedures, but a video would be helpful.

Should be moved to the Document control section – Section 8?

Section 7.3.5: OK

Section 7.4.4.1: Point to Modules for temperature storage requirements. Remove “I”.

Section 7.5.1:
Delete additional language except for the information regarding sample collection records.

Sampling information must be recorded even when the lab does not do the sampling.

Needs to be added to the acceptance criteria.

Will come back to this.

Regarding the Appendix, may need to say whether we use option A or Option B.

The meeting was adjourned at 3pm Eastern.

Attachment C – Internal Audit Finding, Comment and Corrective Action

#	Item	Ref	Freq	Yes	No	N/A	Comments	What factors contributed to 'No' response?	What will or has been done to correct issue - Corrective Action (CA)	CA Verified (Name/Date)
3	Procedures for handling and addressing complaints have been developed by the program.	POL 1-108: II	Self - Annual, External - 5 Years	FALSE	TRUE	FALSE	SOP 2-100 Section 6 - Appeals process related to Standard development. The program does not refer to SOP 1-106 in it's documents - this SOP covers complaints outside of those discussed in SOP 2-100. Recent issue did not follow current procedure. Jerry Parr was notified instead of filing complaint.	The Expert Committee follows procedures developed by the CSDP Executive Committee (CSDP EC). This finding cannot be corrected by the QMS Expert Committee other than to notify the CSDP EC of the finding and request that it be corrected.	The QMS Expert Committee provided the finding to the CSDP EC for correction. An addition could be made to SOP 2-101 or as the CSDP EC deems appropriate. Sent 2/13/24. CLOSED.	
5	Committee Chair meets additional expectations of the position outlined in this policy.	POL 1-129: VIII	Self - Annual External - 5 Years	TRUE	FALSE	FALSE	Comment: CSDP Chair Training should include:3. Advise the TNI Executive Director and seek direction as to whether a member may continue to serve in a specific role, if the Chair discovers an undisclosed conflict of interest arises for a member. Also evaluate whether list should be included in training. (Chairs are not aware of this though it is in Policy 1-129.)			

Attachment D: Review of Technical Specialist Comments – 2/12/24

Citation	Comment	Comment made by	Proposal	Committee Decision
4.1.7.2 If a technical specialist is unable to fulfill responsibilities for a period of time exceeding fifteen (15) consecutive calendar days, the laboratory shall designate another staff member meeting the qualifications of the technical specialist to temporarily perform this function. If a technical specialist is unable to fulfill responsibilities for a period of time exceeding thirty-five (35) consecutive calendar days, the laboratory shall notify the primary accreditation body in writing of the staff member who assumed the technical specialist responsibilities	1. Does the replacement have to meet and be approved as a Technical Specialist to meet the technical specialist's responsibilities/requirements or just assume the duties? It says to appoint another staff member. Does the temporary person need to have been approved by the primary AB to meet the qualifications?	MNELAP	Include in 4.1.7.2 who (the lab, the AB) determines that the temporary staff member meets the qualifications of the technical specialist or delineate if they can be any member of the staff who do not have to meet the technical specialist requirements.	Changes below will be clear on responsibility. Consider if the TS filling in can have minimum set of requirements. This could be for 15 or 35 days. Maybe once a new person must be hired, that person should meet full requirements. When notifying the AB of the TS absence, consider stating that the lab must notify the AB of the plan to cover the absence. Change language that limits to one person covering an absent TS.

Citation	Comment	Comment made by	Proposal	Committee Decision
4.1.7.2.d	having a technical specialist responsible for accreditation at more than one location is very reasonable, if the technical specialist can devote the required amount of time towards their accreditation duties/responsibilities and be available to the AB. The ILELAP position is clearly in favor of being overly restrictive of this, with no rational for this position given. I believe and AB should have valid reasons for rejecting any such plan and provide a recommendation on what the lab needs to do to be approved. Please be so kind to share this email with others on your committee.	S Siders	4.1.7.2 The technical specialist may be responsible for accreditation at more than one location provided the laboratory submits a written plan detailing the technical specialist's availability at each location to the primary accrediting body. The accrediting body shall evaluate the plan to determine if approval is to be granted. If approval of the plan is denied the accrediting body shall provide the laboratory, in writing, a response detailing the specific reasons for denial and a recommendation on possible actions that could be taken to obtain approval. The accrediting body shall complete the evaluation and supply any response, within 60 calendar days of receipt of the written plan submitted by the laboratory.	We cannot place requirements on ABs in V1M2.
4.1.7.2 If a technical specialist is unable to fulfill responsibilities for a period of time exceeding fifteen (15) consecutive calendar days, the laboratory shall designate another staff member meeting the qualifications of the technical specialist to temporarily perform this function.	the requirement to appoint a replacement upon a fifteen day absence is not enforceable and needs to be omitted; it is not possible to hire a replacement within two weeks	Comments from AC Minutes from 9/11/27		Lab should have a plan that covers TS absence rather than a statement to have someone fill after 15 days.

Citation	Comment	Comment made by	Proposal	Committee Decision
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 must evaluate the plan to determine if approval is granted.	I have relied on the language in 2016 TNI V1M2 4.1.7.2.d and would like to VERY STRONGLY recommend that those criteria be incorporated here if they will not be elsewhere in the new module.	ORELAP	Include: not be the technical manager(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body. Circumstances to be considered in the decision to grant such authorization shall include: i. the extent to which operating hours of the laboratories to be directed overlap, ii adequacy of supervision in each laboratory, and iii the availability of environmental laboratory services in the area served.	SUGGEST V2 include this language. Include in V1M2 what ABs will look at.
4.1.7.2 The laboratory shall have technical specialist(s) responsible for every field of accreditation for which the laboratory is accredited or seeks accreditation. Technical specialists however named (e.g., Technical Manager, Technical Director, Technical Expert, Group Leader, Supervisor, Lead Analyst, Department Head) shall:	use only one title for the position of Technical Specialist (for purposes of completing accreditation applications) while clarifying that the job title used in the laboratory need not match the title used in the application itself	Comments from AC Minutes from 9/11/25		Remove examples of roles that could be a TS.

(Addition: Attachment E: Review of Technical Specialist Comments – 2/26/24)

Citation	Comment	Comment made by	Proposal	Committee Decision
4.1.7.2 The laboratory shall have technical specialist(s) responsible for every field of accreditation for which the laboratory is accredited or seeks accreditation. Technical specialists however named (e.g., Technical Manager, Technical Director, Technical Expert, Group Leader, Supervisor, Lead Analyst, Department Head) shall:	If the intention of changing the name to "technical specialist" is to remove the misnomer that the technical specialist must be a person with supervisory capacity, why name only positions with supervisory capacity in the examples given?	Comments from AC Minutes from 9/11/23	Recommend removing the examples altogether and add move the second sentence in 4.1.7.2.a as a second sentence here: 4.1.7.2 The laboratory shall have technical specialist(s) responsible for every field of accreditation for which the laboratory is accredited or seeks accreditation. This individual may have supervisory responsibilities, but this is not required. Technical specialists however named shall:	Remove examples of roles that could be a TS from this section and add only TNI names for this role a examples to the exemption section. Move second sentence in a) to 4.1.7.2.
4.1.7.2 The laboratory shall have technical specialist(s) responsible for every field of accreditation for which the laboratory is accredited or seeks accreditation. Technical specialists however named (e.g., Technical Manager, Technical Director, Technical Expert, Group Leader, Supervisor, Lead Analyst, Department Head) shall: a) have a working knowledge of relevant TNI Standard requirements. This	If the intention of changing the name to "technical specialist" is to remove the misnomer that the technical specialist must be a person with supervisory capacity, why name only positions with supervisory capacity in the examples given? I recommend removing the examples altogether and to move the second sentence in a)	NHELAP	4.1.7.2 The laboratory shall have technical specialist(s) responsible for every field of accreditation for which the laboratory is accredited or seeks accreditation. This individual may have supervisory responsibilities, but this is not required. Technical specialists however named ~~(e.g., Technical Manager, Technical Director, Technical Expert, Group Leader, Supervisor, Lead Analyst, Department Head)~~ shall: a) have a working knowledge of relevant TNI Standard requirements.	same as above

Citation	Comment	Comment made by	Proposal	Committee Decision
individual may have supervisory responsibilities, but this is not required.				
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 bewteen losing a TS and hiring another one.
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.	Change fields of accreditation to "representative technologies" to reflect language throughout the document. This draft proposes to qualify people by fields of accreditation, areas of responsibility and representative technologies. Please edit document for consistency.	MNELAP	4.1.7.2 The technical specialist may be responsible for ~~fields of accreditation~~ **representative technologies** 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.	Review the document to see if "representative technologies" would work throughout the sections. We may want to remove this option--this may only help larger labs who have multiple locations and not really provide any help to smaller labs with only one location.

Citation	Comment	Comment made by	Proposal	Committee Decision
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.	Minnesota doesn't have the database capacity or the bandwidth to track technical specialist to the FOT/FOA. Currently, we track areas of responsibility and ensure they cover the scope/technologies of the laboratory. For example we use responsibility areas: volatile organic compounds, other organic compounds, inorganic chemistry, metal, Air, etc. We will not be tracking a technical specials for each FOT/FOA.	MNELAP	4.1.7.2 The technical specialist may be responsible for ~~fields of accreditation~~ **representative technologies** 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.	same as above
5.2.6.1 ...Where "equivalent" coursework, college education or scientific disciplines are allowed, the laboratory must provide records to demonstrate equivalency.	VELAP has concerns with this statement: (1) The way it reads, the laboratory is the one making the determination on "equivalency" (not the AB); (2) How does anyone (lab or AB) determine "equivalency" to a college course? How will AB's know when/how to accept this? How can/will AB's treat labs consistently? More information / conversations / etc. need to happen before this can be part of a standard, as it's currently too vague to implement. See related comments under radiochemistry for some	VELAP	SUGGESTION: Maybe the "equivalent coursework" phrases need to all be moved to the "Exceptions" paragraph, so they fall under the options for a lab to "seek an educational waiver" – add some examples there to communicate the expectation that instead of substituting experience, the lab presents information on coursework which the requesting lab believes would provide ***substantial relevant education*** outside of a college/university setting. "Equivalent" degrees could be evaluated this way too … so that the coursework is looked at as an Exception and justified to and evaluated by the AB, and the lab knows going into the request that it may be denied, instead of reading the standard and deciding for themselves that they have something "equivalent".	Try to move all references to "equivalent coursework/scientific discipline" to exceptions area. Consider whitling down to the minimum requirements for education so that the use of the term "equivalent" is not necessary.

Citation	Comment	Comment made by	Proposal	Committee Decision
	possible ideas/starting points on that particular use of it.			
5.2.6.1 a) i. 2) successful completion of a course in the use of the instrument ; and	What instrument? TEM or microscope? Or any instrument?	MNELAP	Define/Clarify "instrument" in 5.2.6.1 a) i. 2)	Change "instrument" to TEM.
5.2.6.1 a) i.1) an earned bachelor's degree in a scientific discipline ;	What if you have a degree in English, but have a minor in a scientific discipline that would still qualify you for the role? I think it should say bachelor's degree and exclude the type.	MNELAP	5.2.6.1 a) i.1) an earned bachelor's degree ~~in a scientific discipline~~ ;	We need to be specific about scientific discipline here. We can make it consistent for all modules that as experience increases, the education can be lessened.

Attachment F: 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. 1/8/23: 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.

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								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 Procedure as "written" is not in conflict with any ISO 17025:2017 usage of procedure.

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