Quality Management System Expert Committee (QMS)
Meeting Summary

September 14, 2026

1. Roll Call/Minutes Approval

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on September 14, 2026. Attendance is recorded in Attachment A – there were 11 voting members present. Associate members present: Linda Odonnell, Jeremy Roughton, Christian Abalos, Salima Haniff, Sheela Agrawal, Sushmitha Reddy, Brian Eichelberger, Jeanette Hernandez, Homer Youngblood, Tammy Kreutzer, Amy Lovelace, Bina Kapoor, Lisa Parks, William Reeves, Debra Zeller, Christina Pottios, Nick Evans, Ty Atkins, Paul Mariani, Sumy Cherukara, Nicole Van Aken, Nicholas Johnson, Carion Smith, Anagha Chitre, and Isela Rodriguez Palomares.

The agenda was reviewed. An additional topic was added for discussion of definitions that Carol will share. The agenda was approved by unanimous consent.

2. ISO Standards Updates and Definitions

Carol Gebhart provided an update on changes to ISO reference material terminology, particularly the replacement of ISO Guide 30 with ISO 33400. The new standard uses a more interconnected approach to definitions, with individual terms referring to other defined terms. This structure can make definitions more difficult for users to interpret without navigating multiple entries.

Carol explained that she had proposed to her committee that TNI retain its own user-friendly definitions, aligned with the applicable ISO standards, rather than reproducing ISO definitions verbatim. The relevant ISO documents would be identified in the bibliography when appropriate. This approach would help maintain consistency with ISO while allowing TNI definitions to remain accessible and practical for laboratories.

The Committee discussed whether these changes would significantly affect the current TNI standard. Ilona and Jessica noted that the standard already identifies ISO 17025 as a source of terminology and that the definitions section does not specifically reference the former ISO Guide 30. There was general agreement that the current draft appears unlikely to require extensive changes as a result of ISO 33400.

Carol also noted that ISO 17025 was reconfirmed in 2023 and is within its five-year review cycle, reducing the immediate likelihood of a revised edition. However, work is underway on an updated ISO 9001 standard, with publication expected around September 18, 2026.

3. Review of Comments and Revisions from the Houston Meeting

Debbie Bond summarized the comments and proposed revisions reviewed during the Houston meeting. She explained that some comments had already been received formally on the Draft Standard, while others reflected concerns raised during Committee discussions that might warrant consideration even without a formal comment.

The Committee reviewed the following decisions:

- Accreditation status notifications (Section 4.3.5): The language was revised to require laboratories to inform affected clients of suspension, reduction, or withdrawal of accreditation “without undue delay,” restoring the wording used in the existing Volume 2 requirements rather than introducing laboratory-defined timelines.
- Support equipment documentation: The Committee determined that the existing Draft Standard adequately addresses vendor certificates and did not make the proposed additional changes.
- Support equipment verification exemptions (Section 6.4.6.4): The Committee decided not to add a prescriptive list of exemptions because the applicability of verification depends on the method and the specific equipment use.
- Balance verification: A proposed requirement to verify balances at the end of each day of use was not adopted because there was insufficient support for adding it.
- Verification terminology: Editorial changes were accepted where the wording used “verification” ambiguously or made the requirement difficult to interpret.
- Equipment adjustment controls: A proposed addition concerning measures to prevent unintended equipment adjustments was not adopted because the Committee considered it too prescriptive.
- Document control: The Committee retained the existing approach to document control, including applicable bench sheets and similar records. The draft does not introduce a new exemption from controlling these documents.
- Auditing: Editorial revisions were accepted to clarify expectations for review over the three-year period.
- Technical Specialist coursework: A title was added and the associated course list reorganized to improve clarity in Appendix C covering additional microbiology and radiochemistry coursework.
- Optional quality control (QC) activities: The Committee decided not to restore a general list of optional QC activities to the quality management systems section. Such lists may not apply consistently across methods, and the technical modules are considered the more appropriate place to specify method-specific QC requirements.

Ilona will complete the Houston Meeting Summary and it will be attached to these minutes in Attachment B. They will be reviewed with the minutes for approval at the October meeting.

4. Response to Comments Review

The Response to Comments review continued in Houston. She greyed the comment as a reminder to share it with the Committee.

There were some concerns on Data Integrity and this will be looked into in a future meeting. Debbie explained that the section had previously been organized around four distinct requirements. Subsequent restructuring had removed some of the original headings and distinctions.

There was general agreement that the section might benefit from restoring the headings and reviewing the overall organization. The Committee also needs to consider how prohibited actions should be addressed, including whether they belong in the main body of the standard or in Annex C.

Today's meeting focused on definitions:

Analytical Batch

The existing wording referred to prepared environmental samples and listed extracts, digests, and concentrates. Members questioned whether the language might unintentionally exclude certain types of analyses or imply that every sample must undergo a specific preparation step.

Discussion resulted in agreement on the following revised wording:
"An analytical batch is composed of environmental samples which are analyzed together as a group. An analytical batch can include samples originating from multiple preparation batches."The Committee considered this an editorial revision because the intent was to clarify the definition rather than introduce a new requirement.

A related issue raised by Nicole concerned the relationship between analytical batches, preparation batches, method blanks, and laboratory control samples (LCSs). Different definitions appear to use inconsistent language concerning the same process and whether all preparation or cleanup steps must be included. Situations involving filtered and unfiltered samples, or samples requiring additional cleanup identified after extraction, may create uncertainty about batch composition and associated QC requirements.The Committee agreed that this broader issue requires further work by the Chemistry Committee.

Finding

The Committee considered a comment suggesting that the definition of "finding" could imply that every observation of conformity must be formally reported. The existing definition allows findings to indicate conformity, nonconformity, or opportunities for improvement.

There was support to retain the definition because it reflects current quality management system terminology and recognizes that findings are not necessarily deficiencies. The group acknowledged that this represents a change in terminology and expectations for some laboratories accustomed to using "finding" primarily to mean a nonconformity.

The comment under review was ultimately considered not persuasive.

Laboratory Control Sample

The Committee reviewed a proposal to split the laboratory control sample definition into two sentences. There was stronger preference to keep the existing single-sentence structure because it better connects the sample's characteristics with its required preparation and analytical steps. It was felt that splitting the definition could make it unclear that the sample must contain the relevant analytes at known concentrations.

The Committee kept the original language and agreed that the comment was not persuasive.

Matrix

- Drinking Water and Non-Potable Water

The Committee considered a comment regarding groundwater and the distinction between drinking water and non-potable water. The drinking water definition covers aqueous samples designated as potable or potentially potable sources, while the non-potable water definition includes groundwater and other specified sample types.
It was concluded that the existing language was sufficiently clear because the intended use or designation of the water determines whether it qualifies as drinking water. The proposed change was considered not persuasive.

- Saline and Estuarine Water

The Committee reviewed a proposal to expand the definition of saline/estuarine water to include brackish and brine waters. The Committee discussed the use of “aqueous sample” in the existing definition because the broader definitions distinguish saline and estuarine samples from other aqueous samples.

The committee agreed on revised wording for the draft: “Any sample collected from saline waters, including oceans, estuaries, brackish waters, and brines.”

Members preferred not to include a specific example, such as the Great Salt Lake, because examples could unintentionally limit the scope of the definition.

- Non-Aqueous Liquids and Solids

The Committee discussed a proposed clarification to the definitions of non-aqueous liquids and solids, particularly the existing 15% settleable-solids threshold. The comment highlighted a gap in the existing language because it did not clearly address a result of exactly 15%.

The Committee considered revising the non-aqueous liquid definition to remove the limitation to organic liquids and to clarify that materials with 15% or greater settleable solids would be classified as solids. A corresponding revision to the solids definition was also discussed, with references to soils, sediments, sludges, and other solid or semisolid matrices.

Tentative wording was developed that would classify materials containing 15% or greater settleable solids as solids. However, it could not confirm the technical basis for the 15% threshold or determine whether it should be expressed on a mass or volume basis. The discussion also raised questions about whether the threshold originated in an EPA method or another historical source.

Carol reported finding an EPA-related definition of a non-aqueous-phase liquid that describes an organic liquid that is immiscible with water and has low aqueous solubility, allowing it to persist as a distinct phase in soils and groundwater. The Committee recognized that this definition might not cover all liquids that laboratories need to distinguish from aqueous samples, particularly liquids that are miscible with water. Although the Committee made preliminary Draft changes, it did not consider the issue fully resolved.

- Chemical Waste

The Committee reviewed a proposal to broaden the chemical waste definition so that it would include process residuals, wastes, and mixtures that might not qualify as conventional products or byproducts.

The Committee supported the following revised wording for the Draft Standard:
“A chemical product, process residual, byproduct, waste, or mixture resulting from an industrial or commercial process that does not meet the definition of another specified matrix.”

The proposed revision was persuasive.

The Committee will continue its review in October.

5. New Business

None.

6. Action Items

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

7. Next Meeting and Close

The next Committee meeting will be on October 26, 2026, at 1pm Eastern due to the holiday for many on the usual second Monday of the month.

Debbie adjourned the meeting at 2:37 pm Eastern.

Attachment A
Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) **Present**	Alabama Power	2029	Lab	dbond@southernco.com
Jessica Jensen (Vice Chair) **Present**	KCMO	2029*	Lab	jessica.jensen@kcmo.org
Carla McCord **Present**	Virginia	2028	Accrediting Body	carla.mccord@dgs.virginia.gov
Nicole Cairns **Present**	NYSDOH	2027	Lab	nicole.cairns@health.ny.gov
Alison Boren **Absent**	Vermont	2029*	Accrediting Body	alison.boren@vermont.gov
Carol Gebhart **Present**	ALS Global	2027*	Lab	Carol.gebhart@alsglobal.com
Stephanie Atkins **Present**	Pace Analytical	2027	Lab	stephanie.atkins@pacelabs.com
Lauren Webb **Present**	A2LA	2029*	Accrediting Body	lwebb@a2la.orgK
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**	ANAB	2028	Accrediting Body	zpopovska@anab.org
Kim Fielder **Present**	HRSD	2029*	Lab	kfielder@hrsd.com.gov
Amy Schreader **Present**	UC Laboratory	2027	Lab	amy@uclaboratory.net
Rebecca Pierrot **Absent**	ASQ CQM/OE	2028*	Other	rebecca@labhandler.com
Hunter Nelson **Absent**	Labware	2029*	Other	hunter.nelson@labware.com
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	n/a	Ilona.taunton@nelac-institute.org

Lab/FSMO: 7 AB: 6 Other: 2

TNI QMS Committee
Houston Meeting Summary
August 6, 2026

Voting Member Attendance: Amy Schreader, Jessica Jensen, Debbie Bond, Nicole Cairns, Kim Fielder, Carol Gebhart, Hunter Nelson, Zaneta Popovska, Ali Boren and Lauren Webb.
Program Administrator: Ilona Taunton
A quorum was present.

Part 1: 9-12pm Central

1. Overview

Debbie prepared a presentation for the meeting that can be viewed in Attachment 1. It provided an overview of the Committee and activities since the Boston meeting last January. It also provided Draft V1M2 Highlights for review for the morning session and a reminder that the Committee will work on comments received from the posting of the Draft Standard.

2. Organization

One of the most visible changes is the restructuring of the standard. The existing standard places most management requirements in Section 4 and technical requirements in Section 5. The draft is organized into:

- General requirements
- Structural requirements
- Resource requirements
- Process requirements
- Management system requirements

The draft incorporates Annexes A and B from ISO/IEC 17025 and adds a new Annex C developed by the QMS Expert Committee. Annex C is informative only and provides examples and clarification rather than additional mandatory requirements.

3. Definitions

A number of definitions have been removed or revised because some terms are adequately explained elsewhere, are not used in Module 2, or are already sufficiently understood. Some definitions were revised to improve clarity or remove procedural information. See Attachment 1.

4. Structural Requirements – Responsibilities

A significant change concerns how laboratories maintain continuity when personnel responsible for critical functions are unavailable.

ISO/IEC 17025 no longer contains the same requirement for laboratories to appoint deputies for key managerial personnel. The Committee determined that retaining similar TNI language could create ambiguity because the technical manager function is increasingly viewed as a technical-specialist function rather than strictly a managerial position.
The draft instead requires a procedure describing how responsibilities will be handled when personnel responsible for the laboratory, analytical-data review and release, or the quality

management system are unavailable. The intent is to maintain necessary operations while ensuring that critical functions are performed by appropriately qualified personnel.

5. Personnel

The Draft consolidates existing requirements concerning education, training, skills, and job descriptions into a broader competence requirement. Laboratories must document competence requirements for functions that influence laboratory results. Depending on the function, these may include education, qualifications, training, technical knowledge, skills, and experience. The Committee noted that the intent is generally consistent with the existing standard, although laboratories may use different documentation to demonstrate compliance.

6. Equipment, Verification, and Traceability

Section 6.4 led to conversation concerning support equipment and independent verification. Section 6.4 is directed primarily toward support equipment. Requirements for analytical instruments themselves may be addressed in the applicable technical modules.

A key clarification is that independent verification is not necessarily required for every support component incorporated into analytical equipment when the component's performance is already adequately demonstrated through the analytical process.

For example, automated analytical equipment may incorporate volumetric measurements. When the analytical process includes appropriate verification, such as ICVs or CCVs, the intent is not necessarily to require separate periodic independent verification of every supporting component.

Section 6.4.6.4 addresses verification when quantitative results depend on equipment accuracy. The Draft consolidates requirements for temperature, volumetric measurements, balances, and other areas into Table 1.

Under specified circumstances, laboratories may use a certificate demonstrating that verification has been completed in accordance with Table 1 rather than performing the verification themselves.

The Committee discussed volumetric equipment such as digestion vessels and cups. A vendor or qualified organization may provide a certificate documenting volume measurements at applicable graduation points along with calculations involving measured volume, relative standard deviation, water mass, temperature, and water density.

The rationale is that repeating a sufficient verification already performed by a qualified organization may not provide additional value. However, not every vendor certificate will automatically be acceptable. The certificate must contain enough information to meet Table 1 requirements, including applicable traceability criteria. This issue generated significant discussion because manufacturers may provide very different levels of documentation. Some certificates may contain detailed measurements and calculations, while others may simply state that an item meets a particular specification.

Laboratories will need to evaluate certificates against the Standard's criteria rather than automatically accepting a manufacturer's statement of conformity. The Committee identified a

need for additional clarification so laboratories and assessors can consistently determine what constitutes acceptable verification documentation. This can be considered when developing implementation tools.

There was discussion about temperature measurement. Though inaccuracies can cause bias, Temperature measurement generated related discussion concerning probes incorporated into pH systems, microwave digesters, extractors, and other equipment.
The committee recognized that inaccurate temperature measurement can introduce bias, at the same time, requiring independent verification of every component that could potentially influence an analytical result could become overly broad. The Standard needs to distinguish equipment that is genuinely critical to the measurement from components whose performance is adequately demonstrated through the analytical process. Language in Section 6.4.1.3 will be further reviewed.

The Committee also considered whether ICVs, CCVs, and other routine quality-control activities provide sufficient verification of automated diluters. The answer may depend on how the equipment is incorporated into the analytical process. If the same equipment is used for calibration and subsequently for the verification sample, the check may not be truly independent. In other situations, an appropriate quality-control sample may provide sufficient independent evidence of performance.

The overall intent is to avoid duplicative verification when equipment performance is already effectively demonstrated while retaining independent verification when the analytical process does not provide adequate assurance.

7. Technical Records

The Draft clarifies that requirements for amendments to technical records also apply to changes made to original software output, including manual integration changes and elimination of false-positive results. ISO/IEC 17025 already requires retention of original and amended data, identification of the date and nature of alterations, identification of the responsible individual, and documentation of the reason for amendments when they are not simple transcription errors. The Committee generally viewed the additional software language as a clarification rather than a fundamentally new requirement.

8. Complaints

The Draft expands complaint requirements. Laboratories would need to make their complaint process available to interested parties upon request and determine whether a complaint concerns activities for which the laboratory is responsible. The process must address receiving, validating, investigating, and resolving complaints, including tracking complaints and associated actions. Laboratories are also responsible for gathering and verifying information necessary to validate a complaint.

The outcome must be communicated by, or reviewed and approved by, personnel who were not involved in the original activities being questioned. External personnel may perform this function where appropriate.

9. Management-System Documents

The Committee discussed requirements concerning external documents used by laboratory personnel, including TNI standards and reference methods.

A major issue was the distinction between having access to an external document and placing that document within a controlled-document system. Depending on a license, a laboratory may be permitted a single printed copy, a single-user electronic copy, or broader access. This may require further review.

The Committee clarified that laboratories are not expected to retain every historical version of every reference method. The intended requirement is an authorized edition relevant to the laboratory's work.

10. Risks and Opportunities

The Draft adds requirements concerning risks and opportunities. Laboratories would identify risks and opportunities, plan actions, integrate those actions into the management system, and evaluate their effectiveness. Records of identified risks and mitigation activities would be maintained, with risks and plans reviewed annually and updated as appropriate.

Corrective-action requirements would also require consideration of whether a nonconformity indicates that identified risks or opportunities should be updated or that management-system changes are needed.

11. Internal Audits and Management Reviews

The proposed internal-audit requirements would include:

- Annual review of all requirements in TNI Volume 1, Modules 1 and 2.
- Review of applicable elements of Modules 3 through 7 over three years.
- Annual representative selection of analytes, matrices, and technologies.
- Coverage of all accredited methods, with at least one-third of the methods reviewed each year.

In Management review, a notable addition is personnel feedback as a management-review input.

12. Quality Specialist and Technical Specialist Requirements

The Draft uses the term “quality specialist”, rather than requiring the organizational title "quality manager." The phrase "however named" is intended to provide flexibility. Laboratories may continue using titles such as “quality manager” if appropriate to their organizational structure. Responsibilities are included in the slide in Attachment 1.

If one individual serves as both quality and technical specialist, the laboratory must define how the responsibilities are separated and how required independence is maintained.

Review of the Technical Specialist language led to discussion. The language in the slides in Attachment 1 was reviewed.

It was noted that state requirements may impose different or more restrictive notification periods that would continue to apply.

Attendees also questioned whether language concerning possible accreditation consequences belongs directly in the Standard. The intent was described as identifying potential accreditation implications.

Attendees questioned whether the Technical Specialist provisions are more prescriptive than ISO/IEC 17025 requires. The discussion centered on balancing consistent technical oversight with flexibility for laboratories of different sizes and structures.

The Committee recognized that small and rural laboratories may have fewer technical resources than larger laboratories. The alternate-person and notification requirements are intended in part to prevent laboratories from operating for extended periods without appropriate technical oversight.

Qualification requirements, course work and exceptions are outline in the slides in Attachment 1.

Accreditation bodies may also grant exemptions beyond the listed exceptions. Laboratories would need to obtain and retain the applicable approval documentation. The Committee recognized that establishing qualification requirements that work consistently across all laboratory disciplines and accreditation structures is difficult. The proposed framework reflects extensive discussion and compromise.

13. Annex C

Annex C provides informative examples concerning data integrity, technical-specialist structures, and education, training, and experience. Debbie shared the text for this section on screen.

A technical specialist does not need to personally perform every method or technique within the laboratory's scope. Jerry Parr indicated that this clarification may be important enough to appear in the main technical-specialist requirements rather than only in an informative Annex C. Experience obtained solely through a degree would not be counted separately because the education requirement already accounts for it. Personnel management alone would not necessarily constitute the technical experience required. Clarification may be needed that a technical specialist does not have to be currently performing every method and that relevant prior technical experience can satisfy the intent.

There was some discussion about whether the education must come from an accredited organization. The Draft does not require specific accreditation. It was noted that each option has an education and experience requirement.

Part 2: 1-4pm Central

The TNI QMS Expert Committee met to review comments received thus far on the Draft TNI QMS Standard. When reviewing comments, the Committee distinguished between editorial changes intended to improve clarity and substantive changes that could affect laboratory implementation or assessment.

The Committees goal was that the Standard establish what laboratories are required to accomplish while allowing flexibility in how requirements are implemented. The Committee also sought to avoid unnecessary duplication, overly prescriptive language, and detailed lists.

Committee voting on responses was deferred until the remaining comments have been reviewed and the Response to Comments table is complete.

1. Equipment and Verification – Section 6.4

Certificates and Verification – Section 6.4.64

The Committee reviewed a comment proposing additional requirements for certificates used to verify volumetric equipment, including tolerances, metrological traceability, certificate validity, and qualifications of certificate issuers.

The Committee determined that the existing language adequately establishes the required outcome. Additional detail could create unnecessary laboratory responsibilities and make the provision overly prescriptive.

Conclusion**:** Retain Section 6.4.64 as written; the comment was considered **non-persuasive**.

Verification Exemptions and Acceptance Criteria

The Committee considered proposals to identify specific exemptions from verification and establish universal acceptance criteria for equipment such as balances and thermometers.

It was concluded that an exhaustive exemption list could accidentally omit legitimate circumstances and that appropriate acceptance criteria vary according to equipment, method, intended use, measurement resolution, regulatory requirements, and acceptable uncertainty or error.

Conclusion: Do not add a detailed list of exemptions or universal equipment acceptance criteria.

Balance Verification

A proposal to require balance verification both before and after each day of use was not supported. It was concluded that verification before subsequent use provides an appropriate check and that laboratories may adopt additional practices when warranted.

Conclusion: Do not require mandatory end-of-day balance verification.

Sections 6.4.65(E) and (F)

The Committee supported editorial revisions concerning certificate-based verification. The wording will be clarified to describe acceptable accuracy at the volume of use or at volumes bracketing the range of use, as applicable, without changing the technical requirement.

Section 6.4.12

The Committee concluded that the existing ISO-based language concerning prevention of unintended equipment adjustments is sufficiently clear.

Conclusion: Retain Section 6.4.12 substantially as written; the comment was considered non-persuasive.

2. Data Integrity – Section 4.16

The Committee reviewed a comment to broaden the description of a laboratory's data integrity system beyond preventing intentional misconduct. The broader concept includes ensuring that data are accurate, complete, traceable, reliable, and trustworthy, supported by appropriate review, error correction, monitoring, auditing, and identification of system failures. The Committee agreed with the concept but concluded that the existing Section 4.16 language already addresses these objectives

Conclusion: Retain the general approach of Section 4.16 and defer adoption of the proposed replacement language.

The Committee considered adding a detailed list of required elements covering data accuracy, impartiality, training, prohibited actions, monitoring, confidential reporting, management notification, protection from retaliation, investigations, and records. Because many of these are already addressed elsewhere, there was concern that another extensive list could make the Standard unnecessarily prescriptive or encourage checklist-based assessment.

The committee nevertheless recognized that training and prohibited actions may require additional specificity.

Conclusion: Defer final resolution until all related comments have been reviewed.

<u>Data Integrity Training and Prohibited Actions</u>

The Committee discussed whether prohibited actions should appear in the main standard, Annex C, or both. The list was previously moved to Annex C partly because assessors may have difficulty assessing requirements framed solely as prohibitions.

Some attendees supported greater specificity in the standard to clarify training expectations, while others favored retaining a flexible, risk-based approach with examples in Annex C.

No final decision was reached. If prohibited actions are included in the main standard, "as applicable" may be appropriate to account for differences among laboratories.

Conclusion: Defer pending review of additional comments.

Attendees noted that data integrity training requirements are currently distributed among Sections 4.16.3, 4.16.4, and 4.16.6. This structure may create confusion or make related requirements appear inconsistent.

The Committee discussed consolidating the requirements under a dedicated training subsection addressing training content, frequency, prohibited actions, procedures, and documentation. The existing annual training requirement must remain clear and must not be weakened by restructuring.

Conclusion: Develop a consolidated training structure and review Sections 4.16.3, 4.16.4, and 4.16.6 together.

The Committee discussed language concerning the laboratory's mission and the importance of honesty. It was clarified that this is a training requirement, not a requirement to create a separate policy or mission statement.

The underlying concept was supported: employees should understand why honesty and data integrity are essential to the laboratory's mission, reliable data, and protection of public health and the environment.

Conclusion: Revisit the wording as part of the possible broader Section 4.16 restructuring.

A proposal to clarify that training should include review of data integrity procedures was considered. Because it is closely related to the overall training discussion, the Committee will address it with the other Section 4.16 training provisions rather than independently.

Data Integrity Investigations and Corrective Action

The Committee supported proposed language requiring, when applicable, root cause analysis and corrective action following a data integrity breach.

Attendees emphasized that corrective action should address the underlying cause rather than simply correct the immediate problem. The requirement is consistent with existing provisions concerning nonconforming work and corrective action.

Conclusion: Support the concept of root cause analysis and corrective action when applicable.

The Committee also confirmed that Section 4.16.7B duplicates a requirement already addressed through Section 4.16.3D.

Conclusion: Remove Section 4.16.7B.

3. Notification of Clients Following Accreditation Changes – Section 4.3.5

The Committee reviewed requirements concerning notification of clients when accreditation is suspended, reduced, or withdrawn and when the laboratory can no longer reference accreditation for affected work.

Notification Timelines

A proposal to replace "laboratory-defined timelines" with a universal 30-day requirement was not supported. Regulatory, contractual, or other requirements may establish different timeframes.

The Committee favored flexibility while recognizing that laboratory-defined timelines must remain reasonable and appropriate.

Decision: Do not establish a universal 30-day notification requirement.

Affected Clients

The Committee discussed situations in which accreditation is lost for a specific analyte or method. The laboratory may, where permitted, continue the work as non-accredited testing or may need to subcontract it.

Attendees generally agreed that clients whose work, samples, reporting, or services are directly affected should be appropriately informed. The committee did not support an unrestricted requirement to notify every past, current, or potential client.

4. Document Control – Section 8.3.3

The Committee reviewed a comment concerning printed appendices, makeup sheets, helpful notes, and similar laboratory documents. The committee concluded that the requirement does not create a new burden. Documents used to direct or support laboratory activities have historically been expected to be current and controlled.

Conclusion: Retain the existing document-control requirement; the comment was considered non-persuasive.

5. Internal Audit Program – Sections 8.8.3 and 8.8.3.2

The Committee reviewed proposed editorial revisions to the internal-audit requirements. The Committee supported improving sentence structure and separating the three-year requirement from the annual requirements, provided the existing requirements are unchanged.

Conclusion: Revise the language for clarity while preserving the existing three-year cycle and annual requirements.

6. Annex C

Section C7

The Committee reviewed a comment concerning duplicate wording related to prohibited actions. Because Annex C will undergo a broader data integrity review, the Committee decided not to try to resolve C7 independently.
Conclusion: Defer C7 until the comprehensive Annex C review.

Section C32 – Technical Education and Training

The Committee reviewed proposed changes concerning technical education and training for technical specialists.
Attendees felt that "technical courses" may be too narrow because the material includes education, training, college-level coursework, and other relevant preparation.

The Committee is considering clearer terminology distinguishing in-person, self-paced online, and live virtual training. Members noted that "virtual reality" should not be used as a synonym for live online training because it can refer to a different technology.

Conclusion: Revise the wording for clarity while maintaining the intended scope.

Essential QC Elements

The Committee discussed whether the general "essential QC elements" list from the current Module 2 should be restored to Annex C. The Committee concluded that the individual technical modules provide more appropriate discipline-specific QC requirements and did not identify a compelling need to restore the general list.

Conclusion: Continue relying on applicable technical modules unless further review identifies a gap.

7. Open Discussion

A Committee member shared information regarding **CDC OneLab REACH** as a potential supplemental laboratory training resource. The resource offers free training and certificates and may provide useful material in areas such as laboratory safety and biosafety. It is primarily oriented toward clinical laboratories and may not address all environmental laboratory requirements.

Quality Management Systems Committee

Summer Conference in Houston
August 6, 2026

Chair – Debbie Bond (dbond@southernco.com)

Vice-Chair – Jessica Jensen (jessica.jensen@kcmo.org)

Program Administrator – Ilona Taunton (Ilona.Taunton@nelac-institute.org)

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Quality Management Systems Committee

Member	Organization	Representation
Stephanie Atkins	Pace Analytical	Lab
Debbie Bond - Chair	Alabama Power	Lab
Alison Boren*	Vermont	AB
Nicole Cairns	NYSDOH	Lab
Kim Fielder*	HRSD	Lab
Carol Gebhart	ALS	Lab
Jessica Jensen – vice-Chair*	KCMO	Lab
Carla McCord	Virginia	AB
Hunter Nelson*	Labware	Other
Rebecca Pierrot	ASQ CQM/OE	Other
Zaneta Popovska	ANAB	AB
Amy Schreader	UC Laboratory	Lab
Joann Slavin	NYSDOH ELAP	AB
Caitie Van Sciver	NJDEP	AB
Lauren Webb*	A2LA	AB

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Quality Management Systems Committee

Thursday Morning Session

- Updates since Winter Meeting
- Overview of V1M2 Changes
- Next steps

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Quality Management Systems Committee

COMMITTEE OVERVIEW SINCE BOSTON

- No SIRs!
- Incorporated suggestions from Boston sessions into Draft
- Posted Draft for comment!
  - Draft V1M2 is posted for comment until September 26
  - We've received about 75 comments so far…
- Even Newer Crosswalk WG created
  - Ali Boren, Carl Kircher, Carla McCord, Debra Zeller, Fida Kased, Kim Fielder, Salima Haniff, and Debbie Bond

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Quality Management Systems Committee

DRAFT V1M2 HIGHLIGHTS

DISCLAIMER

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Quality Management Systems Committee

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(Impartiality, Confidentiality, Lab responsibility to AB info, etc.)
5.0 Structural Requirements
6.0 Resource Requirements
(Personnel, Facilities, Equipment, Traceability, Procurement)
7.0 Process Requirements
(Contracts, Methods, Sampling, Calibration, Records, QC, Reporting, Nonconforming Work)
8.0 Management System Requirements
(Control of documents & records, Risk & Opportunities, Improvement, Corrective Action, Audits, Mgmt Review)
Annex A – Metrological Traceability
Annex B – Management System Options
Annex C – Implementation Examples
(General, Data Integrity Prohibited Actions, Technical Specialist)

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Quality Management Systems Committee

DEFINITIONS - Removed

Acceptance Criteria	Critical Supplies and Services	Proficiency Testing
Accreditation	Data Reduction	Proficiency Testing Program
Assessment	Field of Accreditation	Quality Manual
Blank and Method Blank	In-depth Data Monitoring	Record
Calibration Curve	Internal Standard	Sensitivity
Certified Reference Material	Legal Chain of Custody	Standard
Chain of Custody Form	Limit of Detection	Standard Operating Procedure
Confirmation	Limit of Quantitation	Verification
Contract	Physical Parameter	

Removed terms described in V1M2, terms not used in V1M2 (unless used in multiple Testing Modules), generally understood terms in our industry, and terms defined by ISO 17025:2017.

Other terms were clarified, updated to match definition in other Volumes, and procedural information removed. No change to the meaning.

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Quality Management Systems Committee

NEW DEFINITIONS

Annual: A period of 12 months, not to exceed 13 months.

Correction: Action to eliminate a detected nonconformity.

Corrective Action: An action taken by the laboratory to eliminate or correct the cause(s) of a nonconformance and to prevent recurrence.

Customer: A person or organization internal or external to the laboratory that requests services from the laboratory.

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Quality Management Systems Committee

NEW DEFINITIONS

Document (n.): Written component of the laboratory management system (e.g., policy, procedure, instruction, form template, etc.).

Nonconformity: An event that demonstrates failure to meet a requirement in a TNI standard, policy, or procedure.

Quarterly: A period of 3 months, not to exceed 4 months, and occurring 4 times annually.

Test Item (e.g., sample): The sample received, subsamples, or any derivative sample that is subjected to testing.

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Quality Management Systems Committee

DRAFT V1M2 – STRUCTURAL REQUIREMENTS

5.5.1 The laboratory must have a procedure for how roles and responsibilities are filled when personnel responsible for the laboratory, the review and release of analytical data, or the quality management system, are unable to fulfill their responsibilities. The procedure must define:

5.5.1.1 the work that must be halted when those personnel are unable to fulfil responsibilities,

5.5.1.2 the processes that may continue, and for how long, when those personnel are unable to fulfill responsibilities,

5.5.1.3 the duration for which designated alternates may perform tasks, and

5.5.1.4 any relevant qualifications for designated alternates.

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Quality Management Systems Committee

DRAFT V1M2 – PERSONNEL

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

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Quality Management Systems Committee

DRAFT V1M2 – EQUIPMENT

6.4.1.3 Independent verification, as described in section 6.4.6.2, is not required for support equipment incorporated into analytical equipment.

6.4.6.4 Verification is required when quantitative results are dependent on accuracy. The laboratory must ensure verification is completed as listed in Table 1. A certificate that demonstrates verification was completed in compliance with Table 1 may be used.

6.4.6.5 Table 1 [for single-use, non-Class A and "all other volumetric"] Verification may be performed by comparison to a certificate that verifies the volume of use or the volumes bracketing the range of use, as applicable. [**see next slides**]

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Digestion Vessels - Certificate of Volume Accuracy and Metals Background

Representative samples of this lot of digestion cups have been tested for volume accuracy at all graduation lines by the procedures set forth in ASTM E542-01 *Standard Practice for Calibration of Laboratory Apparatus*. Volume accuracy was found to be within the Class A tolerance set forth in ASTM 1272-02 *Standard Specification for Laboratory Glass Graduated Cylinders*. Balances used in test procedures are certified yearly and traceable to NIST. Complete test results and test conditions are available at www.envexp.com.

Metals Background Analysis Report

Samples of disposable digestion cups are collected randomly from each manufacturing lot for analysis. Blank samples are digested and analyzed using current ICP-MS or CVAFS methodology. Results are reported in the chart below. Field results may vary with environmental conditions, analytical techniques, and handling procedures. Care should be taken in storage and handling to prevent background contamination.

Element	Results (ug/L)	Element	Results (ug/L)	Element	Results (ug/L)	Element	Results (ug/L)	Element	Results (ug/L)	Element	Results (ug/L)
Ag	< 0.1	Cr	< 1.5	Ho	< 0.1	Nd	< 0.25	Sb	< 0.5	Tm	< 0.1
Al	< 30	Cs	< 0.1	In	< 0.1	Ni	< 0.25	Sc	< 0.2	U	< 0.08
As	< 0.2	Cu	< 0.5	Ir	< 0.1	Os	< 0.1	Se	< 0.25	V	< 0.5
Au	< .25	Dy	< 0.1	K	< 50	P	< 10	Si	< 50	W	< 0.1
B	< 10	Er	< 0.25	La	< 0.1	Pb	< 0.25	Sm	< 0.25	Y	< 0.1
Ba	< 1	Eu	< 0.1	Li	< 0.5	Pd	< 0.1	Sn	< 1	Yb	< 0.1
Be	< 0.1	Fe	< 25	Lu	< 0.1	Pr	< 0.1	Sr	< 2.5	Zn	< 2
Bi	< 0.1	Ga	< 0.5	Mg	< 15	Pt	< 0.5	Ta	< 0.1	Zr	< 1
Ca	< 150	Gd	< 0.1	Mn	< 0.1	Rb	< 0.1	Tb	< 0.1		
Cd	< 0.2	Ge	< 0.1	Mo	< 0.1	Re	< 0.1	Te	< 0.5		
Ce	< 0.2	Hf	< 0.1	Na	< 50	Rh	< 0.1	Ti	< 0.5		
Co	< 0.1	Hg	< 0.0005	Nb	< 0.1	Ru	< 0.1	Tl	< 0.08		

Lot Number: LV24070610-4304

Contact us for more information!
+1.800.343.5319 or +1.843.881.6560 | info@envexp.com

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Representative Samples of 60mL Digestion Cups for Volume Accuracy

Part #s: [illegible] Lot# LV24070610

Test Date: 06/27/2024
Air Temp: 24.03 °C
Water Temp: 24.03 °C
Water Density: 0.99740 g/cm³

Cavity	13	16	21	24	60	65	70	74	Mean	RSD
5mL Wt	4.99	4.98	4.97	5.00	4.99	5.00	4.99	5.00	4.99	0.20%
Tolerance	0.02	0.03	0.04	0.01	0.02	0.01	0.02	0.01	0.02	
10mL Wt	10.00	10.00	9.98	9.99	9.99	9.99	10.00	10.00	9.99	0.07%
Tolerance	0.03	0.03	0.04	0.05	0.04	0.04	0.03	0.03	0.03	
15mL Wt	15.00	14.98	14.99	15.00	14.99	14.98	14.99	14.98	14.99	0.05%
Tolerance	0.04	0.06	0.05	0.04	0.05	0.06	0.05	0.06	0.05	
20mL Wt	19.98	20.00	20.01	20.00	19.99	19.98	19.99	19.99	19.99	0.05%
Tolerance	0.07	0.05	0.04	0.05	0.05	0.07	0.05	0.05	0.05	
25mL Wt	25.00	24.99	25.00	24.99	24.98	25.00	24.99	24.99	24.99	0.03%
Tolerance	0.07	0.08	0.07	0.08	0.09	0.07	0.08	0.08	0.07	
30mL Wt	29.98	29.99	29.99	30.00	29.98	29.99	29.97	30.00	29.99	0.03%
Tolerance	0.10	0.09	0.09	0.08	0.10	0.09	0.11	0.08	0.09	
35mL Wt	35.00	34.99	35.00	34.98	35.00	35.00	34.99	34.98	34.99	0.02%
Tolerance	0.09	0.10	0.09	0.11	0.09	0.09	0.10	0.11	0.10	
40mL Wt	39.97	39.96	40.00	40.00	39.98	39.99	40.00	39.96	39.99	0.04%
Tolerance	0.13	0.15	0.10	0.10	0.12	0.11	0.10	0.11	0.12	
45mL Wt	45.00	44.98	44.99	44.97	44.99	44.98	45.00	44.98	44.99	0.02%
Tolerance	0.12	0.14	0.13	0.15	0.13	0.14	0.12	0.14	0.13	
50mL Wt	50.00	49.99	50.00	49.99	50.00	49.98	50.00	50.00	50.00	0.01%
Tolerance	0.13	0.14	0.13	0.14	0.13	0.15	0.13	0.13	0.14	

Class A Tolerance +/- 0.25mL

All weights reported in grams (g).
All weights reported in grams (g).
All weights are adjusted based on Water Density at time of testing.
Class A Tolerance based on "To Contain" requirements of Class A graduated cylinder.

Wt = Total raw weight of water (g) prior to density adjustment

Testing performed by: Sandy McLaughlin

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Quality Management Systems Committee

DRAFT V1M2 – EQUIPMENT

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:
a) the identity of equipment, including software and firmware version;

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Quality Management Systems Committee

DRAFT V1M2 – EXTERNALLY PROVIDED PRODUCTS…

6.6.2 b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;

i) When the laboratory subcontracts work that requires TNI accreditation, this work must be placed with a laboratory accredited to this Standard for the tests to be performed.

ii) Where the laboratory arranges for an external sampling organization to be used, the laboratory must 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 as required … Use of a National Environmental Field Activities Program (NEFAP) accredited Field Sampling Measurement Organization (FSMO) meets the requirements of this Standard.

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Quality Management Systems Committee

DRAFT V1M2 – EXTERNALLY PROVIDED PRODUCTS…

6.6.4.4 Purchased or prepared reference materials, standards, and reagents (including media) must not be used beyond their expiration dates unless verified for acceptable use by the laboratory. The laboratory must have a procedure for and maintain records of the verification. TNI Volume 1 Modules 3-7 may have different or additional requirements for the use of reference materials and reagents (including media) beyond their expiration date.

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Quality Management Systems Committee

DRAFT V1M2 – REQUESTS, TENDERS, AND CONTRACTS

7.1.4 Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

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Quality Management Systems Committee

DRAFT V1M2 – SAMPLING

7.3.3 The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:

c) data to identify and describe the sample (e.g. number, amount, name);

e) identification of the equipment used;

7.3.3.2 Where sampling is not performed by the laboratory, sampling records provided must be retained.

7.3.4 Use of NEFAP accredited FSMO meets these [sampling] requirements.

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Quality Management Systems Committee

DRAFT V1M2 – LEGAL CHAIN OF CUSTODY

7.4.1.2 If a customer requires legal chain of custody procedures and the laboratory accepts the samples, the laboratory must have a legal chain of custody procedure describing how it will ensure chronological traceability of custody of a test item from collection to disposal. The procedure must describe how the custody of test items is recorded during possession and handling within the laboratory to ensure the location and possession of the test item can be historically reconstructed.

Samples are considered to be under custody when they are:

a) In the physical possession of laboratory staff;

b) Within view of laboratory staff, after being in their physical possession; or

c) Stored in a secured, restricted, and defined storage location within the laboratory.

Note: A general description of "laboratory" is not a defined storage location.

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Quality Management Systems Committee

DRAFT V1M2 – TECHNICAL RECORDS

7.5.2.2 Requirements for amendments to technical records also apply to changes to the original output of the software such as manual integrations and elimination of "false positives" performed by laboratory personnel. These changes to the original output of the software must be reviewed by technically qualified personnel. Records of this review must be maintained.

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Quality Management Systems Committee

DRAFT V1M2 – COMPLAINTS

7.9.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

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Quality Management Systems Committee

DRAFT V1M2 – COMPLAINTS

7.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

NOTE This can be performed by external personnel.

7.9.7 Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

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Quality Management Systems Committee

DRAFT V1M2 – MANGEMENT SYSTEM DOCUMENTS

8.3.2 The laboratory shall ensure that:

h) 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.

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Quality Management Systems Committee

DRAFT V1M2 – RISKS AND OPPORTUNITIES

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The laboratory shall consider the risks and opportunities …

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;

b) how to:

— integrate and implement these actions into its management system;

— evaluate the effectiveness of these actions.

8.5.4 Records of the identification and mitigation of risk must be maintained.

8.5.5 Identified risks and any mitigation plans must be reviewed annually and updated as applicable.

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Quality Management Systems Committee

DRAFT V1M2 – CORRECTIVE ACTIONS

8.7.1 When a nonconformity occurs, the laboratory shall:

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the management system, if necessary.

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Quality Management Systems Committee

DRAFT V1M2 – INTERNAL AUDITING

8.8.3 In addition to the requirements listed in 8.8.1 and 8.8.2, the internal audit program must:

8.8.3.1 include a review of all requirements of TNI Volume 1 Modules 1 and 2 annually, and

8.8.3.2 include a review of all elements of TNI Volume 1 Modules 3-7 over a 3-year period as applicable to the laboratory's scope, that

a) includes a representative selection of analytes, matrices, and technologies annually, and

b) covers all methods under which the laboratory performs its accredited testing, with at least one-third of the methods being reviewed annually.

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Quality Management Systems Committee

DRAFT V1M2 – MANAGEMENT REVIEW

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a) changes in internal and external issues that are relevant to the laboratory;

b) fulfilment of objectives;

d) status of actions from previous management reviews;

i) customer and personnel feedback;

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QUALITY & TECHNICAL SPECIALISTS

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Quality Management Systems Committee

DRAFT V1M2 – STRUCTURAL REQUIREMENTS

5.6.1 The laboratory must have a Quality Specialist(s) (however named) who:

5.6.1.1 functions independently from laboratory activities for which they have quality assurance oversight;

5.6.1.2 has training and/or experience in the laboratory's quality management system;

5.6.1.3 has a general knowledge of the analytical methods for which data review is performed;

5.6.1.4 has the authority to manage nonconforming work and initiate the actions specified in 7.10.1b); and

5.6.1.5 is responsible for:

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Quality Management Systems Committee

DRAFT V1M2 – STRUCTURAL REQUIREMENTS

5.6.1.5 is responsible for:

a) coordinating quality activities;

b) evaluating data objectively and performing assessments without undue outside or managerial influence;

c) maintaining the quality manual;

d) arranging for or conducting internal audits as per Section 8.8;

e) initiating the actions specified in 7.10.1 b);

f) notifying laboratory management of deficiencies in the quality management system; and

g) monitoring nonconforming work and corrective actions.

5.6.8 The laboratory must define how the responsibilities of the Technical Specialist and the Quality Specialist are segregated when they are filled by the same person.

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Quality Management Systems Committee

GENERAL TECHNICAL SPECIALIST REQUIREMENTS

5.6.3 The laboratory must have a Technical Specialist(s) (however named) to **provide technical guidance** to laboratory personnel for all work associated with the laboratory's scope of accreditation. The **laboratory must clearly define its technical structure and how Technical Specialist responsibilities align with the laboratory's scope**. A laboratory may have one or more Technical Specialists that may also hold additional primary job responsibilities. **Annex C** provides examples of how a laboratory may define this structure.

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GENERAL TECHNICAL SPECIALIST REQUIREMENTS

5.6.3.1 Technical Specialist(s) must:

a) **ensure laboratory activities** related to the generation of analytical data and test results, including but not limited to method development and validation, procedure development, sample preparation, instrument calibration, sample analysis, quality control, and data reduction, **comply with the laboratory's quality management system and with relevant regulatory requirements** for which the data will be used and

b) **have the authority** to halt work, repeat work, withhold reports, and resume work as part **of the management of nonconforming work**, as defined in 7.10.

5.6.4 A Technical Specialist may be **appointed across multiple laboratories**, subject to **approval by the primary accreditation body**. Requests for approval **must include a plan** outlining how the Technical Specialist will meet the requirements in section 5.6.3 across multiple locations. Records of the accreditation body's approval, including the approved plan, must be retained.

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Quality Management Systems Committee

GENERAL TECHNICAL SPECIALIST REQUIREMENTS

5.6.5 If a Technical Specialist is **unable to fulfill** the duties in sections 5.6.3 a) and b) for fifteen **(15) consecutive calendar days**,

5.6.5.1 a designated **alternate must be appointed** per the procedure in 5.5.1 **and assume the responsibilities** of the technical specialist or

5.6.5.2 **work** in that area of responsibility **must be halted or subcontracted** to another qualified laboratory.

5.6.6 The designated alternate is **not required to meet the same qualification requirements** of a Technical Specialist but **must meet the requirements the laboratory defines** in the procedure described in 5.5.1.

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Quality Management Systems Committee

GENERAL TECHNICAL SPECIALIST REQUIREMENTS

5.6.7 When a designated alternate assumes the responsibilities of a Technical Specialist, the laboratory must **notify the primary accreditation body within sixty (60) days** if a qualified Technical Specialist does not resume the responsibilities. The notification must be **in writing for accreditation body approval and must include a plan with a timeline for appointing** a qualified Technical Specialist. If approval is not granted the laboratory accreditation may be suspended.

5.6.8 The laboratory must define how the responsibilities of the Technical Specialist and the Quality Specialist are segregated when they are filled by the same person.

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Quality Management Systems Committee

TECHNICAL SPECIALIST QUALIFICATIONS

6.2.2.1 Technical Specialist (however named) Qualifications

The laboratory must retain a record showing that each Technical Specialist meets the requirements of 6.2.2.2 or exceptions of 6.2.2.3. Where coursework is required, the laboratory must retain records that show courses were successfully completed (e.g., certificate, letter, transcript).

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6.2.2.2 A Technical Specialist must meet one of the combinations of education and experience qualifications listed below. Experience must be in the area of responsibility for the Technical Specialist. If the Technical Specialist is responsible for Microbiology (TNI Volume 1 Module 5) or Radiochemistry (TNI Volume 1 Module 6), completion of a relevant technical course is required, which may or may not be part of the educational qualifications listed below. Further information and examples regarding appropriate courses and experience can be found in Annex C.

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6.2.2.2

a) a master's or doctoral degree in a STEM (science, technology, engineering, or mathematics) field and one year of experience,

b) a bachelor's degree in a STEM field and two years of experience,

c) an associate's degree in a STEM field and three years of experience, or

d) four college level STEM courses and four years of experience. A TNI credential applicable to the areas of the Technical Specialist responsibilities can be substituted for the college level STEM courses. Vendor courses with certificates and a minimum of 3 CEUs may be considered equivalent to a college level STEM course.

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Quality Management Systems Committee

TECHNICAL SPECIALIST EDUCATION/EXPERIENCE EXEMPTION

6.2.2.3 Technical Specialist Qualification Options for Exempting Education and Experience Requirements

a) Any person who was formerly recognized as a Technical Specialist based on requirements or exceptions in previous revisions of this Standard qualifies as a Technical Specialist for the same areas of responsibility at any accredited laboratory. Appropriate records must be available to show previous recognition as a Technical Specialist.

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Quality Management Systems Committee

TECHNICAL SPECIALIST EDUCATION/EXPERIENCE EXEMPTION

b) A water or wastewater operator trained in laboratory procedures as part of their certification and who has completed two years of laboratory experience qualifies as a Technical Specialist at that facility (or another facility of equivalent or smaller size and scope) for the testing required for the facility by their state regulator or Control Authority.

c) An accreditation body may provide an exemption other than those listed in a) and b). The laboratory must receive the exemption from each of its accreditation bodies. The laboratory must retain the record of the exemption for the same duration required for the retention of the data generated during the employment of that Technical Specialist.

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ANNEX C

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Quality Management Systems Committee

Thursday Afternoon Session

- Response to Comments

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Attachment B – Houston Summary

This will be attached when the minutes are posted. See separate document for review.

Attachment C: QSM Action Item Summary – 2026

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. 7/14/25: Review of the definitions has been completed. Some definitions are being removed, but some of those will now be in Expert Modules where only one expert module still needed it. Work

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
								has resumed on Technical Specialist language to prepare for St. Louis. 3/9: The Committee is now doing a final review of the Standard prior to final formatting and vote. 5/11/26: Vote on Draft Standard started and will be completed by email. 6/8/26: Draft Standard completed and posted. Comments being received.
4	Defining Technology (Analytical Disciplines)	Various TNI Standards	Paul Junio Tony Francis Debbie Bond	January 2023	12/11/23		CLOSED	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. 8/6/25 & 8/18/25: Analytical Disciplines removed from Technical Specialist language.
5	Respond to SIRs			Ongoing	Ongoing	Ongoing	NELAP EC	No SIRs received yet in 2026.
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. 7/14/25: Work in progress. 6/8/26: Workgroup formed to complete Draft crosswalk.

Item	Task Description	Document Number	Contact	Task Added	Start Date	Complete Date	External Communications	Comments
14	Technical Specialist Language			7/14/25				7/14/25: Update from the CSDP EC and NELAP AC are being taken into consideration and language is being updated. 8/6,18/25: New Language presented to Committee. Analytical Disciplines removed. LANGUAGE INCORPORATED INTO STANDARD and presented in Boston - Closed
15	Summary of Changes Document							3/9/26: The first DRAFT of the document was presented in Boston and the Committee is now reviewing it for publication with the DRAFT Standard. 5/11/27: Completed and being voted on by Committee by email. 6/8/26: Completed and posted with Draft Standard.
16	Response to Comments Spreadsheet			6/8/26				6/8/26: Comments to the Draft Standard will be tracked in this spreadsheet.