Quality System Expert Committee (QS)
Meeting Summary

September 14, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on September 14, 2020. Attendance is recorded in Attachment A – there were 10 members present. Associate Members present: Lisa Parks, Paul Junio, Joe Manzella, Ashley Larssen, Chris Fuller, Chris Gunning, Renee Jernigan, Brian Lamarsh, Kelvin Yuen, Linda O'Donnell, Karna Holquist, Jeanette Hernandez, Amy Schreader, Patricia Carvajal, Rachel Van Exel, Eric Denman, Carol Barrick, and Cindy Redmond.

The July 16, 2020 minutes were pulled up on Webex. A motion was made by Earl to approve the July 16, 2020 minutes as written. The motion was seconded by Michael. There was no further discussion. Voting: For – 9. Against – 0. Abstain – 1 (Michelle). The motion was approved.

The August 10, 2020 minutes were pulled up on Webex. A motion was made by Earl to approve the August 10, 2020 minutes as written. The motion was seconded by Shari. There was no further discussion and the motion was unanimously approved.

There were no changes made to the agenda.

2. Standard Interpretation Request (SIR) 378

The Committee responded to SIR 378 and just received comments back from the NELAP AC. Jessica reviewed the Committee's original response and reviewed the comments received from the NELAP AC. They would like to see the reference to vendors removed. They offered some other language for the Committee to consider.

Remove "at the frequency provided by the calibration vendor …" replace with: before and after any adjustment, and in accordance with the lab's documented procedure.

The modified response to be voted on:
As long as the reference thermometer is not being used as a piece of support equipment such as described in 5.5.13.1 c, a reference thermometer is a reference standard as described in 5.6.3.1 and would need to be calibrated before and after any adjustment, and in accordance with the lab's documented procedure.

A motion was made by Earl to approve the modified language above. Michelle second the motion. There was no further discussion. Vote: For – 9. Against – 0. Abstain – 1 (Alyssa). The motion was approved.

3. Public Webinar

The webinar is scheduled for 90 minutes. Ilona added a column to the change summary form so people can use the form to make comments.

"No recommended changes" was stated for some items so that people can understand that the Committee does not think a change is needed, but she wanted to leave it open for public comment.

We've gotten lots of response to the postings about the meeting. Ilona will automatically invite all committee members – voting and associates.

Jessica pulled up a copy of the change summary form that shows what was sent in the public webinar invitation and that will be used to prepare her PowerPoint presentation (see Attachment D).

Jessica asked Alyssa about DoD's timing for their standard update and whether it makes sense for the Committee to still target summer 2021 for the Standard update. Alyssa will get back to the Committee on this question.

4. TNI Board Information

The Board is looking at changing TNI documents that refer to Quality Systems and change it to Quality Management Systems. There is also language that they would like to see added back into Module 2. Jessica will send this out to the Committee for discussion at the next meeting and she will probably add some of it to the Public Webinar. (See Attachment E for emal and documents.)

Jessica will change the title of the webinar based on this email.

5. Action Items

A summary of action items can be found in Attachment B.

6. New Business

None.

7. Next Meeting and Close

The next meeting will be scheduled by email since the meeting is a holiday for some committee members. Ilona will send a Webex invitation late morning the day of the meeting.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Jessica adjourned the meeting at 1:47pm Eastern (Motion – Earl, Second - Debbie)

Attachment A

Participants

Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Jessica Jensen (Chair) **Present**		2021	Laboratory	jessica.jensen@kcmo.org
Kristin Brown **Present**	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Michael Demarais **Present**	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis **Present**	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Lizbeth Garcia **Absent**	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Kathi Gumpper (Vice-Chair) **Absent**	ChemVal Consulting	2021*	Other	kgumpper@chemval.com
Nicholas Slawson **Present**	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen **Present**	Retired	2021*	Laboratory	papaearl41@hotmail.com
Jenna Majchrzak **Absent**	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Shari Pfalmer **Absent**	Pace Analytical Services	2021	Laboratory	shari.pfalmer@pacelabs.com
William Ray **Absent**	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross **Present**	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Debbie Bond **Present**		2023*	Lab	dbond@southernco.com
Michelle Wade **Present**	A2LA Workplace Training	2021*	Other	mwade@a2lawpt.org
Alyssa Wingard **Present**	NAVSEA LQAO	2021*	Other	alyssa.wingard@navy.mil
Ilona Taunton (Program Administrator) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – QS Expert Committee

	Action Item	Who	Expected Completion	Actual Completion
63	Consider starting a list of items to add to the small laboratory handbook.	All	TBD	
65	Add ISO/IEC 17025:2017 language from the 2016 TNI Standard into the DRAFT Combined Standard.	TBD	TBD	
73	Change black text in combined Standard to italics in preparation of starting to work on updating language in the Standard.	Jessica	2/2/20	*4/15: Needs to be started.*
77				

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Review charter in November 2020	Ongoing	Ongoing

Attachment D –

Module 2 Standard Update - Summary of Suggested Changes – 8-13-20

Original Text	Suggested Change	Justification
Include reference and language.	*Don't need to work on specific language - just summarize change needed.*	*Why does this need to be changed/updated?*
6.4.6 ISO 5.5.13.1 Support Equipment This Standard applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).	The list should either be removed or included as a note.	The list is not all-inclusive and does not need to be in the standard. There may need to be a guidance document created for this section. There is a section in the small lab handbook that discusses support equipment. Whenever lists are presented in the Standard, they cause issues because people incorrectly look at them as an all-inclusive thing. How can we better make use of lists in the Standard?
7.5.1 ISO 4.13.3 Additional Requirements a) The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities such as laboratory facilities, equipment, analytical methods,	No Change suggested	Audit trail is mentioned in 4.13.2.1 Gray area does exist, however the language is as clear as we can make this. We are open to suggestions for changes.

	and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.		
7.2.1.2 ISO 4.2.8.5 a) Documents that contain sufficient information to perform the tests, do not need to be supplemented or rewritten as internal procedures if the documents are written in a way that they can be used as written. Any changes, including the use of a selected option, shall be documented and included in the laboratory's records. e) The laboratory shall have and maintain an SOP for each accredited analyte or method. f) The SOP may be a copy of a published or referenced method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each method shall	Clarify that paragraph f is not a required outline, all topics must be covered when applicable but exact wording of headers and specific order is not required. Modify the language from F to clarify that it applies to method procedures and add G for "administrative" SOPs Work on language for the final sentence of f) Clarify the difference between types of procedures for instance: administrative SOP and Method/Analytical SOP may not require all of the same components listed.	SOPs can be written in any format that includes all of the information necessary to accomplish what is defined in the standard. The formatting and language needs to be modified so laboratory understand there are many ways to accomplish this requirement. Again, this is a list. Not all of these items are required, and since this list is written for methods, these bullets don't apply to non-method SOPs

	include or reference the following topics where applicable: i. identification of the method; ii. applicable matrix or matrices; iii. limits of detection and quantitation; iv. scope and application, including analytes to be analyzed; v. summary of the method; vi. definitions; vii. interferences; viii. safety; ix. equipment and supplies; x. reagents and standards; xi. ……		
7.4.2 ISO 5.8.5	Additional Requirements – Documentation The following are essential to ensure the validity of the laboratory's data. a) The laboratory shall have a documented system for uniquely identifying the sample containers that hold samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and	Look at the word unique and whether the word should just be removed.	Identifying the sample and being able to track it through the quality systems do not necessarily require every container to be uniquely identified. A unique identifier is required for each sample, and sub-samples need to be tied back to the sample. These are two different requirements

subsequent extracts and/or digestates. b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned to each sample. c) The laboratory ID code shall be placed as a durable mark on the sample container. d) The laboratory ID code shall be entered into the laboratory records and shall be the link that associates the sample with related laboratory activities such as sample preparation.		
8.8.2 ISO 4.14.5. c) The Internal audit schedule shall be completed annually,	Remove “schedule" .Remove the word annual/quarterly and insert language for the specific time frame intended Suggested Language: Instead of annually use every 12 months not to exceed 18 months or Internal audit must be performed every calendar year not to exceed 18 months	There does not seem to be a uniformity in what annually means. We need to clarify this statement.
5.8.7.1 The laboratory shall implement procedures for verifying and documenting preservation.	Change from implement to have and implement.	This change is to insure that procedures are documented and not just implemented.
5.10.11 c) Any non-accredited tests shall be clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables.	Any results that are generated for non-accredited tests shall be clearly identified as such in the analytical report or in the supporting electronic or hardcopy deliverables when claims of accreditation to this Standard are made.	The rewording is to clarify that this only applies when claims of accreditation to this standard are made.
Multiple references to Quality Manual, the first is 1.1 introduction	Remove the requirement of a Quality Manual	Hold off on this change, as many states require it in their regulations. Work towards this goal.

		It's possible to have all of these items in multiple places, especially as more information is stored on-line or in 'the cloud'. If the Quality Manual went away, it wouldn't mean that the requirements contained in it would go away
ISO 8.8.2 d) implement appropriate correction and corrective actions without undue delay;	Define undue delay	Up to the laboratory to define. Clarify that the corrective action process needs to be begin immediately (as soon as practicable), but the actual action taken can be any appropriate timeframe as defined within the individual corrective action.
4.13.3 b) The laboratory shall retain all records for a minimum of five (5) years from generation of the last entry in the records.	Change the word entry to use or add a part in the section about personnel training and initial demonstration and or all training records on the analyst until 5 years after they leave the company.	Training records are different than other laboratory records and need to have clarification within this section. Make a guidance document for records and time frames that are required for keeping (IDOC, maintenance records on instruments)
4.4.1 c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2).	No change suggested	The customer however named is the end user of the data
ISO **7.8.2.1** Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse: f) identification of the method used; n) additions to, deviations, or exclusions from the method **ISO 7.8.3.1** In addition to the requirements listed in 7.8.2, test reports shall, where necessary	Additional Language needs to be added on what is required in the reports: Prep methods Need to add more language to expand on requirements in 7.8.2.1 Need more language to make sure that laboratories are identifying the revision of the methods. Prep methods are not required on PT due to not being in table, but are required on final report by most ABs PT executive committee looking at adding Prep methods to table.	The ISO language needs to be expanded for the specific requirement within an environmental laboratory.

for the interpretation of the test results, include the following: b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);	Qualifiers Should this go under final reports or non-conforming work. 5.10.3.2 f is language from 2005 iso standard, replaced with 7.8.2.1 n, where it talks about deviations from the method. Additional language needs to be added for data qualifiers.	
ISO 7.11.2 NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.	Instrument Software Note in 17025 needs to be added as requirement.	Instrument software- verification and validation is done by using the equipment, so analytical performance would count as the instrument software validation. DOD requires that the calculation on the instrument be validated with a known set of data and run in through the program to do some manual math checking. Should TNI follow this thinking? This is based on old thinking, so maybe we should let it go. Need to consider before making Note 2 a requirement, laboratories do not want the same requirements for LIMS to be applied to off the shelf software, unless it has modification made by or for the laboratory.
5.6.4.2 a) The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.	No Suggested Change	Possible guidance document here Note: C of As only available on the vendor website are by definition uncontrolled record for which labs can't ensure record retention requirements are met without some level of contractual agreement with the vendor.

ISO 3.8 and 3.9 Definitions	No Suggested Change	Data validation/verification is already a requirement of the standard, however named.
5.4.2 Selection of Methods	No Suggested Change	Language is ISO language and may need guidance but does not need additional language.
ISO 8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document. ISO 8.3.2 d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;	Language needs to be added from the current standard 'authorized editions'	There needs to be language added to ensure that accredited laboratories have an authorized copy of the standard for which they have accreditation.
5.5.13.1 d) Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available.	No Suggested Change	Open to suggested language
Continuing Operations Plans	No suggested Change	This would fall under the risk and opportunities clause.
Method validation and verification	Leave up to the technical modules to define.	The QS module needs to state that validations and verification must occur using current ISO language, how they are completed would be up to each technical module.

Attachment E: Documents from Jerry Parr

Email from Jerry Parr: 9/10/20 with 3 attached documents.

Jessica:

Sorry for this last minute surprise. Just got it through the Board yesterday. Paul, Bob and Ilona are all well-informed.

1. **QMS** The Board voted to change the title of Module 2 from Quality System General Requirements to Quality Management System Requirements. The attached document qms091020 contains more information along with suggested revised language. The Board only saw the first 2 pages of this document. The proposed language on pages 8 and 9 are up to the committee to freely edit.

2. Separate issue. Section 1.3 (Applicability) from NELAC 2003

Somewhere along the way, and I can see how it could have happened, this section got deleted. It contains 3 subsections and I want to share why they were added and why some of this may still be relevant.

1.3.1 Applicable EPA statutes. This omission has created at least 6 complaints this year, primarily from California labs using sW-846 methods to test for costume jewelry for phthalates and leather sandles etc. for hexavalent chromium. The fact is the consumer product commission regulates this type of testing and they have their own methods. For example the method for jewelry calls for dissolution of the material in tetrahydrofuran, precipitation of polypropylene by hexane and then analysis for a completely different list of phthalates. NELAP labs should not be doing testing outside of environmental and claiming NELAP accreditation for it.

1.3.2 Exemptions. These were lengthy and bitter arguments in 1995-97.

1.3.2 a, b, and c were brought up by the GLP lab community and ELAB intervened and issue a report. Now that we have evolved, this has pretty much gone away and I cannot see a NELAP AB every venturing into this, but the language may still be relevant. Your call as to what to do with this.

1.3.2 d was specific to EPA's National Enforcement Investigation Center in Denver. Since EPA labs are not required to be accredited, this also may be a non-issue. Just wanted you to have the perspective.

The last sentence in this section still has value, but could be moved to 1.3.1.

1.3.3 was added by the ABs to ensure they could investigate cases of potential lab fraud. I think most ABs have this in their regulation, and it is important, but again your call as to whether or not it should be retained. Maybe poll the ABs?

3. Revision to Section 1.2 Scope

This is also something that has been in development since Newport and finally made it to the Board yesterday. Extensive discussion and while the Board agrees with the general concept, more editing needs to be done. The key language is on page 5 in the table. Discussions center around the words trust vs rely on, and demonstrate. Taking this back to Advocacy the first week of October and then back to the board on October 14. I would welcome any suggestion you or QS has.

Regards and Thank You for all that you and your committee does.

Jerry

Document 1:

Quality System, Management System, or Quality Management System

Background

At the first NELAC meeting in February 1995, a newly formed Quality System Committee, chaired by Silky Labie, presented the first version of the Quality System Standard (Chapter 5).

At that time, the language in the standard stated:

> Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a QA Plan to help ensure and document the quality of the analytical data. These shall include QA policies, which will establish essential QC procedures applicable to environmental laboratories regardless of size and complexity. The laboratory shall meet any additional or more stringent requirements as specified by the analytical methods, specific programs or Agencies.

Note the emphasis on QA/QC versus our now emphasis on the overall management system.

By 1997, NELAC had moved to Guide 25, and in 2002, moved to ISO 17025: 1999. The language remained unchanged until the final 2003 NELAC Standard. The 2009 (and 2016) TNI Standard was revised to contain some, but not all, of the language contained in the 2005 version of 17025 but eliminated a lot of language from 2003 NELAC, including all of Section 1.3.

Appendix 1 to this document contains all these variations.

These documents use the terms management systems, quality systems, and quality management systems somewhat interchangeably. Also used is technical management system and “technical, managerial, and documentation requirements.”

The 2005 version of ISO 17025, contains a definition (in a Note):

> The term 'management system' means the quality, administrative and technical systems that govern the operations of a laboratory.

This definition is very consistent with the TNI Board call on August 12, where the Board indicated items such as financial performance, personnel, and health and safety are outside the scope of TNI's Module 2.

The 2009 TNI Standard contains this definition:

> **Quality System:** A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC activities.

The 2017 version of 17025 takes a very different approach, organized as follows:

Section 4 General Requirements
1) Impartiality
2) Confidentiality

Section 5 Structural Requirements

Section 6 Resource Requirements
1) Personnel
2) Facilities
3) Equipment
4) Traceability
5) Externally provided services

Section 7 Process Requirements
1) Reviews of requests, tenders, and contracts
2) Selection, verification and validation of methods
3) Sampling
4) Handling test items
5) Technical records
6) Measurement uncertainty
7) Ensuring the validity of results
8) Reporting results
9) Complaints
10) Non-conforming work
11) Control of data

Section 8 Management Requirements
1) Management system documentation
2) Control of management system documents
3) Control of records
4) Actions to address risks and opportunities
5) Improvement
6) Corrective actions
7) Internal audits
8) Management reviews

In looking at all of this it is important to note that Section 1 is informative only. It does not impose any requirements for laboratories but helps set the stage for the importance of the requirements contained in Sections 4 though 8 of ISO 17025:2017.

Note: ISO has published close to 100 “management” standards. Some of these could be used laboratories, or organizations that have laboratories. Examples include:

- 24518 – Crisis management of water utilities
- 30401 – Human resource management
- 41001 – Facility management
- 14001 – Environmental management systems
- 35001 – Biorisk management for laboratories

Because of the variety of “management” standards, TNI should use quality management to ensure no confusion with the other management standards.

Proposed Changes to Module 2, Section 1.0

1. The TNI definition says a quality system is a management system. Nonetheless, there is confusion over all of these terms, and to be consistent with efforts of TNI’s Advocacy committee, the term Quality Management System (QMS) is preferred.

2. Because of the new Section 4 in ISO 17025:2017, this module needs to be renamed to Quality Management System Requirements.

3. Section 1 of Module 2 should be revised to be more consistent with the new 17025 while still keeping relevant language from earlier versions of the NELAC/TNI standards and 17025:2005 and the Note in 17025 should be moved into section 3.1, Definitions and combined with or reworded with the TNI definition of Quality Systems.

Appendix 1: QMS Over the Years

5.0 Quality Systems (NELAC 1994)

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a QA Plan to help ensure and document the quality of the analytical data. These shall include QA policies, which will establish essential QC procedures applicable to environmental laboratories regardless of size and complexity. The laboratory shall meet any additional or more stringent requirements as specified by the analytical methods, specific programs or Agencies.

5.0 QUALITY SYSTEMS (1995 NELAC)

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a QA Plan to help ensure and document the quality of the analytical data. Laboratories seeking accreditation under NELAP must assure implementation of all QA policies and the essential applicable QC procedures specified in this chapter. The QA policies, which establish essential QC procedures, are applicable to environmental laboratories regardless of size and complexity.

The intent of this Chapter is to provide sufficient detail concerning QA and QC requirements so that all accrediting authorities evaluate laboratories consistently and uniformly.

5.0 QUALITY SYSTEMS (1997 NELAC)

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a QA Plan to help ensure and document the quality of the analytical data. Laboratories seeking accreditation under NELAP must assure implementation of all QA policies and the essential applicable QC procedures specified in this chapter. The QA policies, which establish essential QC procedures, are applicable to environmental laboratories regardless of size and complexity.

The intent of this Chapter is to provide sufficient detail concerning QA and QC requirements so that all accrediting authorities evaluate laboratories consistently and uniformly.

Chapter 5 is organized according to the structure of ISO/IEC Guide 25, 1990. Where deemed necessary, specific areas within this Chapter may contain more information than specified by ISO/IEC Guide 25.

All items identified in this chapter shall be available for on-site inspection or data audit.

5.1 SCOPE

a) This Standard sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific environmental tests.
b) This standard includes additional requirements and information for assessing competence or for determining compliance by the organization or accrediting authority granting the recognition (or approval). If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met.
c) This Standard is for use by environmental testing laboratories in the development and implementation of their quality systems. It shall be used by accreditation authorities, in assessing the competence of environmental laboratories.

5.0 QUALITY SYSTEMS (NELAC 2002)

Quality Systems include all quality assurance (QA) policies and quality control (QC) procedures, which shall be delineated in a Quality Manual and followed to ensure and document the quality of the analytical data. Laboratories seeking accreditation under NELAP must assure implementation of all QA policies and the essential applicable QC procedures specified in this Chapter. The QA policies, which establish

essential QC procedures, are applicable to environmental laboratories regardless of size and complexity.

The intent of this Chapter is to provide sufficient detail concerning quality system requirements so that all accrediting authorities evaluate laboratories consistently and uniformly. NELAC is committed to the use of Performance-based Measurement Systems (PBMS) in environmental testing and provides the foundation for PBMS implementation in these standards.

While this standard may not currently satisfy all the anticipated needs of PBMS, NELAC will address future needs within the context of State statutory and regulatory requirements and the finalized EPA implementation plans for PBMS.

The growth in use of quality systems generally has increased the need to ensure that laboratories which form part of larger organizations or offer other services can operate to a quality system that is seen as compliant with ISO 9001 or ISO 9002 as well as with this Standard. Care has been taken, therefore, to incorporate all those requirements of ISO 9001 and ISO 9002 that are relevant to the scope of environmental testing and calibration services that are covered by the laboratory's quality system.

Environmental testing and calibration laboratories that comply with this Standard will therefore also operate in accordance with ISO 9001 or ISO 9002.

Certification against ISO 9001 and ISO 9002 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results.

Chapter 5 is organized according to the structure of ISO/IEC 17025, 1999. Where deemed necessary, specific areas within this Chapter may contain more information than specified by ISO/IEC 17025.

All items identified in this Chapter shall be available for on-site inspection and data audit.

5.1.1 This Standard specifies the general requirements for the competence to carry out environmental tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

It contains all of the requirements that environmental testing laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.

If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which requirements are more stringent, the standard from the method or regulation is to be followed. (See the supplemental accreditation requirements in Section 1.8.2.)

5.1.2 This Standard is applicable to all organizations performing environmental tests. These include, for example, first-, second- and third-party laboratories, and laboratories where environmental testing forms part of inspection and product certification. This Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of environmental testing activities. When a laboratory does not undertake one or more of the activities covered by this Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

5.1.3 The notes given provide clarification of the text, examples and guidance. They do not contain requirements and do not form an integral part of this Standard.

5.1.4 This Standard is for use by laboratories in developing their quality, administrative and technical systems that govern their operations. Laboratory clients, regulatory authorities and accreditation authorities may also use it in confirming or recognizing the competence of laboratories. This Standard includes additional requirements and information for assessing competence or for determining compliance by the organization or accrediting authority granting the recognition (or approval).

5.1.5 Compliance with regulatory and safety requirements on the operation of laboratories is not covered by this Standard. It is the laboratory's responsibility to comply with the relevant health and safety …

5.1.6 If environmental testing laboratories comply with the requirements of this Standard, they will operate a quality system for their environmental testing and calibration activities that also meets the requirements of ISO 9001 when they engage in the design/development of new methods, and/or develop test programs combining standard and non-standard test and calibration methods, and ISO 9002 when they only use standard methods. ISO/IEC 17025 covers several technical competence requirements that are not covered by ISO 9001 and ISO 9002.

5.1.7 An integral part of a Quality System is the data integrity procedures. The data integrity procedures provide assurance that a highly ethical approach to testing is a key component of all laboratory planning, training and implementation of methods. The following sections in this standard address data integrity procedures:

Management Responsibilities 5.4.2.6, 5.4.2.6.1, and 5.4.2.6.2
Training 5.5.2.7
Control and Documentation 5.4.15

ISO/IEC 17025 (2005)

Growth in the use of management systems generally has increased the need to ensure that laboratories which form part of larger organizations or offer other services can operate to a quality management system that is seen as compliant with ISO 9001 as well as with this Standard. Care has been taken, therefore, to incorporate all those requirements of ISO 9001 that are relevant to the scope of testing services that are covered by the laboratory's management system.

Conformity of the quality management system within which the laboratory operates to the requirements of ISO 9001 does not of itself demonstrate the competence of the laboratory to produce technically valid data and results. Nor does demonstrated conformity to this Standard imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001.

The acceptance of testing results between countries should be facilitated if laboratories comply with this Standard and if they obtain accreditation from bodies which have entered into mutual recognition agreements with equivalent bodies in other countries using this International Standard.

The use of this Standard will facilitate cooperation between laboratories and other bodies, and assist in the exchange of information and experience, and in the harmonization of standards and procedures.

1 Scope

1.1 This Standard specifies the general requirements for the competence to carry out tests, including sampling. It covers testing performed using standard methods, non-standard methods, and laboratory-developed methods.

1.2 This Standard is applicable to all organizations performing tests. These include, for example, first-, second- and third-party laboratories, and laboratories where testing forms part of inspection and product certification.

This Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing activities. When a laboratory does not undertake one or more of the activities covered by this Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

1.3 The notes given provide clarification of the text, examples and guidance. They do not contain requirements and do not form an integral part of this Standard.

1.4 This Standard is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. This Standard is not intended to be used as the basis for certification of laboratories.

NOTE The term 'management system' means the quality, administrative and technical systems that govern the operations of a laboratory.

1.5 Compliance with regulatory and safety requirements on the operation of laboratories is not covered by this Standard.

1.6 If testing laboratories comply with the requirements of this Standard, they will operate a quality management system for their testing activities that also meets the principles of ISO 9001.

INTRODUCTION, SCOPE AND APPLICABILITY (TNI 2009)

1.1 Introduction

Each laboratory shall have a quality system. The laboratory's quality system is the means by which an organization ensures the quality of the products or services it provides and includes a variety of management, technical, and administrative elements such as:

a) policies and objectives,
b) procedures and practices,
c) organizational authority,
d) responsibilities, and
e) performance measures.

The quality system provides the framework for planning, implementing, assessing, and improving work performed by an organization so as to provide the client with data of known and documented quality, sufficient to evaluate the usability of the data to the clients needs. The quality system shall be documented in the laboratory's quality manual and related quality documentation, and shall be referenced in the quality manual.

This Standard contains detailed quality system requirements for consistent and uniform implementation by the laboratories conducting testing and the consistent and uniform evaluation of those laboratories by accreditation bodies. Each laboratory seeking accreditation under this Standard shall ensure that they are implementing their quality system and that all Quality Control procedures specified in this module are being followed. The Quality Assurance policies, which establish quality control procedures, are applicable to environmental laboratories regardless of size and complexity.

1.2 Scope

The requirements in this document give the basis for a laboratory's quality system in order to carry out environmental tests. It covers testing performed using reference methods, non-reference methods, and laboratory-developed methods. This document contains the essential elements required to establish a quality system that produces data of known and documented quality, and demonstrates proficiency through the use of proficiency testing and employee training.

The general requirements of this document apply to all organizations performing environmental tests, regardless of the number of personnel or the degree of environmental testing activities. When the use of the data requires compliance with the Standards, these Standards shall be followed.

This document is for use by laboratories, clients, regulatory authorities, and accreditation bodies to ensure the laboratory has appropriate management and technical quality systems to perform

environmental testing. This document specifies technical, managerial, and documentation requirements needed for assessment by organizations or accreditation bodies to grant approval. This document provides the requirements needed for laboratory accreditation. If the requirements of this document are met, the laboratory operates a quality system in conformance with the applicable clauses of ISO/IEC 17025:2005.

The notes given provide clarification of the text, examples and/or guidance. They do not contain requirements and do not form an integral part of this Standard.

ISO/IEC 17025 (2017)

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system. As a minimum, the management system of the laboratory shall address the following:

— management system documentation;
— control of management system documents;
— control of records;
— actions to address risks and opportunities;
— improvement;
— corrective actions;
— internal audits;
— management reviews.

Appendix 2: Proposed Changes to Volume 1, Module 2

Volume 1, Module 2
Quality Management System Requirements

1.0 Introduction, Scope and Applicability

1.1 Introduction

Note:
Green highlighting = 17025:2017
Blue highlighting = TNI 2009
Grey highlighting – 17025:2005

Each laboratory shall implement and maintain a Quality Management System (QMS) as described in this Module. The QMS is the means by which an organization ensures the quality of the products or services it provides and includes a variety of management, technical, and administrative elements such as:

a) structural requirements (Section 5),
b) resource requirements (Section 6),
c) process requirements (Section 7), and
d) management requirements (Section 8).

The QMS provides the framework for planning, implementing, assessing, and improving work performed by the laboratory. The QMS shall be documented in the laboratory's quality manual and related quality documentation.

This Standard contains detailed requirements for consistent and uniform implementation by the laboratories conducting testing and the consistent and uniform evaluation of those laboratories by accreditation bodies. Each laboratory seeking accreditation under this Standard shall ensure that they are implementing their QMS and that all Quality Control (QC) procedures specified in this Standard are being followed. The Quality Assurance (QA) policies, which establish QC procedures, are applicable to environmental laboratories regardless of size and complexity.

All items identified in this document shall be available for an on-site assessment.

1.2 Scope

1.2.1 This Standard specifies the general requirements for the competence, impartiality, and consistent operation of laboratories to carry out tests, including sampling. It covers testing performed using reference methods, non-reference methods, and laboratory-developed methods. This Standard contains the essential elements required to establish a QMS that produces data of known and documented quality.

1.2.2 This Standard is applicable to all organizations performing laboratory activities, regardless of the number of personnel. When a laboratory does not undertake one or more of the activities covered by this Standard, such as sampling and the development of new methods, the requirements of those clauses do not apply.

1.2.3 The notes given provide clarification of the text, examples and/or guidance. They do not contain requirements and do not form an integral part of this Standard.

1.2.4 This Standard is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities, and accreditation bodies may also use it in confirming or recognizing the competence of laboratories.

1.2.5 Compliance with safety requirements on the operation of laboratories is not covered by this

Standard.

Note: The ISO/IEC 17025:2017 language is incorporated verbatim into this Standard and appears as italicized text.

3.1 Additional Terms and Definitions

Quality Management System: The quality, administrative and technical systems that govern the operations of a laboratory. It describes the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality management system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA/QC activities.

Document 2:

1.3 Applicability

1.3.1 Applicable EPA Statutes

Applicable EPA statutes include the Clean Air Act (CAA); the Comprehensive Environmental Response Compensation and Liability Act (CERCLA); the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Federal Water Pollution Control Act (Clean Water Act; CWA); the Resource Conservation and Recovery Act (RCRA); the Safe Drinking Water Act (SDWA); and the Toxic Substances Control Act (TSCA). The standards shall also include provisions to permit special requirements or fields of accreditation promulgated by any of the accreditation bodies.

1.3.2 Exemptions

This standard applies to federal and state mandated testing. Exceptions to EPA-mandated testing include those provided below:

a) laboratory analyses associated with FIFRA (40 CFR Part 160) good laboratory practices (GLP), for testing performed for studies that support applications for research or marketing permits for pesticide products regulated by EPA under FIFRA.

b) laboratory analyses associated with TSCA (40 CFR Part 792) good laboratory practices (GLP), for studies relating to health effects, environmental effects and chemical fate testing as directed under Section 4 and Section 5 of TSCA.

c) State governmental laboratories when conducting analyses such as pesticide formulation, efficacy and residue testing to support FIFRA compliance and enforcement activities under pesticide cooperative agreement grants.

d) governmental laboratories engaged solely in the analysis of forensic evidence.

This Standard may be used for testing not mandated by law or regulation such as ambient water quality monitoring.

1.3.3 No Restriction on Legal Actions

This Standard shall not be implemented or administered in a way which limits the ability of local, State or

federal agencies to investigate and prosecute enforcement cases. Specifically, when engaged in the collection and analysis of forensic evidence to support litigation, those agencies may use any procedure that is appropriate given the nature of the investigation, subject only to the bounds of sound scientific practice.

Document 3:

Does Laboratory Accreditation Make a Difference?

Data You Can Trust

September 9, 2020

DRAFT

INTRODUCTION

The NELAC Institute (TNI) and other proponents of environmental laboratory accreditation have always promoted accreditation as a demonstration of competency. TNI believes that accreditation to the TNI Standard and its Quality Management System (QMS) requirements ensures data of "known and documented quality." The basic premise is that accreditation to the TNI Standard ensures laboratory competency with the outcome being that a competent laboratory will generate quality data.

Accreditation bodies that are considering becoming recognized under TNI's standard as well as laboratories considering accreditation often ask TNI for data to justify becoming an Accreditation Body (AB) or accredited laboratory. TNI can provide considerable evidence supporting the benefits of environmental laboratory accreditation. After focusing on the connection between accreditation and data quality, we have come to believe that accreditation is not just about a quantitative improvement in data quality and a Quality Management Systems that is committed to the maintenance of quality but also rather it is about generating data that can be trusted for use in decision making.

Quality System, Management System, or Quality Management System

The 1990 version of ISO/IEC 17025 used the term Quality System to describe the process by which a laboratory manages its operations to "assure the quality of the test results it generates." By the time the second edition was published in 2005, this term was changed to Management System, although the phrase quality management system also appeared in this version. The NELAC Institute started using Quality System in 1994, and to date has not made the transition to Management System. As a transitional step, this document uses the term Quality Management System.

BACKGROUND

Environmental laboratory accreditation to the TNI standard provides an independent, third party evaluation of a laboratory's QMS and technical competence, resulting in a formal recognition by a recognized authority, called an Accreditation Body (AB). TNI's National Environmental

Laboratory Accreditation Program (NELAP) and recognized non-governmental accreditation bodies (NGAB) accredit over 2000 laboratories in 47 states and four foreign countries. Accreditation to the TNI standard is unique among laboratory accreditation programs because:

- it is based on internationally recognized standards (ISO 17025 and ISO 17011) that have been expanded to focus on unique aspects of environmental testing,
- it is performed with respect to a specific scope of accreditation through assessments conducted by qualified assessors, and
- it involves review of results of periodic proficiency testing (PT) performed by the laboratory.

For data users, accreditation serves a consumer protection purpose. It provides assurance that the laboratory has been evaluated and has met accepted standards established by experts in the environmental laboratory profession. Using a technically competent organization minimizes the risk of producing unreliable data and minimizes the need for expensive re-testing. Regulators will have more confidence in data produced by an accredited organization. TNI believes that accreditation provides an objective way to demonstrate to clients, the community, and the government that an organization has the capability to provide the services they conduct.

For over 25 years TNI (and its predecessor organizations) has promoted laboratory accreditation as a way to positively impact laboratory performance. However, some are still skeptical of the value of laboratory accreditation and have alleged that many of the requirements in the TNI standards have little to do with data quality. We disagree with this argument, and over the past few years TNI has begun a series of activities to explore the impact accreditation has on laboratory performance and data quality.

This white paper focuses on **laboratory measurements**. TNI recognizes **sampling** can be just as important, if not more so, in the overall measurement error. While this document does not address sampling, the concepts of implementing a quality management system apply equally to sampling and TNI encourages organizations that perform sampling to become accredited to the TNI Standard for Field Sampling

DISCUSSION

Previous Efforts

Various studies and papers prior to 2019 have noted the connection between data quality and accreditation by a TNI recognized accreditation body. These include:

- A survey of accredited laboratories in 2008[1] showed that 85% of the laboratories reported improvement in data quality as well as in defensibility and in traceability of process.
- A National Academy of Science[2] report reviewing the U.S. Geological Survey Laboratories noted these advantages of an externally defined QMS:
    - Compliance with an external standard allows a laboratory to conduct analyses that meet regulatory requirements to support high-risk applications and to demonstrate a high level of accountability through accreditation by independent and external assessors.
    - Most formal consensus-based standards are written with the understanding that there are many ways to comply with a given requirement. Therefore, the laboratory can customize how it will meet the requirements.
    - Accreditation provides external recognition that the measurement was made under

conditions that optimize the likelihood that the measurement is verifiable.
    - A laboratory may have both accredited and nonaccredited test methods. If so, the QMS put in place to support the accredited tests is likely to enhance the mangement of the nonaccredited tests as well.
- A comprehensive study[3] of two laboratories showed multiple advantages achieved from implementing a QMS:
    - better traceability,
    - involvement of personnel in decision making processes,
    - acknowledgement of testing competence,
    - benchmark for performance,
    - marketing advantage,
    - international recognition,
    - risk minimization,
    - customer confidence, and
    - cost reduction.
- Available research has shown that accredited labs tend to perform better on proficiency testing.[4,5]
- State statistics show fewer than 10% repeat deficiencies and fewer serious findings in accredited laboratories.[6]
- TNI Mentor Sessions[7] have shown how an effective QMS can quickly correct problems.

To further explore the connection between accreditation and data quality, TNI sponsored a panel discussion at its New Orleans meeting in August 2018 to solicit input. This discussion resulted in a draft white paper which proposed that we collect and analyze laboratory and AB performance data that can be used to demonstrate the value of accreditation, e.g. timeliness, PT data, numbers and types of enforcement cases, numbers and types of deficiencies, number of repeat deficiencies. A "pre-accreditation vs. post-accreditation" comparison study of California laboratory performance in three years was also proposed. In addition, TNI could promote opportunities for current accreditation bodies and others to establish uniform quantitative indicators to compare performance of accredited laboratories vs. non-accredited laboratories. However, the discussion at this meeting showed most attendees did not feel these options were viable and suggested a different approach, which was to collect case studies to document laboratory improvement.

Recent Initiatives

Thus, to continue to explore ways to provide more substantive data supporting laboratory accreditation, TNI began a series of activities in 2019 aimed at gathering quantitative information from laboratories who had experienced improvements as a result of accreditation as well as examples of failures resulting from lack of adherence to QMS principles.

Following further discussion of these recommendations at the Jacksonville meeting in August 2019, TNI decided that the best way to obtain data was to invite laboratories to attend the Newport meeting in February 2020 and share individual stories on the impact of TNI accreditation on their laboratory experience.

Invited speakers at the Newport meeting gave actual examples of the impact of non-conformances to Module 2, Section 4 and 5 of the TNI standard on Data Quality. These impacts included:

- Data quality problems
- Inaccurate or incorrect result
- Insufficient documentation
- Non-conformance to mandated method
- Diminished confidence in result
- Not meeting customer requirements
- Lack of training
- Not having a QMS

The Case Studies from this session is included in an Appendix.
A second panel of speakers related their experiences obtaining TNI accreditation and the impacts they saw on their laboratories. While some acknowledged that there were short term negative impacts on their laboratory while acquiring accreditation, the long-term benefits outweighed the short-term cost. Comments from speakers included:

"Continuous Improvement can result from corrective and preventive action"
"Data validation and flagging which improves communication on data quality and facilitates better decision making based on data quality objectives."
"Legally defensible data is produced."
"SOPs are aligned with methods."
"More documentation helps identify sources of error associated with analyses."
"Routine audits of SOPs and procedures ensure continuous quality improvement."
"Training is easier."
"'Questioning'" of data by regulated industries is reduced."
"TNI accreditation provides a business model with uniform standards, industry reference point, requirements to fulfill due diligence, and removing guesswork from identifying 'What is good enough?'"
"The TNI Standard provides the laboratory with the necessary foundation for all methods, instrumentation, documentation, and personnel."
"TNI is an insurance policy that you hope you'll never use."
"We owe it to our community to be prepared to identify, or rule out, our municipal water supply as a source of contaminants or contagion and to do so quickly."

The presentations from this session can be found at Hyperlink.

Independent of the two efforts above, TNI had already collected information on how accredited laboratories that identified non-conforming activities were quickly able to resolve these non-conformances.[7] The session focused on data integrity issues such as data errors affecting multiple clients, an ethics violation that impacted data, and a computer issue resulting in data losses. It explored the frequency of these kinds of problems and the steps taken to remedy them. The session documented that laboratories that had implemented a TNI QMS were able to address such issues effectively.

CONCLUSION

There is no doubt that accreditation to the TNI standard makes a difference in the quality of the data and in laboratory performance.

However, the experiences of the laboratories that participated in this effort led TNI to believe that we need to redefine what we mean by "data quality". Providing quality data is much more than getting the right answer and being able to reconstruct the result. Quality includes confidence in the data as well as better laboratory operations. Laboratories accredited to the TNI standard have documented significant improvements which include efficiency, additional capability, and quicker reports. Traceability, training, sample tracking, and documentation all contribute to better decisions and contribute to laboratories with TNI accreditation having more confidence in their data.

Our New Guiding Principle - Data You Can Rely On

The value of accreditation to the TNI Standard is that it provides confidence in the data, which means:

- The reported result is a good measure of the true concentration.
- The reported result is of known and documented quality.
- The laboratory complied with mandated method requirements.
- The laboratory implemented a strong Quality Management System to ensure confidence in the result.
- The laboratory met customer requirements.
- Accreditation to the TNI Standard improves laboratory performance.

Relying on the data means:

- The processes leading to the result can be reconstructed because there is sufficient documentation for the sample, calibration, QC results, and SOP s used,
- The reference materials, reference standards, and reagents are all traceable,
- Competency of analysts is demonstrated by training records, PT results, and Demonstration of Capability results,
- Samples are handled correctly and can be traced from receipt to reported result,
- Quality control results document data quality,
- The data meet Daubert standards for data admissibility (e.g., "legal defensibility") because the technique has been tested, there is a known rate of error, and there are standards controlling the technique's operation,[8] and
- The result is reported correctly and has met requirements relating to quantitation limits and data flagging.
- The requested methodology was followed in generating the data.

Next Steps

TNI will continue to pursue opportunities to document the value of accreditation to the TNI standard by:

- Continuing to collect case studies of non-conformances,
- Continuing to collect examples of laboratory improvement,
- Collecting data on AB performance, and
- Refining the new guiding principle.

In addition to the points above, we will propose revising EL-V1M2-2016-Rev2.1: Quality Systems General Requirements, Section 1.2 (Scope) to reflect the new guiding principle. The proposed change is noted below.

Current language	"This document contains the essential elements required to establish a quality system that produces data of known and documented quality and demonstrates proficiency through the use of proficiency testing and employee training."
Proposed new language	"This document contains the essential elements required to establish a quality **management** system that **can demonstrate the laboratory's technical competence including its ability to produce reliable and trustworthy data** and demonstrates proficiency through the use of proficiency testing and employee training."

REFERENCES:

[1] Morgan, Judith. *The Benefits of Laboratory Accreditation*, TNI Forum on Laboratory Accreditation, January 12, 2009, Miami, FL.

[2] National Academies of Sciences, Engineering, and Medicine. 2019. *Assuring Data Quality at U.S. Geological Survey Laboratories*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25524.

[3] Khodabocus, F. and Balgobin, K. (2011) *Implementation and Practical Benefits of ISO/IEC 17025:2005 in a Testing Laboratory*, UNIVERSITY OF MAURITIUS RESEARCH JOURNAL, Vol. 17, pp. 27-80.

[4] Middlebrook, Ken. (2017) *Do accredited laboratories perform better in proficiency testing than non-accredited laboratories?* Accred Qual Assur Vol.22, pp.111-117.

[5] Wood, Curtis J. (2019) *Does PT Data Support the Value of Laboratory Accreditation?* Paper presented at NEMC 2019, Jacksonville, FL.

[6] Minnesota Dept. of Health (2018) Minnesota Environmental Laboratory Accreditation Program, *Key Performance Indicators*.

[7] TNI Mentor Session (2018) *Responding to Data Integrity Problems*, Presented at NEMC 2018, New Orleans, LA.

[8] Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 US 579 (1993).

TNI is active in working with many stakeholders, including state and federal agencies as well as trade associations representing different types of laboratories. If you want to learn more, please contact TNI.

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