Quality System Expert Committee (QS)
Meeting Summary

June 29, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on June 29, 2020. Attendance is recorded in Attachment A – there were 10 members present. Associate Members present: Jeanette Hernandez, Rachel van Exel, Joe Manzella, Paul Junio, Eric Denman, Carol Barrick, Halley Hastings, Karna Holquist, Amy Schreader, Tiffany Shaw, Cindy Gaddis, Renee Jernigan, Linda O'Donnell, Brian Lamarsh, Carl Kircher, John Gumpper, Anna DiSalvo, and Tyler Sullens.

A motion was made by Earl to accept the June 8, 2020 minutes as written with updated contact information for Jessica. The motion was seconded by Lizbeth and unanimously approved.

There were no changes made to the agenda.

2. Summary of Suggested Changes Form

Jessica reviewed the work that had been done previously. The file did not save previously, so Jessica reviewed the recording to update the table the Committee will work from today.

Validation/Verification - A discussion on WET plans ensued, which is based on feedback from Chemistry. Jessica read from an e-mail from WET as well as her response. Two Associate members of QS are also Associate members on Chemistry. They indicated that the discussion regarding validation and verification is consistent with Chemistry's position.

Validation/verification needs to be differentiated from Data Validation (3rd party data review/reconstruction) as opposed to Method Validation (laboratory responsibility per the TNI Standard and ISO language). If data validation is a 'systematic check of data', then yes, the TNI Standard requires that.

Latest version of a method – the laboratory is required to perform the method that the client requests, unless that method is inappropriate. The client SHOULD know the appropriate method. This may be an issue of education and not clarification.

Section 4.3.1/4.3.2.2 – should an assessor need to verify that the laboratory has a valid copy of the TNI Standard? Section 4.3.2.2 in the ISO language notes that authorized editions of documents must be available at all locations where operations essential to the effective functioning of the laboratory are performed.

This concern was raised in SIR 363. A discussion of 'authorized' ensued. SIR 363 addressed this and the decision was made that yes, the laboratory must have an authorized version (such as by having a receipt for the purchase of the Standard). There was some discussion that this was outside the realm of the Standard, but it was pointed out that if the ABs require it, this will be a change from some current practices. Language does need to be added to the Standard to make this clear.

Section 6.5.2: John noted if the lab has a certificate, they will generally accept it. Section 5.5.13.1 d) of the new ISO language is good as written and this will not be included as a change. The new ISO language makes less difference between reference standards and reference materials. The wording in 5.5.13.1 should include "reference" when referring to standards to aid in clarity. ISO 17025:2017 leans toward data being metrologically traceable, especially as outlined in Annex A. It was asked if the revised Standard would address Accredited Providers, i.e., would a certificate of traceability be sufficient, given that certificate's reliance on being ISO compliant? This isn't currently allowed, but maybe could/should be as the concept of 'risk' gains traction.

Are Continuing Operations Plans relevant to the Standard? This is part of risks and opportunities. May be part of management review reports. It stands to reason that a laboratory needs to have a backup plan to address its situation, such as a Hurricane Plan in Florida. The COVID-19 pandemic seemingly expands that to any laboratory.

Returning to Method Validation and Verification, each module has this. No one thinks there can be one set of language to cover all modules. This isn't different than the current Standard – there is likely to be changes in how each Module addresses these items. It won't (and shouldn't be) one size fits all, as each technical Module has its own ways to assess these topics. Education will likely be needed for these topics and changes.

See Attachment D for progress made on the Summary of Proposed Changes form.

3. Action Items

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

4. New Business

A Webinar regarding the potential new Standard is likely for late July.

5. Next Meeting and Close

The next meeting will be on July 13, 2020 at 1pm Eastern. Ilona will send a Webex invitation late morning 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 2:30pm Eastern (Motion Earl, Second Lizbeth).

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 **Present**	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Kathi Gumpper (Vice-Chair) **Present**	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 **Present**	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross **Absent**	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Debbie Bond **Absent**		2023*	Lab	dbond@southernco.com
Michelle Wade **Absent**	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.*
75	Update Summary of Suggested Changes table from Newport meeting and send to Committee for review.	Jessica	3/9/20	Complete
77				

Attachment C

Backburner / Reminders – QS Executive Committee

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

Module 2 Standard Update - Summary of Suggested Changes – 6-29-2020

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).	Analytical Equipment vs Support Equipment	Wet may need to define the specific requirements within their module
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, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.	How much information is required, do we need to have the specific pipet on the benchsheet. Support Equipment Audit Trail SIR 328	Audit trail is mention in 4.13.2.1 Gray area does exist, however the language is as clear as we can make this
7.2.1.2 ISO 4.2.8.5	SOP Headers Too proscriptive?	Clarify that this is not a required outline, all areas must be covered when

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Deleted: Review TNI definition for Annual and update as needed. ¶

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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 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;		applicable but exact wording of headers and specific order is not required. Keep the language from F and add G for administration SOP Work on language for the final sentence of f) Administration SOP not be called SOP change it to procedure.	Deleted: Glossary
7.4.2 ISO 5.8.5 Additional Requirements – Documentation	Unique Identifier what is a sample container 5.8.5.a. Does a digestate	Look at the word unique and whether the word should just be removed.	Deleted: NA Deleted: Glossary

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 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.	require a unique identifier, look specifically at 5.8.5 d	
8.8.2 ISO 4.14.5. c) The Internal audit schedule shall be completed annually,	Internal Audit- Annual-Periodically (Schedule)	Change scheduled to performed? Take out the word annual/quarterly and insert language for the specific time frame intended Instead of annually use every 12 months not to exceed 18 months Internal audit must be performed every calendar year not to exceed 18 months
5.8.7.1 The laboratory shall implement procedures for verifying and documenting preservation.	Sample Receipt Protocol	Should the wording be changed from implement to have and implement
5.10.11 c) Any non-accredited tests shall be clearly identified as such to the client when claims of	Presenting non-accredited analysis as TNI	Any results that are generated for non-accredited tests shall be clearly identified

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5.5.13.1→Support Equipment ¶
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→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).¶

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Support Equipment Audit Trail ¶
SIR 328

accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables.		as such in the analytical report or in the supporting electronic or hardcopy deliverables when claims of accreditation to this Standard are made.
Multiple reference first is 1.1 introduction	Quality Manual- Policies	Do we want to keep this or move towards ISOKathy's Language…Major change give examples of the quality manual. If you have a QM and you don't want to change it, you will not have to except to modify for risk assessment
ISO 8.8.2 d) implement appropriate correction and corrective actions without undue delay;	Internal Audits- Undue delay? Methods listed?	How do we define undue delay? Up to the laboratory to define. 4.14.5 a) talks about time frame for notifying clients, use this language for a policy about time frame to define undue delay.
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.	Initial Demonstration document retention	Change the word entry to use or add a part in the section about personal training and have an initial demonstration and or all training records on the analyst until they leave the company the current language in 4.13.3 b) to establish a control of initial DOC to be kept five years after last reference. 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)	Request for tenders – formal contracts	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:	Prep Method- Is it required to be listed on final report and PT samples Reporting Qualifiers on analytes	Additional Language needs to be added on what is required in the reports: Prep methods

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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, and related laboratory activities, such as sample receipt, sample ... [1]

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5.8.5 → Additional Requirements – Documentation ¶... [5]

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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 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);		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 not required on PT due to not being in table, but required on final report by most Abs PT executive committee looking at adding Prep methods to table. 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. There currently is additional language in the QSM
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 that would count as the instrument software.

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		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 Note 2 for a requirement, laboratories do not want the same requirements for LIMS to be applied to off the shelf software.
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.	1)Secondary Source- Vendor identifying individual lot uniquely (however it was the same lot) 2) Cof A electronic controlled record – not just on website of manufacturer	Guideance nothing to change. Note: C of A only available on the vendor website are by definition uncontrolled documents.
ISO 3.8 and 3.9 Definitions	Data Validation/Verification- Should that be required by TNI	Data validation/verification is already a requirement of the standard, however named.
5.4.2 Selection of Methods	Using most recent methods SIR 180 Make sure to look at responses from SIRs when clarifying language	Language in 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;	Clarification of possessing a copy of the standard	Language needs to be added from the current standard 'authorized editions'

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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.	Needs to say reference standards SIR 378.	Not relevant to current standard.
Continuing Operations Plans		This would fall under the risk and opportunities clause.
	Method validation and verification.	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.

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