Quality System Expert Committee (QS)
Meeting Summary

July 16, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 2:30pm Eastern by teleconference on July 16, 2020. Attendance is recorded in Attachment A – there were 10 members present. Associate Members present: Carl Kircher, John Gumpper, Amy Schreader, Cindy Redmond, Jeanette Hernandez, Joe Manzella, Karna Holquist, Linda O'Donnell, Lisa Parks, Paul Junio, Rachel Van Exel, Renee Jernigan, Tiffany Shaw and Chris Fuller.

A motion was made by Tony to accept the June 29, 2020 minutes as written. The motion was seconded by Kristin 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 Committee's goal is to have a new Standard by August 2021. This means meeting more frequently and establishing subcommittees to work on sections. We are waiting to hear back from Jerry to confirm this time frame.

The Committee is looking at doing a public meeting on Monday, September 14, 2020.

Next call will be on 7/27 at 1:30pm Eastern. *(Addition: The call was canceled, and the committee met on 8/10/20.)*

On support equipment, the SLH has some information. Ilona read what was in the Handbook. The Committee should look at developing some implementation guidance. See note in the summary form (Attachment D). The Committee decided to leave it on the summary form and ask for recommendations for a wording change.

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

The Committee will start with Section 5.8.7.1 at their next meeting. The Committee is reviewing the summary to finalize it for the public webinar.

3. Action Items

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

4. New Business

   None.

5. Next Meeting and Close

   The next meeting will be on July 27, 2020 at 1pm Eastern. Ilona will send a Webex invitation late morning of the meeting. *(Addition: Next meeting changed to 8/10/20.)*

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

   Jessica adjourned the meeting at 3:43pm Eastern (Motion Elizabeth, 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 **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 **Absent**	Retired	2021*	Laboratory	papaearl41@hotmail.com
Jenna Majchrzak **Absent**	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Shari Pfalmer **Present**	Pace Analytical Services	2021	Laboratory	shari.pfalmer@pacelabs.com
William Ray **Absent**	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross **Absent**	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Debbie Bond **Present**		2023*	Lab	dbond@southernco.com
Michelle Wade **Absent**	A2LA Workplace Training	2021*	Other	mwade@a2lawpt.org
Alyssa Wingard **Absent**	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

Attachment D

Module 2 Standard Update - Summary of Suggested Changes – 7-16-2020-v3

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.
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	No Change suggested	Audit trail is mention in 4.13.2.1 Gray area does exist, however the language is as clear as we can make this. We are open for suggestions for changes.

	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 include or reference the following topics where applicable: i. identification of the method; ii. applicable matrix or matrices;	Clarify that this is not a required outline, all areas must be covered when applicable but exact wording of headers and specific order is not required. Modify 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. Clarify the difference between procedure for instance: administration 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 areas that are 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.

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 subsequent extracts and/or digestates. b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned to each sample.	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.

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,	Change schedule to perform? Take out 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.	Should the wording be changed 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 reference 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.

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 open to a timeframe 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 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.	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	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	

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 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 2016 standard QSM	The ISO language needs to be expanded for the specific requirement within an environmental laboratory.

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. 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.
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	Guideance nothing to change. Note: C of A only available on the vendor website are by definition uncontrolled record.
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	Not relevant to current standard.
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.