Quality System Expert Committee (QS)
Meeting Summary

August 10, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on August 10, 2020. Attendance is recorded in Attachment A – there were 12 members present. Associate Members present: Carol Barrick, Cindy Redmond, Brian Lamarsh, Tiffany Shaw, Linda O'Donell, Eric Davis, Ashley Larssen, Eric Denman, Karna Holquist, Amy Schrader, Paul Junio, Patty Carvajal, Rachel van Exel, Joe Manzella and Lauren Wicklund.

The July 16, 2020 minutes will be reviewed during the September meeting.

There were no changes made to the agenda.

2. Summary of Suggested Changes Form

The Committee started with Section 5.8.7.1. The Committee is reviewing the summary to finalize it for the public webinar. Changes to the summary can be found in Attachment D.

Discussion:

<u>Quality Manual</u>

Paul Junio thinks it would not be a good idea to delete the Quality Manual requirement at this time. He thinks this partially due to the response in Newport Beach.

Nick noted that his organization is not requiring a Quality Manual under ISO/IEC 17025:2017. He finds that most labs still have one anyways. Some are doing something different because they have computer systems that store all their procedures. He thinks we should remove the requirement – "pull the band aid off".

Alyssa reminded the group that ISO/IEC 17025:2017 are baseline requirements. It is OK to tighten up the elements of a quality system.

Eric Davis asked if the ABs have been asked about this? This has not been done at this point. Some states do have Quality Manual requirements in their regulations. Some states have it in their applications.

Paul Junio provided the language out of the DW Manual:

11. Laboratory Quality Assurance Plan

All laboratories analyzing drinking water compliance samples must adhere to any required QC procedures specified in the methods. This is to ensure that routinely generated analytical data are scientifically valid and defensible, and are of known and acceptable precision and accuracy. To accomplish these goals, each laboratory should (EPA Order 5360.1 A2) prepare a written description of its QA activities (a QA plan). It is the responsibility of the QA manager to keep the QA plan up to date. All laboratory personnel need to be familiar with the contents of the QA plan. This plan should be submitted to the auditors for review prior to the on-site visit or should be reviewed as part of the on-site visit.
The laboratory QA plan should be a separately prepared text. However, documentation for many of the listed QA plan items may be made by reference to appropriate sections of this manual, the laboratory's standard operating procedures, (SOPs) or other literature (e.g., promulgated methods, *Standard Methods for the Examination of Water and Wastewater*, etc.). The QA Plan should be updated at least annually (EPA Order 5360.1 A2).
At a minimum, the following items should be addressed in each QA plan:

Jessica noted that the Committee will have to talk more about this when the Standard is updated and check-in with the NELAP AC with ideas.

The Committee is still hoping to do the Public Webinar on September 14, 2020 at 1 pm EDT. *(Addition: It was actually scheduled for September 25, 2020 at noon EDT.)* Jessica will begin work on the presentation 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 September 14, 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 2:05pm Eastern (Motion – Debbie , Second - Shari.)

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 **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.*
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 – 8-10-2020

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).	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 sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.	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.
7.2.1.2 ISO 4.2.8.5	Clarify that this is not a required outline, all areas must be covered when	SOPs can be written in any format that includes all of the areas that are

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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; xi. ……	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	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.
7.4.2 ISO 5.8.5 Additional Requirements – Documentation	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

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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.		not necessarily require every container to be uniquely identified.
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.

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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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		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.

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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 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

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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.

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Attachment D – See PDF attachment

Module 2 Standard Update - Summary of Suggested Changes – 8-10-20