Quality System Expert Committee (QS)
Meeting Summary

March 9, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on March 9, 2020. Attendance is recorded in Attachment A – there were 12 members present. Associate Members present: Amy Schrader, Brian Lamarsh, Amy Schreader , Chris Fuller, Eric Denman, Jeanette Hernandez, Joe Manzella, Linda O'Donnell, Rachel Van Exel, Chris Gunning, Karna Holquist, Paul Junio and Carl Kircher (added in at 1:27).

Jessica is changing jobs this next week.

A motion was made by Kathi to accept the February 3, 2020 minutes as written with deletion of Paul H's name and AB inserted instead. The motion was seconded by Earl and unanimously approved.

A motion was made by Earl to accept the February 4, 2020 minutes as written. The motion was seconded by Bill and unanimously approved.

A motion was made by Earl to accept the February 10, 2020 minutes as written with the addition by Jessica of the associate roster, deletion of new business (from previous meeting) and editorial correction of "due" instead of "to" in John Gumpper's comment. The motion was seconded by Bill and unanimously approved.

2. Committee Membership and Leadership

Earl motioned to nominate Jessica and Kathi to continue in their leadership roles as Chair and Vice-Chair. It was asked if Kathi had interest in chairing, but she does not have time at this point. The motion was seconded by Mike and unanimously approved.

New member Donna could not continue on the committee due to a job change and Debbie Bond was next on the ballot. She was still interested, so she was voted in by email. Jessica welcomed Debbie to the committee.

Email vote:
Michelle nominated Debbie Bond to be added to the Quality Systems Committee on 2/24/20. The motion was seconded by Tony Francis on 2/24/20.

Vote:
Kathi – For (2/24/20)
Lizbeth – For (2/24/20)

Mike – For (2/24/20)
List of votes received from Jessica on 2/25/20:
Jenna – For
Earl – For
Tony - For
Michelle – For
Kristin – For
Jessica – For
Bill – For
Nick – For

The motion passed and Debbie Bond was added to the Committee.

3. Summary of Suggested Standard Changes Table

   Jessica reviewed the entries and made updates to the table (Attachment D). The Committee will start at Section 5.8.7.1 of the Standard at the next meeting.

4. Action Items

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

5. New Business

   None.

6. Next Meeting and Close

   The next meeting will be on April 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 2:45pm Eastern. (Earl- motion Kathi – second, Unanimous approval).

Attachment A

Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Jessica Jensen (Chair) **Present**	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown **Absent**	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) **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 **Present**	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Shari Pfalmer **Present**	Pace Analytical Services	2021	Laboratory	shari.pfalmer@pacelabs.com
William Ray **Present**	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**	Alabama Power Co.	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
25	Follow-up with Bob Wyeth and Jerry Parr about experience vs. course hours for Technical Directors.	Paul	TBD	
26	Provide in writing, thoughts regarding options for Technical Director approval.	Robin	TBD	
38	Continue SIR 246 and 296 discussions.	All	TBD	
40	Get PT root cause analysis example from Scott Hoatson.	Paul	8/31/17	
45	Review Ch 1 Application section for the use of "shall" and "may". Are uses correct?	Paul, Sara	11/20/17	
51	Send example of Shari's report to NELAP AC to confirm format of listing all certifications without logo's is an acceptable process to report certifications for work being done.	Shari Paul	5/11/18	
53	Look into CWEA certification requirements.	Nick Jacob	7/9/18	
56	Reach out to Marlene Moore for additional information on Class A glassware.	Paul	7/9/18	
57	Look into status on labware SIR.	Paul	7/9/18	
59	Review Milwaukee minutes and add to Parking Lot list as appropriate.	Paul/Jessica	4/8/19	
60	Send Technical Manager Questions to Committee to get comments and ideas for other questions.	Jessica	3/11/19	
61	Send SIR 350 Response to Lynn.	Jessica	7/31/19	
62	Update SIR Summary to match procedure used by the PT Expert Committee.	Jessica/Paul Junio	8/5/19	
63	Consider starting a list of items to add to the small laboratory handbook.	All	TBD	

	Action Item	Who	Expected Completion	Actual Completion
64	Review language in DRAFT Combined Standard to make sure all TNI language was transferred.	TBD	TBD	
65	Add ISO/IEC 17025:2017 language from the 2016 TNI Standard into the DRAFT Combined Standard.	TBD	TBD	
66	Send out DRAFT Chemistry Technical Manager requirements to QS Expert Committee and then to Chemistry Expert Committee.	Jessica	QS: 9/10/19 Chemistry: 9/13/19	
68	Send note to Lynn about status of LAB language requested to be added.	Jessica	1/10/20	
71	Send final response to SIR 363 to Lynn Bradley.	Jessica	1/20/20	
72	Start reviewing SIRs to add to list of possible changes to the Standard.	Jessica	2/2/20	
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	
74	Notify new members about membership. First meeting as members will be 2/10/20.	Jessica	2/3/20	
75	Update Summary of Suggested Changes table from Newport meeting and send to Committee for review.	Jessica	3/9/20	

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 - 2-3-20-v1

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?*
NA	Need to develop a definition for Quarterly.	Glossary
NA	Review TNI definition for Annual and update as needed.	Glossary
NA	Ilona noted there may be some changes to some of the field related definitions. A Field Task Force has been working on these.	Glossary
NA	Debbie Bond suggested looking at definition for Controlled Document.	Glossary
NA	Jessica would like to define Duplicate.	Glossary
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	Analytical Equipment vs Support Equipment	Wet may need to define the specific requirements within their module

Original Text	Suggested Change	Justification
and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).		
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 mentioned 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 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.	SOP Headers Too proscriptive?	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. Keep the language from F and add G for administration SOP

Original Text	Suggested Change	Justification
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;		Work on language for the final sentence of f) Administration SOP not be called SOP change it to procedure.
7.4.2 ISO 5.8.5 Additional Requirements – Documentation The following are essential to ensure the validity of the laboratory's data.	Unique Identifier what is a sample container 5.8.5.a. Does a digestate require a unique identifier, look specifically at 5.8.5 d	Look at the word unique and whether the word should just be removed.

Original Text	Suggested Change	Justification
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.		
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

Original Text	Suggested Change	Justification
		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
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.	Presenting non-accredited analysis as TNI	
Multiple reference first is 1.1 introduction	Quality Manual- Policies	Do we want to keep this or move towards 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?
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
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	What if there are no customer
NA	Definition of customer	Is the client themselves (Data User)

Original Text	Suggested Change	Justification
???	Prep Method- Is it required to be listed on final report and PT samples	Metals for instance
???	Instrument Software Note in 17025 needs to be added as requirement	
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.	
	Data Validation/Verification- Should that be required by TNI	
	Reporting Qualifiers on analytes	
5.4.2 Selection of Methods	Using most recent methods SIR 180 Make sure to look at responses from SIRs when clarifying language	
4.3.1/4.3.2.2	Clarification of possessing a copy of the standard.	