

## Quality System Expert Committee (QS) Meeting Summary

April 13, 2020

### 1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on April 13, 2020. Attendance is recorded in Attachment A – there were 10 members present. Associate Members present: Carl Kircher, Eric Davis, Chris Gunning, Ashley Marssen, Amy Schreder, Brian Lamarsh, Carol Barrick, Chaney Arend, Christopher Fuller, Cindy Gaddis, Eric Denman, Joe Manzella, Paul Junio, Rachel Van Exel, Renee Jernigan, Tiffany Shaw, Eric Davis, Jeanette Hernandez, Rose Cruz, John Gumper and Linda O'Donnell.

A motion was made by Earl to accept the March 9, 2020 minutes as written with the addition of Nick and Debbie as present. The motion was seconded by Jenna and unanimously approved.

### 2. Action Items

Jessica pulled up the Action Table for review. See notes in Table in Attachment B. *(Addition: Paul Junio (former Quality Systems Expert Committee Chair), Jessica and Ilona met a few days later to complete the review and update of the Action Items table. Updates are in italics in Attachment B.)*

### 3. Standard Update - Summary of Suggested Standard Changes Table

Jessica reviewed the entries and made updates to the table (Attachment D). The Committee started at Section 5.8.7.1 of the Standard. The Committee got to Section 5.10.11.

- Need to decide if “Implement” needs to be added to all procedures. Look at Section 8.2.1. It requires that policies and procedures are implemented.
- End on multiple references – about policies.

Jessica asked that people continue to review the Standard to see if more additions are needed in the table and to make comments on what is already in the table. Please send this directly to Jessica.

#### 4. New SIR #378

The following SIR was received for consideration. Jessica will email it to everyone and begin review by email. It will be further discussed at the May meeting.

SIR 378 to QS April 6, 2020

<b>Standard</b>	2016 TNI Standard
<b>Volume and Module (eg. V1M2)</b>	EL-V1M2-2016-Rev2.1: Quality Systems General Requirements
<b>Section (eg. C.4.1.7.4)</b>	5.5.13.1 Support Equipment

**Describe the problem:**

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.

Question: do reference thermometers need to be calibrated annually? These are traceable to NIST.

**Committee Comment:**

**Response:**

---

#### 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 on May 11, 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 2:15pm Eastern. (Jenna- motion Kathi – second, Unanimous approval).

Attachment A

**Participants**  
**Quality Systems Expert Committee (QS)**

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

**Attachment B**

**Action Items – QS Expert Committee**

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
25	Follow-up with Bob Wyeth and Jerry Parr about experience vs. course hours for Technical Directors.	Paul	TBD	COMPLETE Being addressed in work on Technical Manager Requirements.
26	Provide in writing, thoughts regarding options for Technical Director approval.	Robin	TBD	COMPLETE Being addressed in work on Technical Manager Requirements.
38	Continue SIR 246 and 296 discussions.	All	TBD	COMPLETE
40	Get PT root cause analysis example from Scott Hoatson.	Paul	TBD	4/15: <i>COMPLETED</i>
45	Review Ch 1 Application section for the use of “shall” and “may”. Are uses correct?	Paul, Sara	11/20/17	4/15: <i>Handbook Complete COMPLETED</i>
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	4/13/20: Paul has report. Will see what was done with it. 4/15: <i>Reviewed. No longer needs to be sent. COMPLETED</i>
53	Look into CWEA certification requirements.	Nick Harding Jacob O.	7/9/18	CLOSE
56	Reach out to Marlene Moore for additional information on Class A glassware.	Paul	7/9/18	COMLETE
57	Look into status on labware SIR.	Paul	7/9/18	4/13/20: Paul checking into this. 4/15: <i>SIR 274. COMPLETED</i>

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
59	Review Milwaukee minutes and add to Parking Lot list as appropriate.	Paul/Jessica	4/8/19	COMPLETE
60	Send Technical Manager Questions to Committee to get comments and ideas for other questions.	Jessica	3/11/19	COMPLETE
61	Send SIR 350 Response to Lynn.	Jessica	7/31/19	COMPLETE
62	Update SIR Summary to match procedure used by the PT Expert Committee.	Jessica/Paul Junio	8/5/19	COMPLETE
63	Consider starting a list of items to add to the small laboratory handbook.	All	TBD	
64	Review language in DRAFT Combined Standard to make sure all TNI language was transferred.	TBD	TBD	COMPLETE
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	COMPLETE
68	Send note to Lynn about status of LAB language requested to be added.	Jessica	1/10/20	COMPLETE
71	Send final response to SIR 363 to Lynn Bradley.	Jessica	1/20/20	COMPLETE
72	Start reviewing SIRs to add to list of possible changes to the Standard.	Jessica	2/2/20	COMPLETE Finished in Newport Beach.
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.
74	Notify new members about membership. First meeting as members will be 2/10/20.	Jessica	2/3/20	COMPLETE
75	Update Summary of Suggested Changes table from Newport meeting and send to Committee for review.	Jessica	3/9/20	



**Attachment D:**

**Module 2 Standard Update - Summary of Suggested Changes - 2-3-20-v1**

Original Text	Suggested Change	Justification
<i>Include reference and language.</i>	<i>Don't need to work on specific language - just summarize change needed.</i>	<i>Why does this need to be changed/updated?</i>
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
<p>6.4.6 ISO 5.5.13.1 Support Equipment</p> <p>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</p>	Analytical Equipment vs Support Equipment	Wet may need to define the specific requirements within their module



Original Text	Suggested Change	Justification
<p>sample preparation devices and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).</p>		
<p>7.5.1 ISO</p> <p>4.13.3 Additional Requirements</p> <p>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.</p>	<p>How much information is required, do we need to have the specific pipet on the benchsheet.</p> <p>Support Equipment Audit Trail</p> <p>SIR 328</p>	<p>Audit trail is mention in 4.13.2.1</p> <p>Gray area does exist, however the language is as clear as we can make this.</p>
<p>7.2.1.2 ISO</p> <p>4.2.8.5</p> <p>a) Documents that contain sufficient information to perform the tests, do not</p>	<p>SOP Headers Too proscriptive?</p>	<p>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.</p>

Original Text	Suggested Change	Justification
<p>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.</p> <p>e) The laboratory shall have and maintain an SOP for each accredited analyte or method.</p> <p>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:</p> <ul style="list-style-type: none"> <li>i. identification of the method;</li> <li>ii. applicable matrix or matrices;</li> </ul>		<p>Keep the language from F and add G for administration SOP</p> <p>Work on language for the final sentence of f)</p> <p>Administration SOP not be called SOP change it to procedure.</p>

Original Text	Suggested Change	Justification
<ul style="list-style-type: none"> <li>iii. limits of detection and quantitation;</li> <li>iv. scope and application, including analytes to be analyzed;</li> <li>v. summary of the method;</li> <li>vi. definitions;</li> <li>vii. interferences;</li> <li>viii. safety;</li> <li>ix. equipment and supplies;</li> <li>x. reagents and standards;</li> </ul>		
<p>7.4.2 ISO</p> <p>5.8.5 Additional Requirements – Documentation</p> <p>The following are essential to ensure the validity of the laboratory’s data.</p> <p>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,</p>	<p>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</p>	<p>Look at the word unique and whether the word should just be removed.</p>

Original Text	Suggested Change	Justification
<p>preservations, sample containers, tests, and subsequent extracts and/or digestates.</p> <p>b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned to each sample.</p> <p>c) The laboratory ID code shall be placed as a durable mark on the sample container.</p> <p>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.</p>		
<p>8.8.2 ISO 4.14.5. c) The Internal audit schedule shall be completed annually,</p>	<p>Internal Audit- Annual-Periodically (Schedule)</p>	<p>Change scheduled to performed? Take out the word annual/quarterly and insert language for the specific time frame intended</p> <p>Instead of annually use every 12 months not to exceed 18 months</p> <p>Internal audit must be performed every calendar year not to exceed 18 months</p>

Original Text	Suggested Change	Justification
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	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.
Multiple reference first is 1.1 introduction	Quality Manual- Policies	Do we want to keep this or move towards ISO(No specific policies are called for)— What is a policies and objective in ISO language.. Is it a procedure??
8.8.2 d) <i>implement appropriate correction and corrective actions without undue delay;</i>	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.	