Quality System Expert Committee (QS)
Meeting Summary

June 8, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on May 11, 2020. Attendance is recorded in Attachment A – there were 14 members present. Associate Members present: Jeanette Hernandez, Ashley Larson, Rachel van Exel, Joe Manzella, Paul Junio, Eric Denman, Carol Barrick, Halley Hanstings, Karna Holquist, Amy Schreader, Tiffany Shaw, Cindy Gaddis, Renee Jernigan, Linda O'Donnell, Chris Fuller, and Brian Lamarsh.

A motion was made by Michelle to accept the May 11, 2020 minutes as written. The motion was seconded by Debbie and unanimously approved.

2. Standard Interpretation Request (SIR) #378

The following SIR was received for consideration and finalized by email vote:

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	EL-V1M2-2016-Rev2.1: Quality Systems General Requirements
Section (eg. C.4.1.7.4)	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:

The NMI traceable reference mentioned in 5.5.13.1 d) refers to a reference standard as described in 5.6.3.1; therefore, it would need to be calibrated before and after any adjustment.

5.6.3.1 Reference Standards

The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

Response: As long as the reference thermometer is not being used as a piece of support equipment such as described in 5.5.13.1 c, a reference thermometer is a reference standard as described in 5.6.3.1 and would need to be calibrated at the frequency provided by the calibration vendor.

A motion was made by email by Tony Francis to approve the response to SIR 378 sent by Jessica Jensen on 5/26/20. The motion was seconded by Shari Pfalmer.

Michelle – For (6/1/20)
Lizbeth – For (5/26/20)
Bill Ray – For (5/26/20)
Earl Hansen – For (5/26/20)
Michael D – For (5/26/20)
Nicholas – For (5/26/20)
Debbie- For (5/26/20)
Amber – For (5/26/20)

The motion passed and Jessica forwarded the response to Lynn Bradley and the LASEC on 6/2/20.

3. Standard Timeline

Jessica asked Ilona to describe the request received from Jerry and timing on the Standard. He asked if the Committee could complete a Standard for DoD use by August 2021.
(Addition: This will be further discussed at an upcoming TNI Board Meeting.)

To hit this target, the Committee would need to have a Voting Standard within the next 6 months to share by the Winter meeting.

Jessica noted that the Committee would likely need to put some workgroups together to work on specific topics and have some extra Quality Systems meetings. These workgroups are open to voting and associate members.

Jessica would like to start meeting the second and fourth Mondays at 1pm Eastern.

Jessica commented that if the Committee can't find resolution on something, it doesn't mean we won't still be able to add it to the next Standard we develop.

Kathy is concerned that the timeline is challenging. She would not like to see the Standard migrate more after they adopt the Standard. There was agreement with this comment, but it will need to be discussed if an issue arises.

A sound problem caused everyone to leave the meeting and call in on a new call. Voting members on the call were confirmed. Bill, Michelle and Tony did not call back in due to another meeting. They left the call at 1:30.

4. Summary of Suggested Changes Form – new recording 1:36

   Jessica has been working on cleaning up the form. She only left the changes the committee thinks need to be made. She would like to finish going through the document. The Committee left off talking about DOC. This topic will be further discussed at the end of the call so progress can be made on other items due to time constraints.

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

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 June 29, 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.

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 **Present**	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Michael Demarais **Present**	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis **Present (until 1:30)**	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 **Present (until 1:30)**	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 (until 1:30)**	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	
76	Prepare DRAFT response to SIR 378 and discuss and possibly finalize by emai.	Jessica	6/8/20	COMPLETE

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 – 6-8-2020-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?*
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,	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.

such as 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; iii. limits of detection and quantitation; iv. scope and application, including analytes to be analyzed; v. summary of the method;	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 Work on language for the final sentence of f) Administration SOP not be called SOP change it to procedure.

vi. definitions; vii. interferences; viii. safety; ix. equipment and supplies; x. reagents and standards;		
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. 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.	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.

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 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 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: f) identification of the method used;	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

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. 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 **ISO 6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: a) development, modification, verification and validation of methods;	Data Validation/Verification- Should that be required by TNI	
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 **ISO 8.3.1** The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.	Clarification of possessing a copy of the standard.	
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	
Continuing Operations Plans		