Quality System Expert Committee (QS)
Meeting Summary

May 11, 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: Carl Kircher, Dale Piechocki, John Gumpper, Ashley Larssen,

A motion was made by Bill to accept the April 13, 2020 minutes as written with the addition of John Gumpper as an associate member attending the meeting. The motion was seconded by Shari and unanimously approved.

2. Standard Interpretation Request (SIR) #378

The following SIR was received for consideration:

SIR 378 to QS April 6, 2020

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:

Response:

Jessica shared this request by email and got comments. She shared Marlene's comments received on 5-10-20 with the committee:

> *Regarding SIR 378 to QS April 6, 2020*
>
> *The metrology standard is for Thermometers to be calibrated by a National Metrology Institute (NMI) or an accredited cal lab to ISO/IEC 17025:2017. ANSI Z540.3 indicates the calibration interval is based on the labs use. That being said. EPA SDWA program requires the thermometers to be calibrated every year, That requirement was made before the international standards were created and was used in some military programs so EPA made the similar requirement. The mil specs have been changed and follow the requirement os Z540.1*
>
> *Most environmental labs today: The "master" thermometer is calibrated by an NMI (such as NIST) or accredited cal lab. That thermometer is used by environmental lab to verify the working thermometers in the lab. The working thermometer must measure acceptably for the use at least once per year. Most temp measurements are for support equipment which defines the range that is works within.*
>
> *So the lab must have a policy for the master thermometer calibration and the working thermometers verification.*

John Gumpper: Section 5.5.13. Vol 1 Mod 2 – There is no time frame in there. There is no time frame in the Standard. It is 5 years in the DW manual. Our Standard doesn't say.

Robin Cook agrees with Marlene's comments about checking master and then comparing other lab thermometers. Paul noted that a lab needs to make sure they talk about their master thermometer and that it is differentiated from the daily measuring devices.

Perhaps reference John's sections and note that there is a master thermometer? John thinks reference standard is mentioned in Section 5.6.3.

It doesn't reference Section 5.6.3 in Section 5.13 … that is the problem.

Many calibration thermometers are giving an expiration date. ISO calibrated providers are not supposed to send you a recertification date.

We can state it is not an SIR and give Lynn some information in the comments to use in her response.

Jessica will work on a response and send it to the Committee for email review. She asked everyone to watch for it and send comments as needed.

This will no longer be a problem in the new Standard because the wording has changed. This needs to be marked in the Summary of Changes form.

3. Continuing Operations Plans

Added to Summary of Changes form and will be further discussed.

4. Summary of Changes Form

The Committee left off at Quality Manual Policies and will be starting there today. Have to define policies needed.

The Committee discussed whether a Quality Manual is really needed. The general thought is that a specific manual is not needed, but a manual could be used to cover the elements of a quality system. People think the manual is too rigid and other options should be open to the lab.

Kathy would like to see SOP and Policy defined. What is included in a Policy instead of an SOP.

Need text in the Standard that makes it clear what procedures and policies a lab needs to have. They can put this in a manual or have it distributed through various control documents.

John G. thinks people are getting used to the changes needed to move a lab closer towards ISO/IEC 17025:2017. It gives labs more flexibility in how to implement the Standard.

Ilona noted that when this comes up, we should be prepared to include more information about what the Committee is thinking in order to avoid the issues we dealt with on Technical Manager. This could be included in the third column of the form.

Jessica asked the Committee to think about wording that could be used to allow a formal quality manual or through another means of quality documentation. Kathy provided some thought on this in Attachment D.

Carl thinks we should look at the DW program to see what they require as far as a quality manual. He is concerned about removing Quality Manual and other items from the Standard when updating to the ISO/IEC 17025:2017 version.

John disagrees. The DW is just one program. It's up to the AB to make sure a lab is doing what they should be doing – both DW and TNI. TNI does not need to line-up perfectly with the DW program. John also thinks the DW Manual is up for review, so it may change.

Carl disagreed. He said TNI is required to operate the program in a non-discriminatory manner. If it is required in the DW program, we are obligated and required to use procedures for NPW, SCM, etc … There was general disagreement with this statement.

The updated Summary of Changes Table can be found in Attachment E and includes the conclusions and additions based on meeting discussion.

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 8, 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 2:27pm Eastern. (Michelle- motion Debbie – second, Unanimous approval).

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 **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**		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
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: COMPLETED*
45	Review Ch 1 Application section for the use of "shall" and "may". Are uses correct?	Paul, Sara	11/20/17	*4/15: Handbook Complete COMPLETED*
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: Reviewed. No longer needs to be sent. COMPLETE*
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: SIR 274. COMPLETE*

	Action Item	Who	Expected Completion	Actual Completion
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	

	Action Item	Who	Expected Completion	Actual Completion
76	Prepare DRAFT response to SIR 378 and discuss and possibly finalize by emai.	Jessica	6/8/20	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Review charter in November 2020	Ongoing	Ongoing

Attachment D: Example Language to Discuss Quality Management System Documents

Hi Jessica and Ilona,

Here's my response for the request for a new definition for the requirements for quality manual that includes the minimum content but in a less prescriptive in form.

Instead of incorporating all of the requirements for quality manual from the ISO/IEC 17025:2005 and TNI2016, perhaps we can use the 17025:2017 language and add requirements for particular topics that we want to have them address.

For example (from 17025:2017):

5.5 The laboratory shall:

c. document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

My suggestion for a possible additional TNI requirement to 5.5.c:

In addition to procedural requirements found throughout ISO/IEC 17025:2017, the laboratory shall have documented procedures to address the following:

- **the laboratory's data integrity system,**
- **protecting the confidentiality of customer information**
- **calibration of equipment,**
- **traceability of results,**
- **corrective action**
- **review and reporting of results,**
- **storage, retention and protection of records,**
- **control of documents,**
- **use of electronic signatures, if applicable**

Here's the background information that I used to determine the list. As you'll see from the table of requirements we had previously (see below), most are already covered by 17025:2017 procedure requirements. Some do not have a procedural requirement, but do have requirements that lab has to meet - they just aren't required to have a procedure to describe how they meet them. A few are TNI specific requirements that don't have a perfect equivalent in 17025:2017. I did not include the details from 4.2.8.2 for things like Title page, table of contents, etc. I also skipped the equipment list which is a record, not a procedure. Records of equipment are already required under 6.4. My suggestion includes

a “global” requirement that the 2017 requirements for procedures be addressed and then only added the shorter laundry list of items that do not specifically require a procedure in 2017.

Current list of required items in the Q Manual section.	17025:2017 requirement for same procedure
1. A data integrity system (see TNI 4.2.8.1)	None
2. All maintenance, calibration and verification procedures used by the laboratory in conducting tests; (see TNI 4.2.8.4.a)	6.4.3 is similar, 6.4.7 for “programme”, 6.4.10, 6.5.3.b (sort of an orthogonal concept – not direct)
3. A list of major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests; (see TNI 4.2.8.4.b)	No list of equipment required No procedure for reference measurement standards Facilities in 6.3.2 Services in 6.6.2
4. Verification practices, which may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes; (see TNI 4.2.8.4.c)	See verification - calibration in item 2 7.7.1 monitoring validity of results – these include interlaboratory comparisons, QC, PT, etc.
5. Procedures for reporting analytical results; (see TNI 4.2.8.4.d)	No procedure required, just requirements for specific how items are to be reported.
6. The organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts; (see TNI 4.2.8.4.e)	5.5.a
7. Procedures to ensure that all records required under this Standard are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures (SOPs), manuals, or documents clearly indicate the time period during which the procedure or document was in force; (see TNI 4.2.8.4.f)	No procedures required, just requirements that records be retained and documents be controlled.
8. Personnel roles, responsibilities, training, qualifications and authorizations (see TNI 2016 4.2.6, TNI 4.2.8.4.g)	6.2.5. a – f, 6.2.6
9. procedures for achieving traceability of measurements; (TNI 4.2.8.4.h)	No procedure required, just requirements to ensure measurements are traceable.

10. a list of all methods under which the laboratory performs its accredited testing; (TNI 4.2.8.4.i)	5.3 is similar
11. procedures for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;(TNI 4.2.8.4.j)	7.1.1.a - d
12. procedures for handling samples; (TNI 4.2.8.4.k)	7.4.1
13. procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur; (TNI 4.2.8.4.l)	7.10.1 Nonconforming work sort of, but no procedure required specifically for corrective action
14. policy for permitting departures from documented policies and procedures or from standard specifications; (TNI 4.2.8.4.m)	7.10.1 Nonconforming work 7.2.1.7
15. procedures for dealing with complaints; (TNI 4.2.8.4.n)	7.9.1
16. procedures for protecting confidentiality (including national security concerns), and proprietary rights; (TNI 4.2.8.4.o)	No procedures are required, just requirements that the lab shall protect confidentiality
17. procedures for audits and data review; (TNI 4.2.8.4.p)	8.8.2 requires plan and programme, but not procedure – I think plan and programme cover the procedural requirement
18. procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed training; and (TNI 4.2.8.4.q)	6.2.5.1 a– f, 6.2.6
19. policy addressing the use of unique electronic signatures, where applicable. (TNI 4.2.8.4.r)	None

Commented [KG1]: I would suggest we mean procedure for how and when departures are allowed.

Commented [KG2]: I would suggest this should actually require a procedure for how/when to use electronic signatures

Attachment E:

Module 2 Standard Update - Summary of Suggested Changes

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, such as sample receipt, sample	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.

Original Text	Suggested Change	Justification
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;	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.

Original Text	Suggested Change	Justification
v. summary of the method; 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	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
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 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.

Original Text	Suggested Change	Justification
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 recordsMod on the analyst until they leave the companyify 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	What if there are no customer
ISO **7.8.2.1** Each report shall include at least the following information, unless the laboratory has valid	Prep Method- Is it required to be listed on final report and PT samples	Metals for instance

Original Text	Suggested Change	Justification
reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse: f) identification of the method used; **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: a) information on specific test conditions, such as environmental conditions; b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when: — it is relevant to the validity or application of the test results; — a customer's instruction so requires, or — the measurement uncertainty affects conformity to a specification limit; d) where appropriate, opinions and interpretations (see 7.8.7);	Reporting Qualifiers on analytes	

Original Text	Suggested Change	Justification
e) additional information that may be required by specific methods, authorities, customers or groups of customers.		
ISO 7.11.2 NOTE 1 In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems. NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated. ISO 6.4.1 ?	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.	

Original Text	Suggested Change	Justification
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; **ISO 7.2.2.1** The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items. NOTE 2 The techniques used for method validation can be one of, or a combination of, the following: a) calibration or evaluation of bias and precision using reference standards or reference materials; b) systematic assessment of the factors influencing the result; c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; d) comparison of results achieved with other validated methods;	Data Validation/Verification- Should that be required by TNI	

Original Text	Suggested Change	Justification
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		