

**Quality System Expert Committee (QS)
Meeting Summary**

October 21, 2019

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 11:30am Eastern by teleconference on October 21, 2019. Attendance is recorded in Attachment A – there were 13 members present. Associate Members present: Eric Denman, Carl Kircher, Rob Waite, John Gumpfer, Paul Junio, Michael Desmarais, and Rose Cruz.

Jessica distributed the minutes for July, August and September by email. She pulled them up on Webex for review.

A motion was made by Earl to approve the July 22, 2019 minutes as written. The motion was seconded by Jenna. Vote: For - 12 Against – 0 Abstain – 1 (Michelle). The motion passed.

A motion was made by Earl to approve the August 5 and 8, 2019 minutes as written. The motion was seconded by Jenna and unanimously approved.

A motion was made by Earl to approve the September 9, 2019 minutes as written. The motion was seconded by Alyssa. Vote: For - 12 Against – 0 Abstain – 1 (Michelle). The motion passed.

2. Membership:

There is room for another committee member since Pepa Sassin is no longer on the Committee.

Chris Gunning will serve until the end of this year. Nick Slawson from A2LA submitted an application.

Dale and Matt will be rotating off at the end of the year.

Membership will continue to be discussed during the November and December meetings.

3. Standard

Jessica reviewed the 2016 TNI Standard that was placed into the Standard update document the Committee has been using. She thinks all the 2016 TNI Standard language was transferred into the update document. The Committee still needs to look to see if there is any ISO/IEC 17025:2005 language that needs to be moved over.

Jessica, Kathi, Paul and Ilona will meet on Tuesday to figure out what to do with the numbering that changed too soon in the process and to discuss any remaining issues with the language inserted into ISO/IEC 17025:2017.

The Committee started today with Section 7 – Process Requirements. They looked for duplicate language and whether any language was moved to the wrong place. Webex was used to review the document (Standard Update – a document that is a combination of the 2016 TNI Standard and ISO/IEC 17025:2017).

The list of contents for SOPs should be looked at. The list doesn't need to be in a specific order and the SOPs just need to contain the information. John Gumpper mentioned that in the past there were 3 formats and a lab could use any of the formats.

Some ABs have mandated that certain sections had to be laboratory SOPs. Many expect to see them in the order in the Standard and with the titles given in the Standard. Jessica thinks labs should be able to define their own SOP section headings and that the SOP just needs to contain all the elements listed in Standard. Others were in agreement.

Sampling:

There is a note to consider FSMO standard when reviewing this section. Should it be referred to? Could the two standards be combined?

Rob Waite noted that he works at a permitted facility and their sampling is built into their permit.

Jessica read 7.4.1. Section 5.8.6 a) and 5.8.9b) from the 2016 Standard were added.

Jessica asked about where sample receipt belongs. Chris said it should be 7.4.1 in the ISO/IEC 2017 language - "Shall have a procedure for receipt, handling, etc ...". Right now the Committee has it in 7.4.3. John Gumpper thinks this is where it belongs because it relates to the actual checking of samples. Chris noted that 7.4.3 discusses when something goes wrong and this is why receipt belongs in 7.4.1.

John Gumpper noted that the parts about sample number should go under 7.4.2.

Jenna wasn't sure language from Section 5.8.7.1 (2016 Standard) should be deleted because of statement in 7.4.1. She doesn't think it requires documentation. It says they have to have a procedure, but not that it is documented. Michelle and Kristin agreed that it is not the same. Keep.

Alyssa noted that DoD is not planning to do any renumbering. Leave ISO as it is.

Robert suggested another option for consideration – put TNI and place it where it needs to be and then uniquely number the TNI language. Jessica noted that if this happens, it needs to start with the ISO language Section so it is clear where it belongs.

Kathi commented that labs have been reading the standard and seeing the word “documented” and “recorded”. They have ended up with elaborate document control systems for their records. This is because the TNI Standard is not clear whether someone needs to record information or document a process. She would like the Committee to get this straight so labs can interpret the Standard accurately. John Gumper noted that the ISO/IEC Standard is very good about stating where a document is needed on how to do something and then it states the lab “shall maintain records” when it wants a lab to write something down. Clean up making records vs documenting. Jessica agrees the distinction needs to be made.

Under 7.4.3 – she deleted TNI Standard section heading 5.8.7 and Section 5.8.7.1(The laboratory shall implement procedures for verifying and documenting).

She also deleted TNI Standard Section 5.8.7.4 – All documentation, such as memos, chain of custody, etc ... and moved to Records Section 8.4.1. Kathi noted that there are other records in Sample Receiving that are not discussed in the Records section, so maybe it does still belong in this section. Jessica noted this.

Remove TNI Standard Section 5.8.7.5 (7.4.3.5 in new document) if it is redundant. Possible duplicity - need to evaluate COC in above language.

Jessica ended at Section 7.4.3.5. The Committee will start again at Section 7.4.4.

Jessica asked that people continue to look for language that was not transferred from the 2016 TNI Standard - Module 2. She also asked that people continue to read the document and suggest movement of any language that may not be in the appropriate place. Send her an email with any findings or comments.

4. Action Items

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

5. New Business

Carl Kircher asked about the TNI Strategic Planning meeting that occurred last week. Paul and Ilona summarized a few highlights about the meeting.

6. Next Meeting and Close

The next meeting will be planned by email since the next meeting date is Veteran's Day. Ilona will send a Webex invitation the morning of the meeting. (*Addition: The next meeting was scheduled for 11/12/19 at 3pm Eastern.*)

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Jessica adjourned the meeting at 1:13pm Eastern. (Shari- motion Michelle – 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 Present	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Lizbeth Garcia Present (12:05pmEastern)	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsosha.state.or.us
Kathi Gumpfer (Vice-Chair) Present	ChemVal Consulting	2021*	Other	kgumpfer@chemval.com
Chris Gunning Present	A2LA	2021	Accrediting Body	cgunning@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	ESC Lab Sciences	2021	Laboratory	spfalmer@esclabsciences.com
Dale Piechocki Present	Eurofins Eaton Analytical	2020	Laboratory	DalePiechocki@eurofinsUS.com
William Ray Present	William Ray Consulting	2020*	Other	Bill_Ray@williamrayllc.com
Amber Ross Present	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Matt Sowards Absent	ACZ Laboratories, Inc.	2020	Laboratory	MattS@acz.com
Michelle Wade Present	Wade Consulting	2021*	Other	michelle@michellefromks.com
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	
67	Send DRAFT Technical Manager Language to the NELAP AC.	Jessica	10/1/19	

