

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

July 22, 2019

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 12:10pm Eastern by teleconference on July 22, 2019. Attendance is recorded in Attachment A – there were 10 members present. Associate Members present: Carl Kircher and Paul Junio.

The May 2019 minutes were distributed for review and Jessica pulled them up using Webex. Michelle made a motion to accept the 5/13/19 minutes as written. The motion was seconded by Earl and unanimously approved.

The June 2019 minutes were distributed for review and Jessica pulled them up using Webex. Earl made a motion to accept the 6/10/19 minutes as written. The motion was seconded by Michelle and unanimously approved.

2. Standard Interpretation Request (SIR)

SIR 350 was sent to the Committee on 7/9/19. This is a new SIR. After review and discussion, the following response recommendation was made:

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.2.6.2 C

Describe the problem:

Do all criteria (i, ii and iii) listed need to be met in order to qualify under experience or is one of the items sufficient to qualify as meeting the conditions for the requisite experience?

Committee Comment (if any): None

Response:

Yes, all three conditions listed in 2009 TNI Standard V1M2 5.2.6.2 C apply to this exception.

A motion was made by Earl to approve the response as written above. The motion was seconded by Kathi and unanimously approved.

Jessica will send the response back to Lynn Bradley.

3. SIR Table Review

Jessica pulled up the copy of the Summary Table that Paul Junio sent right before the call. There was some confusion on what needed to be done to the table. Ilona reminded the group that the tab in the Excel spreadsheet with Nicole's (PT Expert Committee, Chair) table has been accepted by Jerry. The Committee needs to do the same thing.

Paul commented that a "No" means nothing was done in the 2016 Standard to address the item. A change was made in the past and nothing needed to be done in the 2016 Standard.

Jessica clarified that she wants to review these SIRs and decide which ones should be discussed in Jacksonville for possible updates in the next Standard. The table should provide this information, but it doesn't. She and Paul will go back through the table before the meeting in Jacksonville and provide an update.

(Addition: Paul sent the following email on 8/5/19 to clarify what should be done with the summary:

Looking at Jerry's comment, I think we would change the answer to many of the 'active and relevant' from Yes to No. Relevance is where many of these become no – I was looking at these thinking more about 'active', in that QS didn't do anything specific to address these points.)

4. ISO/IEC 17025:2017 Standard Update

Jessica pulled up the 2016 Module 2 Standard. She also pulled up the DRAFT the Committee worked on in Spring where the 2016 TNI language was pulled into the new ISO/IEC 17025:2017 Standard. Paul commented that the DRAFT includes the reference to the original place the TNI language came from in the 2016 Standard. He did do some renumbering, so made sure the original reference is clear. Paul noted that the ISO/IEC 17025:2005 language was not carried over into the DRAFT.

Jessica would like to review the DRAFT and see where additional TNI language might be needed to clarify ISO/IEC language.

Ilona commented that the FAC did something similar to what QS did, but they moved all the language – TNI and ISO/IEC 17025:2005. There may be some ISO/IEC 17025:2005 language that will need to be kept. This language needs to be added to the DRAFT the Committee is looking at today.

Ilona suggested that if Paul moved all the TNI language over into the new ISO/IEC 17025:2017 Standard, the Committee could start by looking at the language moved to see if it is still appropriate with the new ISO/IEC text. There may be some instances where the new ISO/IEC Standard covers an item that previously was only TNI text – the TNI text would be deleted because it is now duplicate language. There may be items that are new to the ISO/IEC Standard and TNI needs to add clarification language. Another example might be TNI language that was placed into the new ISO/IEC Standard, but the Committee now thinks they put it in the wrong place and will choose to move it. Once this is done ... go back to the ISO/IEC 17025:2005 language in the 2016 TNI Standard and decide what to move over. This plan only works if all the TNI language was definitely moved into the DRAFT Standard. We need to be sure to keep the original references to the 2016 TNI Standard so we have a starting point.

Review:

5.5.c. – It is a comment to remember something someone suggested considering.

Throughout the document, Paul inserted comments for consideration by using brackets around the language or highlighting the language.

6.2.2.1 (Technical Manager) will not be discussed today because there is an agenda item in Jacksonville on this topic. Exceptions to the technical manager requirements will be kept at this time in the DRAFT.

Chris thinks equipment should go under 6.4.6. Jessica moved the language.

Paul thinks there should be some sort of a statement under 6.4.6. to point to the modules for module specific equipment. Maybe its 6.5.6.1. It came from the old Section 5.5.1.3.

7.2.1.1 Concerns were raised about the note. Kathi noted that it is a Note. They aren't required anyway. Just leave it. Paul is curious if the document referenced in the note needs to be added as a reference in the Standard. This will be discussed later.

7.2.1.2 – Paul thought maybe some language could be added to clarify what should be in Administrative SOPs. Should the different types of SOPs be clarified. Kathi proposed that maybe labs don't want to have all the 23 elements in their SOPs. Perhaps the requirements in SOPs should not be so specific – maybe they want more SOPs and not have everything in one SOP. If this wording changed and the flexibility is there, Administrative SOPs would not be a problem. Ilona asked if making this change makes it harder for assessors. She said it would, but it is important that the lab function better.

Jenna commented that states do usually allow a lab to reference other documents in their SOPs. Kathi noted that usually the references turn out to be outdated and this turns into a deficiency.

Jessica noted that is a topic that will need more input. Ilona noted that this is the type of item that needs to be included

7.3.3 – Define responsibility of sampling vs subsampling and impact on labs.

Numbering will need to be corrected as the real work begins on the Standard.

7.4.2.1 and 7.4.2.1.i – Needs to be striked out because it duplicates ISO/IEC language. Need to make sure documentation is addressed. Notes added to remember.

7.4.3 – Some TNI language stricken where duplicated.

7.5.1 – 4.13.3 a) There may be some repetitive language, but this needs to be looked at more closely before it is deleted.

This completes the initial review of Section 7. Section 8 will be reviewed in Jacksonville during the Thursday meeting. There will be a phone available for this part of the meeting.

Jessica will send a copy of the work done today to the Committee members.

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 in Jacksonville, Florida the first week of August. There will be a meeting on Monday form 1:30-5pm Eastern and Thursday at 9-12. There will not be a teleconference in August. The next teleconference will be on 9/9/19 at 1pm Eastern. . Ilona will send a Webex invitation the 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 1:40pm Eastern. (Earl- motion Jenna – 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 Absent	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 Absent	ESC Lab Sciences	2021	Laboratory	spfalmer@esclabsciences.com
Dale Piechocki Present	Eurofins Eaton Analytical	2020	Laboratory	DalePiechocki@eurofinsUS.com
William Ray Absent	William Ray Consulting	2020*	Other	Bill_Ray@williamrayllc.com
Amber Ross Absent	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Pepa Sassin Absent	US-EPA Region III	2022*	Other	Sassin.Pepa@epa.gov
Matt Sowards Present	ACZ Laboratories, Inc.	2020	Laboratory	MattS@acz.com
Michelle Wade Present	Wade Consulting	2021*	Other	michelle@michellefromks.com
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
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	

