

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

January 13, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 3pm Eastern by teleconference on January 13, 2020. Attendance is recorded in Attachment A – there were 11 members present. Associate Members present: Chris Fuller, Carol Barrick, Debbie Bond, Eric Denman, Jeanette Hernandez, Joe Manzella, Linda O'Donnell, Paul Junio, Rachel Van Exel and Robert Waite.

Jessica distributed the minutes for December and pulled them up on Webex for review. A motion was made by Earl to approve the December 9, 2019 minutes as written. The motion was seconded by Jenna. Vote: For - 11 Against – 0 Abstain – 0. The motion passed.

2. SIR 363

Chris and Lizbeth agreed with Kathi's first attempt at responding to the SIR.

4.3.1 General: The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

4.3.2.2 The procedure(s) adopted shall ensure that: a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

Because the TNI standard contains specific requirements that laboratories must address, and because these requirements are not universally available from other sources, yes, an authorized edition of the appropriate TNI standard revision under which the lab holds accreditation must be available within the laboratory's controlled document system.

A motion was made by Earl to approve the response to SIR 363 above. The motion was seconded by Lizbeth and unanimously approved.

Jessica will send the final response to Lynn Bradley (Program Administrator, LASEC). She will also ask if Chris Gunning's name needs to remain in the question.

3. Standard

Ilona talked to Jerry and ISO/IEC 17025:2005 language needs to be referred to as 2005 language if it is something we want to retain. We can use the concept without needing to refer to 2005, but if we use the language ... we must reference it.

Ilona will talk to Scott about sharing what FAC found did not carry over from ISO/IEC 17025:2005 to 2017. Jessica will prepare a list of omissions the committee can look at their next meeting.

Jessica brought up a copy the combined language and asked the Committee to look to see what changes need to be made to the Standard. This information will be used to begin preparing for the Public Webinar to get input on needed changes to the Standard.

Ilona noted that reviewing the SIR table would also provide insight into needed changes to the Standard.

Jessica asked if definitions should be removed? All ISO/IEC definitions definitely need to be left in. TNI isn't sure how they are implementing definitions yet.

Suggested Changes to Standard:

- Need to develop a definition for Quarterly.
- Review TNI definition for Annual and update as needed.
- Ilona noted there may be some changes to some of the field related definitions. A Field Task Force has been working on these.
- Debbie Bond suggested looking at definition for Controlled Document.
- Jessica would like to define Duplicate.
- Technical Manager (will be discussed in Newport Beach).
- Personnel section will need updates. Add Technical Manager, Quality Manager.
- Technical Manager Exceptions need to be reviewed and updated as needed.
- Define Support Equipment vs Analytical Equipment. Make sure the definition of Support Equipment makes it clear when it is not analytical equipment. (Section 5.5.13.1 of the 2016 Standard is a starting point.)
- Note: Keep in mind that the other Modules may need to be referenced in some sections of Section 6.4, 7.2 and perhaps in other areas of Module 2.

- Note: Need to look at document vs. record throughout the Standard.
- Look at language describing what is in an SOP. Is it too proscriptive?
- Look at better defining unique identifiers for samples (2016 Section 5.8.7.3 a) iii) and 5.8.5 a)). There have been SIRs.
- Sample Receipt Protocols should be looked at. Questions have arisen in the past.
- Look at language surrounding identification of results that are not NELAP certified. When can and can't you use the TNI logo? (2016 Standard 5.10.11 c) Can language be any more clear since there still appears to be confusion?
- Addition of Quality Manual back into 2017 requirements.
- Review content requirements of Quality Manual. Is it too proscriptive?
- Need to look at Corrective Action and root cause analysis procedures and missing language from ISO/IEC 17025: 2005.
- Internal audits (ISO/IEC 17025:2017 8.8, 2016 Standard Section 4.14)

Jessica will start taking a look at SIRs to see what needs to be considered in the Standard. Ilona will also share a complete list of SIRs received – accepted and rejected. This may give Jessica some more ideas.

Note: Black language will need to be italicized as we get started on the Standard. It is very important that it is clear what is ISO/IEC language.

She also encouraged people to continue to review the Standard and look for needed changes.

4. Committee Membership

Chris Gunning is stepping down from the Committee early.

There are 4 candidates being considered today based on the review and vote of all candidates by email:

Michael Demarais Lab
 Donna Ruokonen Lab
 Tony Francis Other
 Nicholas Slawson AB

If these candidates are voted in, committee membership will look like: 5 – Lab 6 – AB
 4 – Other.

One comment was to add lab people that are not necessarily QA people. Need business administrators too. Committee members are asked to keep an eye out to find someone when there is an opening again. The Committee also needs to look for small labs in the future. Jessica will be leaving a smaller lab and moving to a larger municipality.

A motion was made by Earl and seconded by Shari to approve Michael Demarais, Donna Ruokonen, Tony Francis and Nicholas Slawson for membership to the Quality Systems Expert Committee. The motion was unanimously approved and membership will begin after Newport Beach meeting.

Jessica will notify all new members that they have been approved. She also thanked the members rotating off - Chris, Matt and Dale.

5. Action Items

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

6. New Business

- There will be a closed door working session in Newport Beach to discuss Technical Manager.

7. Next Meeting and Close

The next teleconference meeting will be a short meeting on February 10, 2020 at 1pm Eastern. Ilona will send a Webex invitation the morning of the meeting.

The Committee will be meeting face-to-face in Newport Beach, CA on February 3rd and 4th. There will be no phone service.

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

Jessica adjourned the meeting at 2:44pm Eastern. (Earl- motion Lizbeth – 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	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	Pace Analytical Services	2021	Laboratory	shari.pfalmer@pacelabs.com
Dale Piechocki Absent	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 Absent	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	
68	Send note to Lynn about status of LAB language requested to be added.	Jessica	1/10/20	
69	Prepare membership candidate list for email voting to develop a slate of candidates to vote on in January.	Jessica	1/10/20	Complete
70	Work on SIR 363.	Jessica	1/13/20	Complete
71	Send final response to SIR 363 to Lynn Bradley.	Jessica	1/20/20	
72	Start reviewing SIRs to add to list of possible changes to the Standard.	Jessica	2/2/20	
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	
74	Notify new members about membership. First meeting as members will be 2/10/20.	Jessica	2/3/20	

