Quality System Expert Committee (QS)
Meeting Summary

June 11, 2018

1. Roll Call:

   Paul Junio, Chair, called the meeting to order at 1pm Eastern on April 9, 2018 by teleconference. Attendance is recorded in Attachment A – there were 9 members present. Associate Members present: Nick Haring, Silky Labie, Eric Davis, Eric Denman, Carl Kircher, Gil Dichter, Tyler Sullens and John Gumpper.

   The May minutes were distributed by email. A motion was made by Jessica to accept the 5/14/18 minutes as written. The motion was seconded Kathi and unanimously approved.

2. Louisiana Meeting

   There is no update yet on the agenda for the special meeting in New Orleans.

3. ISO/IEC 17025:2017 and Revision to Module 2

   The committee is now re-reading the language that has been placed into the different sections of the new DRAFT Standard to make sure it has been properly placed. Once the committee is done with this, it will begin to add and change language as needed.

   Paul started on Webex with Section 5.6 of ISO/IEC 17025:2017. Last time language was added for the Quality Manager and Technical Manager. The committee reviewed the Quality Manager language and will now begin reviewing the Technical Manager language. This is from Section 4.1.7.2 (V1M2) of the current TNI Standard.

   Paul asked if anyone knows of a Technical Manager of more than one laboratory. Shari noted that John Mitchell is listed for more than one lab. City of San Diego also has satellite labs that the technical manager is responsible for. This is something California is working on to figure out how to apply the TNI Standard in this area.

   Paul asked if there are multiple ABs involved in any of the organizations where a technical manager is responsible for more than one location. Jessica is the technical manager for a lab in Kansas and a lab in Oklahoma. What happens if one AB is OK with it and another is not? She goes down to Oklahoma once a month and she is always available. The AB did not consider her to be missing since she was available. Since no one has complained about this, the committee will move on.

   Paul noted that numbering references will need to be corrected as the committee starts going through the document more closely. He is adding some notes with corrections.

Qualification requirements are currently in Section 5.2.6.1 of the 2016 Standard (V1M2).

Nick commented that he understands that California will be changing some of the Technical Manager requirements. Jacob noted that a technical manager can be responsible for more than one lab in California. The qualifications will include some exceptions to TNI requirements. There will be some allowances for wastewater certifications (CWEA) instead of only allowing the education requirements. There are already some allowances in the Standard for this, but it is not for all types of laboratories (private and public). Jacob thinks the technical experience may be an issue too. They felt that once someone received the CWEA certificate, they should be able to act as a Technical Manager. The certificate does not require specific experience.

Paul is hoping to get some guidance on the Technical Manager requirements in New Orleans. In the past, exceptions to education requirements have not been listened to. He is not sure how much time to work on this before getting some guidance on what people are willing to look at. He feels he needs more direction before any language is worked on.

Silky asked if the CWEA certificate requires any type of testing? Nick and Jacob were not sure. They will reach out to get more information before the next meeting.

Paul asked for some initial concerns about language in this section. Is it organized clearly. There have been SIRs in the past to get clarification. Maybe the requirements could be re-formatted and broken up a little to show the separate requirements. Make it clear what is "either/or". Use bullets. There was agreement that better formatting would help. Paul added some formatting changes to the DRAFT document.

Paul moved on to the Microbiology requirements for the technical manager. Gil thinks the parameters listed are limiting. They don't encompass everything. Silky noted that this language is the same as when it was first introduced and needs to be upgraded and modernized. It needs to cover more types of laboratories. Gil also thinks experience should be considered beyond only education. Paul will send these concerns to Robin and the Microbiology Expert Committee. He would like them to propose language to the Committee.

Paul moved on to look at the Asbestos and Radon requirements for the technical manager. He made a few changes to the Draft document. The multiple requirements in the Technical Manager sections have been broken down into individual bullets to more clearly delineate each required piece of education and/or experience.

All of this will be looked at further after New Orleans.

Language was added about the Quality Manager being responsible for updating the Quality Manual.

Paul moved back to the ISO/IEC 17025:2017 updated DRAFT Standard. Support equipment language has been added. Working on Section 5.5.13.1 – Support (V1M2 – 2016).

Silky does not think a beaker is a dispensing device. Kathi asked if the term volumetric measuring device might be more appropriate. A graduated cylinder could be determined to be a volumetric measuring device. The determining factor is when the device must measure an "exact" amount.

Paul asked if the list is accurate. Kathi asked if a list is even needed. Remove the examples. The committee looked at the language and proposed some changes to the DRAFT Standard.

Kathi commented that some of the information in this section is about traceability. Should it be moved to traceability requirements (Section 6.5 of the ISO/IEC 17025:2017)? Paul thinks it should be moved. Paul moved it under Section 6.5.4. in the ISO/IEC 17025:2017.

Tyler would like to be sure the frequency for calibration checks is clearly defined and he would like to do away with the term glassware. Mechanical devices make sense to check more frequently, but he thinks a glass flask does not need to be checked this frequently. Initial versus ongoing calibration checks should be clearly defined too.

Kathi commented that plastic ware should be taken into consideration. Dale noted that it was determined that getting Class A grade plastic ware was not the same as getting something Class A certified. ASTM does not recognize anything other than borosilicate glass as Class A. Kathi said she has seen plastic ware with an A on it.

Ilona noted that was discussed in a recent training Marlene did on glassware. It was an excellent training. She confirmed that there was not Class A plastic ware, but the committee could go back and check with her. Michelle remembered the speaker brought in to a TNI meeting to discuss this and it was also verified that there is no real Class A non-glassware.

Paul asked Kathi to send him a picture of Class A non-glassware. In Paul's experience the catalogs use language that is actually different from Class A. It was calibrated against a Class A device. Dale noted there was also an issue with autoclaves – only glassware holds it volume. Paul will reach out to Marlene for additional information. Paul will also check on the status of non-glassware SIR. [EDITOR's NOTE – SIRs have been approved which require non-glassware to be verified on a quarterly basis]

Tyler will work on some proposed language that he would like to see added to allow Class A like glassware to be checked less frequently. He has Corning labware that is not glass and is marked as Class A.

4. Action Items

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

5. New Business

None.

6. Next Meeting and Close

The next meeting is planned for July 9, 2018 by teleconference from 1-3pm. 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.

Paul adjourned the meeting at 2:30pm Eastern. (Jessica - motion Shari – second, unanimous approval).

Attachment A

Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Paul Junio (Chair) **Present**	Northern Lake Service	2019	Laboratory	paulj@nlslab.com
Jessica Jensen (Vice Chair) **Present**	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown **Absent**	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Lizbeth Garcia **Present**	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Kathi Gumpper **Present**	ChemVal Consulting	2021*	Other	kgumpper@chemval.com
Chris Gunning **Present**	A2LA	2021	Accrediting Body	cgunning@a2la.org
Earl Hansen **Absent**	Retired	2021*	Laboratory	papaearl41@hotmail.com
Sara Hoffman **Absent**	Kansas DHE	2019*	Accrediting Body	sara.hoffman@ks.gov
Jacob Oaxaca **Present**	California State Water Board	2019*	Accrediting Body	Jacob.Oaxaca@Waterboards.ca.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 **Absent**	William Ray Consulting	2020*	Other	Bill_Ray@williamrayllc.com
Matt Sowards **Absent**	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	
52	Send copy of Chris and Paul's presentation to Jerry.	Paul/Ilona	5/15/18	
53	Look into CWEA certification requirements.	Nick Jacob	7/9/18	
54	Send request to Robin and Micro Expert Committee to look at Technical Manager requirements and propose changes in the language back to QS.	Paul	7/9/18	
55	Send a picture of a Class A non-glassware item.	Kathi	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	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Update charter in October 2016.	n/a	Delayed. Waiting for format from Policy Committee.