

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

November 12, 2018

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 1pm Eastern on November 12, 2018 by teleconference. Attendance is recorded in Attachment A – there were 8 members present. Associate Members present: Charles Hardtke, Chaney Arend, Patty Carvajal, Linda O'Donnell, Jeanette Hernandez, John Gumper, Eric Davis, and Dorothy Love.

There was no quorum at the start of the meeting so the September and October minutes will be reviewed and voted on by email or at the next meeting.

(Addition:

Voting took place to approve the September and October minutes by email, but voting was started before a motion and second were made. A new vote was taken on 1/4/19: A motion was made by Chris to approve the 9-10-18 and 10-15-18 minutes as written. The motion was seconded by Jessica.

Vote:

Paul – For (1/4/19)

Jessica – For (1/4/19)

Chris – For (1/4/19)

Dale – For (1/4/19)

Michelle – For (1/4/19)

Earl – For (1/4/19)

Jenna – For (1/4/19)

Shari – For (1/4/19)

Bill – Abstain (1/4/19)

Matt – Abstain (1/4/19)

The motion passed and the minutes were approved.)

2. Status Update on ISO/IEC 17025:2017 Impact on Standard

Paul noted that the TNI Board of Directors has formed a subcommittee to look at the direction TNI should take in the next update of the TNI Standard. There are people that feel TNI should take the plunge and update to the 2017 version of ISO/IEC 17025 and others that think a step approach would be less disruptive to the laboratory community. The subcommittee is made up of a variety of people with different views. They will prepare a recommendation to the TNI Board of Directors.

Kathi thinks both options could work. She asked if people are looking and commenting on the new DoD document. They added the 2017 requirements to it. She does not think either option will be easier on the lab community.

3. Technical Manager

Paul thought it would be helpful to start looking at some of the bigger issues that have been raised about the latest TNI Standard rather than starting to get into the details of the Standard while the subcommittee and the Board are having their discussions. Technical Manager requirements has been a big issue for many labs. Paul provided the committee with 4 handouts that include the notes from the open forum in New Orleans, copies of comments he has received on the current language and some information on what other states are doing. Paul has also shared various State requirements in previous meetings.

Paul opened the Standard so the Committee could look at the current requirements. He then opened the document with California's requirements and started to review the language.

Looking at California, Michelle noted that Ohio has their own program for how to "credential" analysts. Kathi commented that maybe the technical assessor trainings could provide something similar to California. Perhaps TNI could look at putting something like it together.

Michelle noted that Florida asked their assessors to look closer at whether the Technical Director qualifications are being met. The assessors don't make any final decisions, but they turn it over to the Florida Department of Health to make any decisions on whether a lab is meeting these requirements.

California has an option for a temporary Technical Director while a new Technical Director is being hired. This can total as much as 180 days. Paul thinks this is too long and questions if it is OK for someone that does not meet all the requirements to step in for that time period.

There is also a section describing that the Department can disqualify a lab supervisor. Paul questioned whether something like this could go into the TNI Standard because there may be AB specific procedures that might be hard to combine into something everyone can comply with.

Other states include exemptions based on specific criteria.

Paul asked if there is a new path this Committee can take that might work better for the labs and that the ABs would not feel compromises the quality of the data?

Linda noted that when Pennsylvania put their requirements in place in 2017 they were not as stringent as what was there before. She asked why TNI is doing the same thing. She

thinks people have put a lot of energy into meeting the requirements and now they don't need to have done everything they did. Paul thinks that possible exemptions may indeed make the TNI Standard less stringent. He noted that some of the correspondence on this topic by email makes the argument that the lab should be able to determine the qualifications needed within an individual lab. Paul thinks this option may be an issue for ABs. that would be looking for something more auditable.

John Gumpper commented that there are many people in the environmental community that think some of the strict educational requirements are an unnecessary hurdle for some of the people and there is also no guarantee that the person you put in charge will be good at what they are doing. This has to be balanced with the AB's need to have qualified people in place for things like Drinking Water where there are strong enforcement rules.

Eric, as a lab, doesn't like that the ABs think they know better who should be hired. If the system is working, the qualifications don't matter. They have had issues hiring people with all the right qualifications. They have had people rejected because the AB did not think it was a good enough chemistry class. Geochemistry was not considered a chemistry class by that AB.

Paul noted that the challenge for this Committee is coming up with something that works for both sides ... lab and AB.

Linda commented that it may work most of the time to have people with less stringent training, but what happens when something goes wrong? They need a depth of knowledge or experience. This usually falls on the supervisor. How should a supervisor be trained to be prepared for these unexpected events.

Dale commented that the Standard does not really address experience. It emphasizes credit hours. There are some exceptions for new labs, but replacing someone makes it difficult to find someone because they can't be grandfathered in.

John Gumpper's personal opinion is to look for competence. He thinks the ABs that are concerned about this are worried about enforcement. Paul asked what would make them less concerned. John thinks the Committee needs to talk to the ABs and see if they can enforce from the requirement that the quality management system has to be effective. John thinks we are now 20 years down the road and not everyone has embraced the concept of management systems. This is why we have a lot of specific requirements in the TNI Standard like technical director requirements.

Kathi noted that when the Standard was originally written it added specific degrees that were required. Education systems are changing and there are new courses and disciplines being added that may or may not apply to this. We need more flexibility. Dorothy Love strongly agreed with this.

Dorothy commented that the ABs are not consistent in how they look at experience. Some look at exactly which methods were run, but this makes it difficult to hire people for some

of the new technologies that are coming out. They have very skilled people that aren't being approved. We need to set this up to accommodate new degrees, new technologies, etc ... Numerous people agreed with this. We need to possibly define what is meant by experience – specific methods, technology, discipline? How should this be done?

Dorothy mentioned that in her company they had to put new systems in place to address the new technologies where people could be independently trained because there was no one who could sign-off on these training records. They couldn't be trained by anyone because it was new.

John Gumpfer commented that the new ISO/IEC Standard allows the lab to define these kinds of things. What Dorothy did falls into this.

How do you convince the ABs that the lab's can do this properly? It was asked ... why would a lab put someone in charge who could not properly run the lab. Paul noted he overheard a non-TNI agency person make a comment that you have to be involved with a State to have any care of the environment or health and safety of the public. If you don't work for a State ... you don't really care. They essentially think labs are after the dollar.

It was also commented that there are labs out there that would not hire a qualified person.

Paul asked if people would please send ideas to the group as a whole. Maybe we can piggy-back off each other's writing. Paul will try to put something together to spur the conversation.

3. Action Items

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

4. New Business

None.

5. Next Meeting and Close

The next meeting will be planned be on Monday, December 10th 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.

Paul adjourned the meeting at 2:27pm Eastern. (Earl - 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) Absent	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown Absent	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 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 Absent	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Jacob Oaxaca Absent	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 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	
58	Look into SIR 154 Response. Incorrect response may be posted.	Paul/Ilona	9/10/18	

