

## Quality System Expert Committee (QS) Meeting Summary

September 9, 2019

### 1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on September 9, 2019. Attendance is recorded in Attachment A – there were 7 members present. Associate Members present: Carol Barrick, Chaney Arend, Eric Denman, Carl Kircher (off call at 1:30pm Eastern), Rob Waite, Debbie Bond, Robin Cook (off call at 2:05pm Eastern) and Cindy Gaddis.

The minutes will be voted on by email or at the next meeting.

### 2. Overview of Jacksonville Meeting

There were two meetings for Quality Systems. The first agenda included Technical Manager Requirements, SIRs and an open floor discussion. The second meeting covered information on WET Technical Manager Requirements and work on the DRAFT Combined Standard.

The Committee will send DRAFT Technical Manager requirements to the NELAP AC by October 1, 2019. They will review and discuss the language and send comments and recommendations before the Long Beach meeting. The language sent does not have to be final. Comments from the meeting in Jacksonville will be shared and this will be worked on today.

The Committee needs to go back before we go forward on the Standard. We only transferred TNI language into the new ISO/IEC 17021:2017 format. The changes made to the Combined Standard so far have not all been tracked well and we need to make sure there isn't any language from the 2005 ISO/IEC Standard we want to keep. The document needs to be cleaned up so we have a better starting point to track changes.

### 2. Technical Manager

Jessica reviewed the current text from Microbiology, Radiochemistry and Chemistry (prepared by Quality Systems). Jessica reached out to Val and the Chemistry Expert Subcommittee and they will review it and provide comment.

The feedback received at the meeting was that it would not be approved by the NELAP AC if the 6<sup>th</sup> bullet is left in. Amber noted that it has not been officially discussed by Pennsylvania. NJ hasn't done any detailed review either.

It open up ABs for too much liability if they did something like this. They would have to defend their decision every time if they do make allowances.

Jessica noted that some ABs do make some allowances, but this cannot be in the Standard.

#5 – What is an objective way to evaluate experience?

Jessica noted that Amber sent the following comments by email on 7-8-19:

- I'm still not entirely sure why we'd include everything but astronomy.
- Our concern is that we are trading experience for credits. Credits are objective and experience is subjective. How can we come up with an objective way to evaluate experience? For example, one AB might say you have experience because you worked at the lab, while another AB might say your experience only counts if you were the analyst. There needs to be a serious discussion on what ABs can and cannot consider to be experience and how the ABs are expected to evaluate that experience. If this ever was approved, we believe there should be a cap on how many years you can trade for credits.
- This goes along with the experience questions/concerns in #2. The person from Radiochemistry that was on one of our calls made a point that someone that had 10 years of experience with GC would not then be approved to be a Technical Director of an entire Organics department because they lack experience with GC-MS, HPLC, etc. That caveat should appear somewhere in the language.
- If we begin to take away the number of credits someone needs to become a technical director, is there any way we can put some degree of responsibility back on the analyst. For instance, Shimadzu offers training on their instruments. Could a requirement be added that your analysts need to have some sort of certification that they've been trained on that instrument?

How do we show that they have the experience? Maybe there could be a Technical Manager course that could be used to show the experience. Jerry noted that something like this could be done.

Robin – Should how they determine the increasing knowledge be in the AB Module instead of the Lab Module?

Michelle – The labs would need to do this, so it needs to be in Volume 1. They need to know what they are being assessed to.

Rob Waite – What if you have an industrial lab with limited tests? The criteria for this Technical Manager should be less than someone that has a lab doing Organic and Metals, etc ... Michelle commented that there is other language in the Standard – exemption section. This hasn't been discussed by the committee yet. This would cover Rob's issue.

Iлона suggested that the exemptions in Sections 5.2.6.2 be mentioned with the information being sent to the NELAP AC. This language still applies. Jessica will be doing this.

Jessica asked who would be using the language that Microbiology is developing for Technical Manager requirements? There would still be facilities that just do Fecal Coliform that will take advantage of the exemptions. Robin noted that the same question could be asked about the Standard today. Operators go through training and testing ... and they have experience requirements. This person would be qualified to run their tests. Robin noted that she has lab people and operators. The language applies to the lab people and the exemptions apply to the people with the operator licenses.

Jessica asked if anyone thinks anything in Section 5.2.6.2 needs to be changed, deleted, or added to before the language is sent to Chemistry for review.

Jessica asked what the group would like to send Chemistry. Should bullet #6 be left in? It needs to be clear that you need to petition all the ABs in bullet #6 – not just the primary.

Jessica will note in the letter that there has been some concern about #6, but we still want the feedback to make the comment official.

Jenna: Does “must” eliminate the use of the exemptions. This needs to be looked at. Maybe this bullet belongs down below.

Kathi: When we send the letter caveating bullet point #6 “in lieu of” – I suggest we phrase it that we recognize that we recognize that this language has been “controversial” in preliminary discussions, rather than that we see the language as “unacceptable”.

Jenna: Perhaps add Bullet #6 to below the exemption section. This removes the controversial bullet from the Technical Director requirements and treats it as an exemption. This makes more sense.

Paul read the new Radiochemistry language for bullet point #6 and people liked it. It seemed more doable. A consistent format is discussed. This wording should be placed into both the Microbiology and Chemistry wording for bullet #6.

Robin noted that the thought behind removing the language of bullet #6 is that if it is not strictly prohibited, it is allowed. Leaving the language in makes it harder for states to give exemptions.

Michelle – Legal liability. They (states) have to defend everything they do. All actions have to be handled legally – remove a lab from the program, etc ... The NGABs can pull an accreditation anytime.

Iлона suggested looking at Radiochemistry and see if any of their explanation of experience could be used in the Chemistry definition. Jessica will move some of it over.

There are two thoughts – is a college degree enough to make someone a technical director? Does working in a lab for 12 years with increasing number of methods and experience make someone a technical director?

Kathi asked if a course with an exam showing competency could be accepted. We haven't allowed for it in any of the language worked on so far.

Iлона asked if it could be added to the letter to get some input on the concept.

Send to Chemistry and Microbiology so they can work on it. She will send it to the committee and needs comments by noon tomorrow before she sends it to the committees.

Change the language a little from radiochemistry so that is not all new methods and techniques. What happens if there is only one method in a smaller lab? This needs to be considered.

Kathi thinks you need to strike “in a different analytical method” from the wording before it goes to Chemistry. Each year does not have to be a different technique. Maybe it needs to cover the breadth of what is on the laboratory's scope? Years of experience in two methods should be OK if that is all they do.

Jessica will send a copy of the work done on the Chemistry Technical Manager requirements to the Committee (Attachment D). She will ask for any comments and then send it to the Chemistry Expert Committee for final comment.

#### 4. Committee Membership

Jessica asked all associates to step off the call so the Committee could discuss membership. Committee members left on the call included: Jessica, Kathi, Jenna, Shari, Bill, and Michelle. Paul also stayed on the call as the Chair of the CSDP Executive Committee.

The Committee decided to replace one member on the Committee.

#### 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 on Monday, October 14, 2019 at 1pm Eastern. Ilona will send a Webex invitation the morning of the meeting. (*Addition: October meeting rescheduled to October 21, 2019.*)

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

Jessica adjourned the meeting at 2:37pm Eastern. (Jenna- motion Kathi – second, Unanimous approval).

Attachment A

**Participants**  
**Quality Systems Expert Committee (QS)**

Member	Organization	Expiration	Representation	Email
Jessica Jensen (Chair) <b>Present</b>	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown <b>Absent</b>	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Lizbeth Garcia <b>Absent</b>	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsosha.state.or.us
Kathi Gumpfer (Vice-Chair) <b>Present</b>	ChemVal Consulting	2021*	Other	kgumpfer@chemval.com
Chris Gunning <b>Absent</b>	A2LA	2021	Accrediting Body	cgunning@a2la.org
Earl Hansen <b>Late?</b>	Retired	2021*	Laboratory	papaearl41@hotmail.com
Jenna Majchrzak <b>Present</b>	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Shari Pfalmer <b>Present</b>	ESC Lab Sciences	2021	Laboratory	spfalmer@esclabsciences.com
Dale Piechocki <b>Absent</b>	Eurofins Eaton Analytical	2020	Laboratory	DalePiechocki@eurofinsUS.com
William Ray <b>Present</b>	William Ray Consulting	2020*	Other	Bill_Ray@williamrayllc.com
Amber Ross <b>Present</b>	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Pepa Sassin <b>Absent</b>	US-EPA Region III	2022*	Other	Sassin.Pepa@epa.gov
Matt Sowards <b>Absent</b>	ACZ Laboratories, Inc.	2020	Laboratory	MattS@acz.com
Michelle Wade <b>Present</b>	Wade Consulting	2021*	Other	michelle@michellefromks.com
Alyssa Wingard <b>Absent</b>	NAVSEA LQAO	2021*	Other	alyssa.wingard@navy.mil
Ilona Taunton (Program Administrator) <b>Present</b>	The NELAC Institute	n/a	(828)712-9242	<a href="mailto:Ilona.taunton@nelac-institute.org">Ilona.taunton@nelac-institute.org</a>

## Attachment B

### Action Items – QS Expert Committee

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
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	

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
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	





Attachment D: Chemistry Technical Manager Language - worked on during 9/9/19 meeting

Quality Systems-Chemistry

- a) Any technical manager of an accredited environmental laboratory engaged in environmental analysis shall be a person:
- i. with a bachelor's degree; and
  - ii. with twenty-eight (28) college semester credit hours of chemistry and/or biological science ~~natural sciences excluding astronomy~~; and
  - iii. with two (2) or more years of experience in the environmental analysis of environmental samples.
  - iv. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.
  - v. ~~1 year experience working in an environmental laboratory may be substituted for 4 credit hours. Multiple years of substitution should show increasing level of knowledge in environmental analyses (preparation and/or instrumentation).~~  
1 year experience working in an environmental laboratory may be substituted for 4 credit hours. Multiple years of substitution may be utilized, but each year substituted must be related to the learning of and proficiency across the scope of accreditation for analytical method/technique or instrumentation type. This will help ensure an increasing level of knowledge in environmental analyses (preparation and/or instrumentation) during that time period. No more than 14 hours total may be substituted – at least 14 hours must be from actual college courses.
  - vi. ~~In lieu of any of the above, the laboratory may petition the primary all applicable accrediting body, presenting the candidate's qualifications.~~ In lieu of any of the above, the laboratory may petition each body for which accreditation is sought, presenting the candidate's qualifications in a consistent format to each.  
(maybe add to end of 5.2.6.2)

## Microbiology

Any technical manager of an accredited environmental laboratory engaged in microbiological/biological analysis shall be a person:

- i. with a bachelor's degree; and
- ii. with sixteen (16) college semester credit hours of biological science to include at least one 4 credit hour course in general microbiology; and
- iii. with two (2) or more years of experience in the analysis of microbiological environmental samples representative of the analyses for which the lab seeks and maintains accreditation,
- iv. A master's or doctoral degree may be substituted for one (1) year experience.

- v. 1 year experience working in an ~~environmental~~ **microbiological** laboratory may be substituted for 4 credit hours.
  - a. Multiple years of substitution shall show increasing level of knowledge in environmental analyses (preparation, instrumentation and/or technology).
  - b. The 4 credit hour general microbiology **and a 4 credit hour biological science** course cannot be substituted with experience
- vi. In lieu of any of the above, the laboratory may petition all applicable accrediting bodies, presenting the candidate's qualifications to document competency.

#### Rad Chem

- a) Any technical manager of an accredited environmental laboratory engaged in radiological analysis shall be a person:
  - i. with a bachelor's degree; and
  - ii. with thirty-two (32) college semester credit hours of chemistry and physics; and
  - iii. with sixteen (16) college semester credit hours of radiochemistry; and
  - iv. with two (2) or more years of experience in the radiological analysis of environmental samples.
  - v. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.
  - vi. 1 year experience working in an environmental radioanalytical laboratory may be substituted for 4 credit hours. Multiple years of substitution may be utilized, but each year substituted must be related to the learning of and proficiency in a different analytical method/technique or instrumentation type. This will help ensure an increasing level of knowledge in radiochemistry analyses (preparation and/or instrumentation) during that time period. No more than 24 hours total may be substituted – at least 24 hours must be from actual college courses.
  - vii. In lieu of any of the above, the laboratory may petition each body for which accreditation is sought, presenting the candidate's qualifications in a consistent format to each.