

**Quality Management System Expert Committee (QMS)  
Meeting Summary**

**November 14, 2022**

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on November 14, 2022. Attendance is recorded in Attachment A – there were 11 voting members present. Associate members present: Rachel Van Exel, Tiffany Shaw, Tammy Kreutzer, Fida Kased, Doug Kablik, Annmarie Beach, Kathleen Loyd, Cody Danielson, Debra Zeller, Jeanette Hernandez, Alma McAmmond, Ty Atkins, Karna Holquist, Eric Davis, Paul Junio, Tom Fritz, Lisa Parks, Lizbeth Garcia, Kristin Brown and Brian Lamarsh.

2. Technical Specialist Language

The Committee met October 24<sup>th</sup> and made progress on language (see October 17, 2022 minutes addition). Debbie also met with Terry Romanko (Chair, Radiochemistry Expert Committee) and Ilona to discuss the Radiochemistry language.

Debbie reviewed the Technical Specialist language:

Section 4.1.7.2 – Remove language: who has/have the education and experience as specified in Section 5.2.5.1 or 5.2.6.2. It simplifies the language.

Section 4.1.7.2.a – Should this include that the Technical Specialist can stop work? It was questioned whether it is too proscriptive? Let the lab decide who should be approved. Each lab may run differently and perhaps some require “stop work” needs to go through the Quality Manager. Debbie looked at Section 7.10 (Nonconfirming work) to see if that is better place to put this type of language. It could also go into Section 6.2 – Personnel. It was noted that this should be written as “at a minimum” so a lab could have people beyond the Quality Manager and Technical Manager with authority to stop work. Section 6.2.6 is a good section because it includes language about specific authorizations. It should only be in one place. Debbie added a note to add it to the DRAFT Standard to Section 6.2.6.

Section 4.1.7.2 - Would it be OK for a lab to just notify the AB if there is a change in Technical Manager? Not require that the AB has to respond in any specific way. Leave wording as it is in the 2016 Standard. Tony commented that with all the virtual capabilities this happens less now. There was agreement with the language.

## Section 5.2.6.1 -

### Asbestos

Section i.3 – Debbie checked into this and proposed the language marked as an addition after getting clarification on what Asbestos committee intends for the term ‘supervision’ and discussing how best to convey the intent with Mitzi Miller. This language will be extended to ii as appropriate. There was agreement.

### Chemical Testing

“Representative technologies” is being questioned. This needs to be further discussed.

Pennsylvania would like to see a degree only substitute for 3 months of experience instead of 6 months as written. Tony Francis (Vice-Chair, Chemical Testing) thinks this is excessive. There was agreement an this will not be changed.

### Radiochemistry

“Radiochemistry laboratory” or “radiochemical testing laboratory” are the same. Debbie will confirm this with Terry Romanko (Chair, Radiochemistry Expert Committee).

Tony asked how do you assess to i.4. How do you know what their experience is in another laboratory? Use the resume? Leave as is. We’ve always allowed experience at other labs.

### Toxicity Testing

No additional language.

## Section 5.2.6.2 – Exceptions

Debbie is fine with leaving them as they are, but there were comments on Section 5.2.5.2.ii regarding technical specialists with no degree. PA will not accept this section.

Ilna asked if we only have PA’s comment because of their involvement in the Committee or are there other states that feel the same way. Should we be requesting comment from the other States and/or NELAP AC? We should reach out to see if this a show stopper. Debbie isn’t sure how to change this if it is a show stopper. The question could be how do we change this if there is a problem? Ask for some direction. We can reach out to Lynn to see if we can get on one of the upcoming NELAP AC agendas. Debbie would like to do this before she adds this language to the DRAFT.

It was commented that States currently add things to their regulations. Is this an out for a state that doesn’t hold things up. The language being looked at is that a lab may seek a waiver. A state still has the ability to turn it down ... so perhaps this language works?

Kristin reminded people that when this was previously discussed, it was noted that a lab would have to approach each state for the waiver. It would not just go to the Primary AB. This does impact reciprocity.

Paul asked if this not allowed by PA's regulations or is this just something they don't like.

Lizbeth noted that Oregon would just ask for the lab's scope in considering secondary accreditation.

Debbie emphasized that a lab can ask for a waiver, but a state does not have to provide the waiver.

Kristin is willing to look at adding this to an upcoming NELAP AC meeting.

Annmarie from PA noted that they believe education is important and their regulations will reflect this going forward. They value both education and experience. She thinks the language being proposed is OK because it still leaves it to the state to decide whether to grant or not grant a waiver.

Kristin noted that many states currently have it in their regulations that the degree is required. They would have to update their requirements to change this. Some states incorporate the current Standard through reference and it is simpler and quicker to make updates.

Kristin will work with Debbie to get her on the Agenda for the December 5<sup>th</sup> NELAP AC meeting. Discussion will continue on this topic at the next meeting.

### 3. SIR 433

The response approved last month has been returned with further comment: please omit the specific responses to the submitter's "examples", and try for general language that's more broadly applicable?

Debbie asked if the Committee would have issue with removing the examples. There was no issue. The Committee would prefer to keep them, but it is OK to delete them.

The Committee believes the response is as clear and as broadly applicable as possible. Debbie also thinks this is something to evaluate in the Standard for possible revision.

The Committee provided the following update:

SIR 433 to QMS, May 6, 2022 – returned to QMS for revision 9/17/22 and 10/25/2022

<b>Standard</b>	2016 TNI Standard
<b>Volume and Module (eg. V1M2)</b>	V1M2

**Describe the problem:**

Throughout the 2016 TNI Standard, and specifically within section V1M2: 4.13.3, the laboratory is required to produce, ensure, implement, etc., a system that produces records that document all laboratory activities, have documentation that allows historical reconstruction, etc. Labs are also required to have and maintain SOPs that meet all of the method and regulatory requirements as well as accurately reflect the laboratory's operations, and the analysts are required to read, understand, and follow their SOPs.

Question: Is the laboratory required to have a record, that they fill out like a benchsheet or logbook (or whatever terminology the lab might use), electronic or hardcopy, where they document every step of the test or every action that is taken in the laboratory? Such as:

- exact times of each step of a organics sample extraction
- reaction times/wait times of a sample digestion or extraction
- pH checks within a sample digestion/extraction (note, not a pH check for preservation acceptance purposes, but a pH adjustment that is required within a digestion/extraction step)

Or, is having these times, steps, requirements, etc. listed in the SOP acceptable as part of the laboratory's proof of 'historical reconstruction' of all laboratory activities?

**Committee Comment:**

**Response:** No, the laboratory is not required to have a record that they fill out like a bench sheet or logbook (or whatever terminology the lab might use), electronic or hardcopy, where they document every step of the test or every action that is taken in the laboratory. However, a record keeping **system** that allows the history of the sample and associated data to be readily understood through documentation and that documents all laboratory activities is required per TNI V1M2 4.13.3.a). While an SOP is part of the historical reconstruction of the sample and associated data, per TNI V1M2 4.13.3 f) ii, "...reference to the specific method used..." is part of the "information necessary for the historical reconstruction of data", it would not produce a complete record of the history of the sample.

Per TNI V1M2 4.13.3 f) v, "time of analysis is required if the holding time is seventy-two (72) hours or less, **or when time critical steps are included in the analysis (e.g., extractions and incubations)**" and per TNI V1M2 4.13.2.2 "observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task." Therefore, a record is required for these instances.

A motion was made by Nicole and seconded by Kathi to approve the revised response to SIR 433 as described above. There was no further discussion. A roll call vote was taken:

Debbie – For

Kathi - For

Nicole – For

Michael – For

Tony – For

Carla – For

Zaneta – For

Amber – For

Alyssa – For

Nick – For

Ashley - For

The motion passed and Debbie will forward the revised response to LASEC.

4. New Business

No new business.

5. Next Meeting and Close

The next meeting will be December 12, 2022 by teleconference at 1pm Eastern.

Debbie adjourned the meeting at 2:30pm Eastern.

## Attachment A

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

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) <b>Present</b>	Alabama Power	2023*	Lab	dbond@southernco.com
Kathi Gumper (Vice-Chair) <b>Present</b>	ChemVal Consulting	2024	Other	kgumper@chemval.com
Nicole Cairns  <b>Present</b>	NYSDOH	2024	Lab	nicole.cairns@health.ny.gov
Michael Demarais  <b>Present</b>	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis  <b>Present</b>	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Carla McCord  <b>Present</b>	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins  <b>Absent</b>	Pace Analytical	2024*	Lab	<a href="mailto:stephanie.atkins@pacelabs.com">stephanie.atkins@pacelabs.com</a>
Nicholas Slawson  <b>Present – 1:10</b>	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen  <b>Absent</b>	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak  <b>Absent</b>	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Zaneta Popovska  <b>Present</b>	ANAB	2025*	AB	zpopovska@anab.org
Amber Ross  <b>Present</b>	PA DEP/Bureau of Laboratories	2025	AB	ambross@pa.gov
Amy Schreader  <b>Present – left early.</b>	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard  <b>Present by phone.</b>	NAVSEA LQAO	2024	Other	<a href="mailto:alyssa.wingard@navy.mil">alyssa.wingard@navy.mil</a>
Ashley Larssen  <b>Present – 1:10</b>	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) <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>