

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

December 12, 2022

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on December 12, 2022. Attendance is recorded in Attachment A – there were 10 voting members present. Associate members present after 1:20pm Eastern: Alexander Chieh, Nicole Van Aken, Sushmitha Reddy, Rachel Van Exel, Tiffany Shaw, Eric Davis, Debra Zeller, Patty Carvajal, Carol Barrick, Cindy Redmond, Ann Marie Beach, Brian Lamarsh, Brian Hulme, Kelvin Yuen, Sean Hayes and Kristin Brown.

2. Membership

Earl nominated Debbie Bond to continue as Chair of the QMS. The motion was seconded by Alyssa and there was no further discussion. The motion was unanimously approved.

There is one committee member that will be rotating off: Amber.

There are 4 Committee Members that are eligible for a second term: Michael, Nick, Tony and Debbie.

3. Winter Conference – San Antonio

Who will be attending? Michael, Nick, Debbie, and Ilona

No – Earl, Zaneta, Stephanie, Nicole, Jenna, Carla

The associate members joined in at 1:20pm Eastern.

4. Standard Lanaguage

Nicole is taking on an additional work role, so will be resigning as Chair of this Workgroup.

Nicole reviewed the report submitted on Task 4 (Attachment B):

Task #4: V1M2, 4.13.3 b) – change the word “entry” to “use” or other change that clarifies that while the record is in use and up to 5 years after last use, it must be retained.

Suggested Change	Justification
<p>Change the word entry to use or add a part in the section about personnel training and initial demonstration and or all training records on the analyst until 5 years after they leave the company. If we change the language to use this would take care of CRM and IDOC as the initial record would be 'used' every time the standard is reference or a CDOC is done.</p>	<p>Training records are different than other laboratory records and need to have clarification within this section. Make a guidance document for records and time frames that are required for keeping (IDOC, maintenance records on instruments)</p>

If you have a validation record, wouldn't you need to keep the data to support it?

c) Should this be hardcopy only? This stems back to the idea of access logs. For electronics, there is a number of things that need to be considered. Who has permission to access electronic records? This idea still needs to be addressed.

Lists cannot be inclusive. They are only examples, so the workgroup recommends eliminating it and just leave the actual requirement. There are two TNI requirements that need to still be included somewhere in the Standard - Time of analysis when holding time is 72 hours or less and a record of names, initials and signatures.

d) parts are redundant, so eliminated.

e) no changes being recommended.

f) delete

g) see Attachment B.

h) no changes being recommended.

What are the requirements on digitizing the records? If you scan it ... can you get rid of it.

Clean Copy of Final Language Recommended

4.13.3 Additional Requirements

a) The laboratory shall retain all records for a minimum of five (5) years from the last use of the records. Records are considered "in use" when they are required to support current laboratory activities.

Note: Examples of records that are required to support current laboratory activities include, but are not limited to, method validation records, training records of personnel, equipment installation and calibration records, and records of standard preparation.

- b) Records shall be available to the accreditation body.
- c) Access to archived records maintained in hardcopy shall be controlled.
- d) All non-electronic data shall be recorded in permanent ink.
- e) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business. In addition, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

This will be looked at further in San Antonio.

5. Technical Specialist

Comments:

- Education does not have to be a specific degree. Just some science classes would help. The classes would have to be college classes. Learning how to learn. Not just how to do something specific.
- Zero education, but 5 years experience. AA only 1 year difference.
- Clear up May and Must statements.
- Involving other organization to allow their credentialing. Too much risk. No one is sure whether the other credentialing programs exist.
- New technology – Liked that language.
- It needs to be clear that current technical managers do not need to requalify for Technical Specialist.

Debbie is suggesting some language: Section 5.2.6.2 a) Any person who has been approved as technical specialist based on requirements or exceptions in previous revisions of this Standard may continue to be the technical specialist for the same areas of responsibility.

Kristin had noted previously that if a lab asks for an exception, it is expected that they would have to ask every state they have secondary accreditation with too. Kristin noted that they currently write a letter stating that the Technical Manager is accepted when a new Technical Manager is put in place.

States “may” grant a waiver ... gives them the choice. Each AB could make the choice. The AB would need to be able to make an informed decision, so the Technical Specialist would have to provide the appropriate proof.

Should technical Specialists be able to move to other states and maintain their status. There was a lot of debate on this topic. How would a Technical Specialist prove their capability to another state?

Ilona looked for the “grandfathering” clauses of the original language to review for possible use here. It is in the 2016 Standard – c)iii. If similar language was used, it would not allow someone to take the approval with them if the Standard changed, so this language is not helpful.

This topic will take more discussion. Debbie will share it by email to continue the discussion.

6. New Business

- Ilona and Debbie will meet prior to January 4th to finalize the 2023 Goals and 2022 Accomplishments.

7. Next Meeting and Close

The next meeting will be in January at the winter conference in San Antonio.

Debbie adjourned the meeting at 2:37pm Eastern.

Attachment A

Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) Present	Alabama Power	2023*	Lab	dbond@southernco.com
Kathi Gumpfer (Vice-Chair) Absent	ChemVal Consulting	2024	Other	kgumpfer@chemval.com
Nicole Cairns Present	NYSDOH	2024	Lab	nicole.cairns@health.ny.gov
Michael Demarais Present	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis Absent	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Carla McCord Present	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins Present	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson Present	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen Present	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak Present	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Zaneta Popovska Present	ANAB	2025*	AB	zpopovska@anab.org
Amber Ross Absent	PA DEP/Bureau of Laboratories	2025 Requested to rotate off.	AB	ambross@pa.gov
Amy Schreader Present	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard Absent	NAVSEA LQAO	2024	Other	alyssa.wingard@navy.mil
Ashley Larssen Absent	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) Present	The NELAC Institute	n/a	(828)712-9242	ilona.taunton@nelac-institute.org

(Addition: Attachment B – Language – Task #4

Insert PDF attachment when minutes are finalized.