Quality Management System Expert Committee (QMS) Meeting Summary

July 11, 2022

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on July 11, 2022. Attendance is recorded in Attachment A – there were 7 voting members present. Associate members present: Ty Atkins, Eric Davis, Kristin Brown, Annmarie Beach, Justin Brown, Nicole Van Aken, Sushmitha Reddy, Jeanette Hernandez, Tammy Kreutzer, Hong Yu, Lisa Parks, Linda ODonnell, Brian Hulme, Jessica Jensen, Patty Carvajal, Lizbeth Garcia, Robert Waite, Kathleen Lloyd, Cindy Redmond, Tiffany Shaw, Karna Holquist, Debra Zeller, Karina Blanton and Carl Kircher (left early for NELAP AC meeting).

There was not a quorum, so no official business can be done. The June minutes will be distributed at a future meeting or by email for approval.

2. Technical Specialist/Technical Expert

The Committee continued to look at language by reviewing Radiochemistry.

"or equivalent" - classifications have changed so much so may be difficult to say chemistry or physics only. You are leaving it up to the AB to decide if it is equivalent. "Equivalent" technical courses.

Ilona highlighted a note Terry sent along with his Committee's comments. The Radiochemistry Expert Committee struggled with how to define equivalent courses, but they left the language in because they would like to leave the door open for courses outside of college work. It was commented that perhaps looking at a college level syllabus and confirming the same material was covered could be considered?

Need to decide what is equivalent.

It's up to the AB. You have to defend your need for equivalency. If you are going to use the exclusions you are using, you need to share your reasoning that it is equivalent.

Maybe include info for the lab of what could be collected to "prove" equivalency. This shows the lab has done the risk analysis and including the candidate is a good decision.

Move the language regarding new technology/method below since this is new. Doesn't seem like it fits where it is.

Debbie will check with Terry on the following:

- Should it be 2 courses instead of 6 as noted in the description?
- Is it a new technology being brought on line or is it a method?
- Does the language in v prevent a laboratory from bringing on new technologies or methods in a timely manner?

Debbie noted that it would be good to discuss WET and Asbestos before the conference. Could the Committee meet again on 7/18/22 at 1pm Eastern? There could also be a possible preliminary review of the language. There will be no meeting outside of the conference in August.

(Addition: A special meeting was held on July 18, 2022 from 1 – 2:24pm Eastern. Attendance included: Debbie Bond, Fida Kased, Amber Ross, Amy Schreader, Jessica Jensen, Robert Waite, Linda ODonnell, Brian Hulme, Terry Romanko, Sushmitha Reddy, Tiffany Shaw, Dylan Lyon, Tammy Kreutzer, Brian Lamarsh, Michael Desmarais, Lizbeth Garcia, Rami Naddy, Karina Blanton, Alma McCammond, Zaneta Popovska, Nicole Van Aken, Alyssa, Carla McCord, Lisa Parks and Jenna Majchrzak.

The Technical Specialist/Expert language review continued (see Attachment B).)

3. New Business

No new business.

4. Next Meeting and Close

The next meeting will be August 2, 2022 in Crystal City, Virgina in person. The next regular teleconference/Webex will be September 12, 2022 at 1pm Eastern.

Debbie adjourned the meeting at 2:08pm Eastern.

Attachment A

Participants Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Debbie Bond	Alabama Power	2023*	Lab	dbond@southernco.com
(Chair)				
Present				
Kathi Gumpper	ChemVal Consulting	2024	Other	kgumpper@chemval.com
(Vice-Chair)				
Present (until 2pm)				
Nicole Cairns	NYSDOH	2024	Lab	nicole.cairns@health.ny.gov
Absent				
Michael Demarais	SVL Analytical	2023*	Lab	michael@svl.net
Present				
Tony Francis	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Absent				
Carla McCord	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Absent				
Stephanie Atkins	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Present				
Nicholas Slawson	A2LA	2023*	Accrediting	nslawson@a2la.org
THORICIAO CIAWCOTT	7 (2)	2020	Body	noiawoon@azia.org
Absent			,	
Earl Hansen	Retired	2024	Other	papaearl41@hotmail.com
Abaant				
Absent	NJ DEP	2024	A care dition	Jama Majahanak@dan ni gay
Jenna Majchrzak	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Present			Бойу	
Zaneta Popovska	ANAB	2025*	AB	zpopovska@anab.org
Zanota i opovena	7.1.0.13	2020	, .5	
Present				
Amber Ross	PA DEP/Bureau of	2025	AB	ambross@pa.gov
	Laboratories			
Present				_
Amy Schreader	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Absent				
Alyssa Wingard	NAVSEA LQAO	2024	Other	alyssa.wingard@navy.mil
Aiyəsa vviliyalu	NAVOLA LUAU	2024	Outer	aryssa.wirigaru@navy.iiiii
Absent				
Ashley Larssen	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Absent	TI NELSOL W.	,	(000)740 0040	
Ilona Taunton	The NELAC Institute	n/a	(828)712-9242	llona.taunton@nelac-
(Program Admin)				institute.org
Present		1		

Language in Option 3 for Technical Specialist

- 4.1.7.2 The laboratory's technical specialist(s), however named (e.g., Technical Manager, Technical Director, Technical Expert, Group Leader, Supervisor, Lead Analyst, Department Head) shall:
 - a) be an individual with education and experience as specified in Section 5.2.6.1. This individual must have detailed knowledge and experience in the fundamentals of each technology he/she is responsible for and at least a working knowledge of relevant, TNI Standard requirements. This individual may have supervisory responsibilities, but this is not required. This individual may also act as a resource to assure that data generated are fit for the purpose required by
 - b) serve as the key authority regarding all processes involved in generating data from a specific area of responsibility (e.g., microbiology, inorganic non-metals) including sample preparation, instrument calibration, sample analysis, quality control, identification and quantitation, and reporting to ensure that all data reported from this specific area meet quality assurance (QA) criteria and regulatory requirements.
 - c) be available to respond in a timely manner to technical issues or problems within the technical specialist scope. If the technical specialist will be responsible for analysis at more than one location, the laboratory must define the technical specialist's availability for each location.
- 4.1.7.2 If a technical specialist is unable to fulfill responsibilities for a period of time exceeding fifteen (15) consecutive calendar days, the laboratory shall designate another staff member meeting the qualifications of the technical specialist to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing.

5.2.6.1 Technical Specialist Qualifications

The laboratory must maintain records that demonstrate the technical specialist(s) meet(s) the qualifications defined below. Where equivalent course-work is used to demonstrate qualification, the laboratory must provide supporting records for the evaluation of the equivalency

a) Any technical specialist of an accredited environmental laboratory engaged in chemical analysis shall be a person with an earned bachelor's degree in the chemistry, environmental sciences, biological sciences, physical sciences or chemical engineering, or equivalent scientific discipline, and at least two (2) years of experience in representative technologies for which the technical specialist will be responsible. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

A technical specialist with responsibilities limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in chemistry, environmental, biological sciences, physical sciences or chemical engineering, or equivalent scientific discipline or equivalent college education. In addition, such a person shall have at least one (1) year of experience in the environmental analysis of representative analytical technologies for which the technical specialist will be responsible. A bachelor's, master's, or doctoral degree in one of the above disciplines may be substituted for six (6) months of experience.

b) A technical specialist of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a person with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences, biochemical engineering, or molecular biology engineering or equivalent scientific discipline with at least one (1) college-level microbiology

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Suggestion: Make this 4.1.7.3. Add 4.1.7.2 that says something like

The laboratory shall have a technical specialist(s) responsible for every method on the laboratory's scope of accreditation who has/have the education and experience as specified in section 5.2.6.1.

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course and at least two (2) years of experience in representative technologies for which the technical specialist will be responsible. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

A technical specialist responsible for microbiological analysis using methods that employ presence/absence tests; membrane filtration; multi-tube fermentation; multi-well culturing devices; or heterotrophic plate count techniques shall be a person with an associate's degree in an appropriate field of the sciences or applied sciences or equivalent college education. In addition, such a person shall have at least one (1) college-level microbiology course and at least one (1) year of experience in the analysis of representative technologies for the technical specialist will be responsible. A bachelor's, master's, or doctoral degree in one of the above disciplines may be substituted for six (6) months of experience.

- c) Any technical <u>specialist responsible for radiochemical</u> analysis shall be a person:
 - i. with 8 college and/or equivalent technical courses in any combination of chemistry, physics or equivalent scientific discipline; and
 - with 1 additional college or equivalent technical course of radiochemistry for each technology, for which the technical specialist is responsible, with a maximum of 4 courses required.
 - a. For example, the technical <u>specialist responsible for only gas-flow proportional</u> counting (GFPC) would need only 1 course of credit, whereas one at a laboratory performing GFPC, alpha spectrometry, gamma spectrometry, liquid scintillation, alpha scintillation, and ICP-MS would require 4 courses.
 - iii. with two (2) or more years of experience in the radiochemical analysis of environmental samples.
 - A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year experience.
 - iv. 1 year experience working in an environmental <u>radiochemistry</u> laboratory may be substituted for 1 course in section <u>oij</u> or <u>oiji</u>
 - a. Multiple years of substitution may be utilized, but at least 6 courses must be from actual college and/or equivalent technical training sources. Each year substituted must be related to the learning of and proficiency in a different analytical technology.
 - v. In the case where a new technology is brought online, the total number of Radiochemistry courses is not yet 4, and the technical specialist does not have a full year of experience in that specific technology, before accreditation is sought, accreditation for the new technology/method may be given based upon the demonstrated performance of the new method sinstallation documentation, method validation, DOCs, PT performance, etc), with a maximum of one new technology per year per technical specialist.
- d) Any technical specialist of an accredited environmental laboratory engaged in microscopic examination of asbestos and/or airborne fibers shall meet the following requirements dependent on the technology utilized;
 - For procedures requiring the use of a transmission electron microscope, a bachelor's degree from an accredited institution in a scientific discipline, successful completion of a course in the use of the instrument, and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.
 - ii. For procedures requiring the use of a polarized light microscope, an associate degree or two (2) years of college study from an accredited institution in a scientific discipline, successful completion of coursework in polarized light microscopy, and one (1) year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

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- iii. For procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, an associate degree or two (2) years of college study from an accredited institution in a scientific discipline, documentation of successful completion of a NIOSH 582 equivalent course in phase contrast microscopy, and one (1) year of experience, under supervision, in the use of the instrument.
- a) A technical specialist of an accredited environmental laboratory engaged in toxicity testing shall be a person with at least:
 - a bachelor's degree in biological, chemical, or physical sciences, or environmental engineering.
 - ii. two (2) years of experience in all parts of the analysis of toxicity testing of environmental samples representative of the analyses for which the technical specialist will be responsible. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.
 - iii. a,minimum of four (4) college-level courses in fields of biological or environmental sciences from an accredited institution. Additional years of experience working in an environmental toxicity laboratory may be substituted for up to two. (2) of the courses specified above. One (1) year of experience shall substitute for one (1) course. Experience must be recent without lapse in related work history of greater than one (1) year.

5.2.6.2 Technical <u>Specialist</u> Qualification Exceptions

- a) The laboratory may seek an educational waiver if the proposed technical <u>specialist</u> meets the following experience criteria:
 - A technical <u>specialist</u> with an earned associate's degree instead of the requisite bachelor's degree shall have at least four (4) years of experience in the analysis of representative analytical technologies for <u>which the technical specialist will be responsible.</u>
 - ii. A technical <u>specialist</u> with no degree shall have at least five (5) years of experience in the analysis of representative analytical technologies for which the technical <u>specialist</u> will be responsible
- b) The laboratory may seek a waiver for the above specified academic credentials for technical specialist(s) who hold a valid plant operator's certificate appropriate to the nature and size of such facility issued by a State Regulatory Agency. Such accreditation shall be limited to the scope of that facility's regulated permit.
- c) |If such a waiver is granted based on paragraphs a) or b), the ↓aboratory shall maintain a record of the waiver.
- d) Notwithstanding the educational and experience requirements in 5.2.6.1, an individual who has been credentialed by an organization such as the American Water Works Association (AWWA), the Water Environment Federation (WEF) or The NELAC Institute (TNI) shall be considered to possess the requisite qualifications.

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