Quality Management System Expert Committee (QMS)
Meeting Summary

February 13, 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: John Gumper (joined 1:13pm Eastern), Lisa Parks, Nicole Van Aken, Tammy Kreutzer, Sushmitha Reddy, Rachel Van Exel, Lizbeth Garcia, Douglas Kablik, Linda O'Donnell, Annmarie Beach, Paul Junio (until 2pm Eastern), Thomas Fritz, Katie Strothman, Debra Zeller, Jeanette Hernandez, Alma McCammond, Carl Kircher, Patricia Carvajal, Michelle Wade, Cindy Redmond, Eric Davis, and Ty Atkins.

(Addition: The Committee met on January 30, 2023 at 1pm Eastern to discuss membership. Voting members in attendance: Debbie, Amy, Carla, Earl, Michael, Nick, Stephanie, Tony, Zaneta, Kathi and Nicole (arrived 1:12pm Eastern – only voted on last motion.)

A motion was made by Earl to have Kathi continue as Vice Chair of the Committee. The motion was seconded by Michael and unanimously approved.

A motion was made by Earl to approve second terms for Nick, Tony and Michael. The motion was seconded by Amy and unanimously approved.

A motion was made by Earl to add Sean Hayes as a new voting member. The motion was seconded by Michael and unanimously approved. Debbie will notify the Chair of the CSDP of this new membership.)

Debbie summarized the results of the special membership meeting held on January 30, 2023:
- Vice Chair – Kathi
- Approved second term for Tony, Michael and Nick.
- Sean Hayes from Oregon was voted in as a new voting member.

2. San Antonio Meeting

Debbie presented a summary of items from the San Antonio meeting:

- Language Update Workgroup:
    - Clause 8.8.2 d) – ISO/IEC 17025:2017 clause – Completed
        - Clarify what is meant by "undue delay"
    - Clause 4.13.3 b) – Completed (Reviewed all of 4.13.3)

        - Review record retention requirement last “entry” versus last “use”
        - In some cases, it could be difficult to track when ‘last use’ was.
- Review of Technical Specialist exceptions
    - Not many comments, a little formatting and typo correction
- Review of Technical Specialist requirements
    - Second 4.1.7.2 – consider allowing the AB to accept or reject the lab plan for a TS to be responsible for multiple labs.
- Review of Internal Audit
    - Support for a 3-year cycle to audit all technologies for accredited methods to Module 1, and 3-7. Audit QMS every 12 months or annually but stick with either 12-month or annual. Language in Suggestion 2 is preferable. (Debbie shared comments received with Nick to consider in preparing language for Internal Audits.)
- Brainstorming on defining Technology and how to decide Representative Technologies.
    - In most cases, the determinative step should help group technologies; in micro, it’ll be the interpretive step that defines the technology since many time determination is done by sight.
    - Technology definition should be updated and be based on the science used for the technology.
    - SM groups technologies and may help in defining
    - Suggest to create a group made up of people with backgrounds in the different technical modules to start identifying technologies and begin grouping to arrive at a pattern of grouping on which to create a definition or process for deciding which technologies are representative of each other.
    - Technology definitions have the potential to impact PT and Chemistry module, among other groups.
    - Some ‘Technologies’ in LAMS need to be a little more split up, ex: Toxicity testing and Physical properties

3. Language Workgroup

A lot more work needs to be done on the Task 4 language received from the Language Workgroup. The Committee expressed additional concerns about the deleted language.

- Removing detail language would build inconsistency between assessors. Kathi, Jenna and Tony would like to see more of this kept. Lizbeth noted that if this language is removed, AB’s would need a road map on where in the new Standard this information is still provided. Debbie reviewed some of the references provided by the Language workgroup, but Kathi pointed out that not all are clear.
- Kathi suggested that it be confirmed that the items that have a reference for where they are still located be confirmed and then keep anything that doesn’t have a specific reference in this section. It was noted that this could be confusing for labs. Maybe the other items should be added to the correct sections of the Standard– don’t leave some here and put others in the appropriate section. Be consistent. The goal is to not duplicate requirements. This will be recommended to the Language Workgroup.

- John noted that the Workgroup should also understand that requirements listed in this section should be in the appropriate section and in the records section.
- Debbie asked people to think about anything that is not included that should be. Message Debbie and Nick (new Chair of the Language Workgroup).

The "last use" concerns were discussed. This could be difficult for a lab to track. You can't dispose of the records until you confirm the records haven't been used in the last 5 years. John commented if you are not sure it has been used … keep it. This could be a problem for labs that are required to dispose of records from a risk based perspective. These labs need to consider this in how they organize their records in regards to disposal. Initial DOCs would likely need to be stored as a separate package instead of left with all the regular data.

It was commented that there are continuing DOCs that should support the work being done. John commented that labs need to do initial demonstrations, so if this came up in a court case and the lab was asked to show that the initial demonstration was done, the lab would have to still have these records. There were mixed views on this topic expressed, but many believe that intial DOCs would have to be maintained. Kathi noted that initial demonstrations have different requirements compared to continuing demonstrations. There are also differences in QC when a new method is brought online verses the daily QC. This is why initial events matter.

It was suggested that an initial DOC could be run every 5 years if a lab wants to dispose of records. This should cover the initial DOC requirement. There was agreement that this could be done, but this shouldn't be added to the Standard. A lab should put a records system in place to meet the requirements.

More work may be needed in defining "last use".

3. Technical Specialist

Suggestions were made during the San Antonio meeting that Debbie incorporated for the Committee to review and modify as needed. She reviewed these changes and made modifications as needed in Attachment B.

4. New Business

No new business.

5. Next Meeting and Close

The next meeting will be by teleconference on March 13, 2023 at 1pm Eastern.

Debbie adjourned the meeting at 2:20pm 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 Gumpper (Vice-Chair) **Present**	ChemVal Consulting	2024	Other	kgumpper@chemval.com
Nicole Cairns **Absent**	NYSDOH	2024	Lab	nicole.cairns@health.ny.gov
Michael Demarais **Present**	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis **Present**	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 **Absent**	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen **Absent**	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
Sean Hayes **Absent**	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov
Amy Schreader **Present**	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard Present **Present - Phone**	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

Attachment B - Updated Language Based on Comments

Language in Option 3 for Technical Specialist

4.1.7.2 The laboratory shall have technical specialist(s) responsible for every field of accreditation for which the laboratory is accredited or seeks accreditation. Technical specialists however named (e.g., Technical Manager, Technical Director, Technical Expert, Group Leader, Supervisor, Lead Analyst, Department Head) shall:

a) have a working knowledge of relevant TNI Standard requirements. This individual may have supervisory responsibilities, but this is not required.

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.

4.1.7.2 The technical specialist may be responsible for fields of accreditation at more than one location provided the laboratory submits a plan detailing availability at each location to the primary accrediting body. The accrediting body shall evaluate the plan to determine if approval is granted.

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 a technical specialist is unable to fulfill responsibilities for a period of time exceeding thirty-five (35) consecutive calendar days, the laboratory shall notify the primary accreditation body in writing of the staff member who assumed the technical specialist responsibilities.

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 coursework is required, the laboratory must provide supporting records that show courses were successfully completed (e.g., certificate, letter, transcript). Where “equivalent” coursework, college education or scientific disciplines are allowed, the laboratory must provide records to demonstrate equivalency.

a) Asbestos Testing (Module 3)

i. Any technical specialist responsible for microscopic examination of asbestos and/or airborne fibers requiring the use of a transmission electron microscope shall be a person with the following 3 items:
   1) an earned bachelor’s degree in a scientific discipline;
   2) successful completion of a course in the use of the instrument; and
   3) one (1) year of experience in the use of the instrument with an experienced analyst available to review observations and trouble-shoot as needed. Such experience shall include the identification of minerals. Experienced support can be available through contractual arrangements.

ii. Any technical specialist responsible for microscopic examination of asbestos and/or airborne fibers requiring the use of a polarized light microscope shall be a person with:
   1) an earned associate degree or two (2) years of college study in a scientific discipline;
   2) successful completion of coursework in polarized light microscopy; and
   3)one (1) year of experience in the use of the instrument with an experienced analyst available to review observations and trouble-shoot as needed. Such experience shall include the identification of minerals. Experienced support can be available through contractual arrangements.

iii. Any technical specialist responsible for microscopic examination of asbestos and/or airborne fibers requiring the use of a phase contrast microscope, as in the determination of airborne fibers, shall be a person with:
   1) an earned associate degree or two (2) years of college study in a scientific discipline;
   2) documentation of successful completion of a NIOSH 582 equivalent course in phase contrast microscopy; and
   3) one (1) year of experience in the use of the instrument with an experienced analyst available to review observations and trouble-shoot as needed. Experienced support can be available through contractual arrangements.

b) Chemical Testing (Module 4)

Commented [PJ1]: Deleting this doesn't change anything. I assume this is written to clarify, correct?

Commented [BD2]: Consider allowing AB to reject a TS Being responsible for multiple locations

Commented [PJ3]: Same as above - have the requirement first in both of these sentences

Commented [PJ4]: What's an expert? This applies to each use of the term

Commented [PJ5]: True - but this isn't a requirement nor auditable. This applies to each use of the sentence.

i. Any technical specialist responsible for chemical testing, with the exception of that noted in 5.2.6.1 b) ii., shall be a person with:
   1) an earned bachelor's degree in the chemistry, environmental sciences, biological sciences, physical sciences, chemical engineering, or equivalent scientific discipline; and
   2) two (2) years of experience in representative technologies for which the technical specialist will be responsible. An earned master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

ii. Any technical specialist with responsibilities limited to inorganic, non-metals chemical testing, shall be a person with:
   1) an earned associate's degree, or equivalent college education, in chemistry, environmental sciences, biological sciences, physical sciences, chemical engineering, or equivalent scientific discipline; and
   2) one (1) year of experience in representative technologies for which the technical specialist will be responsible. An earned bachelor's, master's, or doctoral degree in one of the above disciplines may be substituted for six (6) months of experience.

c) Microbiological Testing (Module 5)

i. Any technical specialist responsible for microbiological testing, with the exception of that noted in 5.2.6.1 c) ii., shall be a person with:
   1) an earned bachelor's degree in microbiological sciences, biological sciences, chemistry, environmental sciences, physical sciences, biochemical engineering, molecular biology engineering, or equivalent scientific discipline;
   2) successful completion of one (1) college-level microbiology course; and
   3) two (2) years of experience in representative technologies for which the technical specialist will be responsible. An earned master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience.

ii. Any technical specialist with responsibilities limited to microbiological testing 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:
   1) an earned associate's degree, or equivalent college education, in an appropriate field of the sciences or applied sciences;
   2)successful completion of one (1) college-level microbiology course; and
   3)one (1) year of experience in representative technologies for which the technical specialist will be responsible. An earned bachelor's, master's, or doctoral degree in one of the above disciplines may be substituted for six (6) months of experience.

d) Radiochemical Testing (Module 6)

i. Any technical specialist responsible for radiochemical testing shall be a person with
   1) successful completion of eight (8) college, or equivalent technical courses, in any combination of chemistry, physics, or equivalent scientific discipline;
   2) an additional college, or equivalent technical course, in radiochemistry for each technology for which the technical specialist will be responsible with no more than four (4) technology specific courses required (e.g., the technical specialist responsible for only gas-flow proportional counting (GFPC) would need only one (1) course, whereas a technical specialist responsible for GFPC, alpha spectrometry, gamma spectrometry, liquid scintillation, alpha scintillation, and ICP-MS would require four (4) courses); and
   3) two (2) years of experience in the radiochemical testing of environmental samples. An earned master's or doctoral degree in chemistry, physics, or equivalent scientific discipline may be substituted for one (1) year experience.
   4) Required courses in 1) and 2) may be substituted with additional years of experience working in an environmental radiochemical testing laboratory beyond the two (2) years required in 3). Multiple years of experience may be substituted for courses, but at least six (6) courses must be from actual

Commented [PJ6]: If we flip the order of these two items, then we don't need to say this, correct? Applies to Micro as well

Commented [PJ7]: For consistency, they should all read 'earned' or none of them should read 'earned'. Applies to the entire section

college or equivalent technical training sources. Each year substituted must be related to the learning of and proficiency in a different technology.

e) Toxicity Testing (Module 7)

i. Any technical specialist responsible for toxicity testing shall be a person with:

1) an earned bachelor's degree in biological sciences, chemistry, physical sciences, environmental sciences or environmental engineering;

2) successful completion of four (4) college-level biological or environmental science courses;

3)and 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. An earned master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience. 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.

5.2.6.2 Technical Specialist Qualification Exceptions

a) Any person who is approved as technical specialist (or however named) based on requirements or exceptions in previous revisions of this standard is considered to continue approved to be technical specialist for the same areas of responsibility for the current ABs.

A person who is admitted as a technical specialist under these conditions, and leaves the laboratory, will be eligible for hire as a technical specialist for the same fields of accreditation in another accredited laboratory, pending approval from the AB.

b) The laboratory may seek an educational waiver and apply to primary and secondary AB through which the laboratory is accredited for the waiver if the proposed technical specialist meets one of the following criteria:

i. A technical specialist with an earned associate degree or equivalent coursework in the allowed disciplines instead of the requisite bachelor's degree shall have at least four (4) years of experience in representative technologies for which the technical specialist will be responsible.

ii. A technical specialist with four (4) courses from a college or university in the allowed disciplines shall have at least five (5) years of experience in representative technologies for which the technical specialist will be responsible.

iii. A technical specialist who holds a valid plant operator's certificate appropriate to the nature and size of such facility issued by a State Regulatory Agency. Such a waiver shall be limited to the scope of that facility's regulated permit.

c) If a waiver is granted based on paragraphs a) or b), the laboratory shall maintain a record of the waiver.

d) In lieu of the educational requirements in 5.2.6.1, an individual who has been credentialed by The NELAC Institute (TNI) shall be considered to possess the requisite qualifications.

If a laboratory seeks accreditation for a new technology, a technical specialist may be assigned responsibility for the new technology based on demonstrating performance of the new method (installation documentation, method validation or verification, DOC, PT performance, etc). In radiochemistry, a maximum of one (1) new technology per year per technical specialist is permitted.

Commented [BD8]: Expand to cover part of requiried coursework?
What degrees are allowed?

Commented [BD9]: Consider reducing to 3 years or increasing years in ii. below. 5 years is not much more experience, so AD and 4 years is a lot more to expect.

Commented [BD10]: What does this mean?

Commented [BD11]: PA will not accept applicants with no degree nor will PA reciprocate accreditation from a state that allows this.

Commented [BD12R11]: Instead of 'no degree' consider '4 courses in the allowed disciplines' or something simliar.

Commented [BD13]: since no credentialing currently exists, this should be removed.

Commented [BD14R13]: TNI can't control AWWA or WEF or other organization's credentialling programs and TNI doesn't have a program yet. Consider removing this statement for now.

Commented [BD15R13]: Consider adding something like "or other credentialling organization with equivalent credentialing process".