Quality Management System Expert Committee (QMS)
Meeting Summary

October 17, 2022

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on October 17, 2022. Attendance is recorded in Attachment A – there were 14 voting members present. Associate members present: Debra Zeller, Rachel Van Exel, Lizbeth Garcia, Linda O'Donnell, Brian Hulme, Karna Holquist, Kathleen Lloyd, Sushmitha Reddy, Alexander Chieh, Annmarie Beach, Tiffany Shaw, Kelvin Yuen, Rob Waite, Carl Kircher (until 1:30pm Eastern) and Fida Kased. Jerry Parr attended as a Guest.

The August and September minutes were distributed by email for review. A motion was made by Jenna to approve the August minutes with a correction to the spelling of Committee's and the September minutes with the substitution of "The" instead of "They" and "Assessor Forum" instead of "QMS meeting. The motion was seconded by Tony and there was no further discussion. The minutes were unanimously approved.

2. Standard Language Workgroup Report

The group completed Task 3 to define what was meant my "undue delay".

Task #3: ISO (2017) 8.8.2 d) – describe/specify what is meant by "undue delay"

Suggested Change	Justification
Define undue delay Distingush between the beginning (Immediately) and implementation (risk based or appropriate timeframe) of a CA	Up to the laboratory to define. Clarify that the corrective action process needs to be begin immediately (as soon as practicable), but the actual action taken can be any appropriate timeframe as defined within the individual corrective action.

When the workgroup discussed this, they agreed it needs to apply to all corrective actions. Not just to internal audits. They are not recommending a language change to the Internal Audit section (Section 8.8).

Section 8.7 on corrective action does have recommended language changes:
i) The corrective action process as described in 8.7 shall begin without undue delay, as soon as practicable.

ii) The laboratory's procedure shall define the time frames for the implementation of corrective actions, including notifying a client when the nonconformity casts doubt on the validity of the results.

iii) The laboratory management shall ensure that these actions are discharged within the defined time frames.

Put timing of corrective action into the hands of the laboratory. Depends on type of performance and what timing is needed. Management is responsible that the actions are discharged in the time frame. This applies to all corrective actions.

The 2016 Standard requires a procedure for corrective action. That language needs to remain in the Standard for their language changes to work.

Jenna is concerned that timing on the corrective action could be abused by a lab. How can an AB say that a year for a corrective action is too much? Does the ISO language still say timely? What is the point of an internal audit if they aren't going to fix everything? Hard situation because some corrective actions can be finished quickly and others take more time.

Nicole found it in the Standard: Wording in ISO changed to "undue delay" instead of timely. Nicole will look at adding "undue delay" to the Corrective Action section. Right now it does say as soon as practible. Jenna recommended adding a reference to Section 8.7.

Task 4: Control of records and how long they are attained.

Last Task is about unique numbering of containers.

3. Definitions Workgroup

The Workgroup is going through the Standard looking for words like "procedure" instead of "instructions", etc. They are trying to be more consistent in wording. They are waiting on input from other committees.

4. SIR 433

The NELAP AC is asking the Committee to consider a revised response to SIR 433, but does not insist upon its use verbatim. This language does show what they are looking for. They believe that it's important to refer back to Section 4.13.2.2 (which is in the 3rd example).

Section 4.13.3.a) states that the laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through documentation. This record keeping system shall document all laboratory activities. A laboratory's Standard Operating Procedure (SOP) would not produce a complete record of the history of the sample. Specifically, an SOP would not document the time critical steps in the analysis as required by Section 4.13.3.f.)v. or any adjustments, checks, or other activities the sample may have been subjected to. These observations would need to be recorded at the time they are made.

Between recommendations by email and discussion, the following response will be submitted to the LASEC:

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	4.13.3

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.

For the examples given:
1) exact times of each step of a organics sample extraction and 2) reaction times/wait times of a sample digestion or extraction do require records if they are time critical steps included in the analysis.

3) pH checks within a sample digestion/extraction do require records as they are observations.

A motion was made by Kathi and seconded by Michael 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
Stephanie – For
Nicholas – For
Jenna – For
Zaneta – For
Amber – For
Amy – For
Alyssa – For
Ashley - For

The motion passed and Debbie will forward the revised response. *(Addition: See November 14, 2022 minnutes for futher update of this SIR.)*

5. Technical Specialist

The group continued to review language for Technical Specialist. Ilona reminded the group about the last meeting where possibility of comparing course work to what might be covered in a college level course was discussed. Earl had noted last month that the Committee needs to look at what the expectations are for the Technical Specialist. Do they need to have some theoretical background? The Committee agreed that this is needed for a Technical Specialist.

The lab must show the equivalency in courses.

Oregon is not sure they are OK. New Jersey is not OK – don't know what they are verifying. PA not sure they would agree with all. Operator certificates may not be equivalent. Debbie asked if they would accept them to cover the education portion? Leave out experience? Many operator licenses require experience. Debbie will go back to the original language and leave out experience. It will be rewritten to include only education.

The group ran out of time for further discussion and will have a special meeting next Monday (October 24th at 1pm Eastern) to continue to discuss and revise Technical Specialist language.

(Addition: The following voting members were present at the meeting on October 24th: Debbie, Amy, Earl, Jenna, Michael, Carla and Kathi. Associate members included: Alma McCammond, Cindy Redmond, Fida Kased, Jeanette Hernandez, Jerry Parr (Guest), Karna Holmquist, Kelvin Yuen, Kristin Brown, Linda O'Donnell, Rachel van Exel, Tammy Kreutzer, Thomas Fritz, Ty Atkins and Justin Brown.

A summary of the changes proposed and discussed can be found in Attachement B.

There were questions about the language within the Radiochemistry section. Ilona suggested that Debbie attend the upcoming Radiochemistry meeting to discuss optional changes to the language. Ilona will add her to the the meeting invitation list. There was concern that the language may be stricter than what is presently in the 2016 Standard.)

6. New Business

   No new business.

7. Next Meeting and Close

   The next meeting will be November 14, 2022 by teleconference at 1pm Eastern. *There will be an additional meeting on 10/24/22 at 1pm Eastern.*

   Debbie adjourned the meeting at 2:40pm 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 **Present**	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 **Present**	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
Amber Ross **Present**	PA DEP/Bureau of Laboratories	2025	AB	ambross@pa.gov
Amy Schreader **Present**	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard **Present**	NAVSEA LQAO	2024	Other	alyssa.wingard@navy.mil
Ashley Larssen **Present**	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

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 who has/have the education and experience as specified in sections 5.2.6.1 or 5.2.6.2. 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 c) 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 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 minimum 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 its 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) a bachelor's degree in a scientific discipline,
   2) successful completion of a course in the use of the instrument,
   3) and one (1) year of experience, under supervision in the use of the instrument with an expert 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 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, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.

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 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, under supervision, in the use of the instrument.

b) Chemical Testing (Module 4)

Commented [CNL(1]: The "or" is a little awkward here, as you can't meet just the requirements of 5.2.6.2 alone. The exceptions go with the content of 5.2.6.1. Since these are the only clauses in 5.2.6, maybe just site the parent clause, 5.2.6.

Commented [KG2R1]: I agree we could just use the more universal parent clause, and perhaps it would be better to just loosely reference Personnel Requirements. Another alternative could be to not put the education and experience requirement here at all. Generally, it's better if we can avoid references to other paragraph numbers (since they can easily become inaccurate in future edits), and better to only state each requirement in one place. Because of that, my personal preference would be to not include the "meet the education and experience" requirement in this paragraph at all since it will be clearly indicated in the personnel section that there are education and experience requirements for this position.

Commented [BD3]: From PA - define working knowledge and add 'This individual must have the authority to stop work due to any issue related to the quality of the results reported to the client(s).'

Commented [BD4]: From PA - add 'approved by the primary AB to meet the..."

Commented [BD5]: Could this be changed to one year of training instead in this paragraph and the following 2? All asbestos analysts need to go through McChrom (NIOSH 582) training. Can we include in all 3 paragraphs?

Commented [CNL(6R5]: I like training... "experience training in the use of..."

Commented [BD7R5]: From Asbestos Committee: We discussed this and feel that "under supervision" is the appropriate term. We felt "Training" implies that the analyst isn't capable of independent work until the year is over, we just want to ensure that they have supervision (meaning a person to go to with questions)

Commented [BD8R5]: From Asbestos Committee on NIOSH 582:
No- this is only applicable for the third paragraph. The 582e is a PCM course only. We suggest the following

"Any technical specialist responsible for microscopic examination of asbestos and/or airborne fibers for procedures requiring the use of a phase contrast microscope, as in the determination of airborne fibers, shall be a person with an associate degree or two (2) years of college study in a scientific discipline, documentation of successful completion of training equivalent to that of a NIOSH 582 course in phase contrast microscopy, and one (1) year of experience, under supervision, in the use of the instrument."

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. A 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. A bachelor's, master's, or doctoral degree in one of the above disciplines may be substituted for six (6) months of experience.

Commented [BD9]: PA requires experience for each technology the technical specialist is responsible for. Experience in flame AA should not grant you approval for LC-MS-MS.

Commented [BD10]: PA would like bachelor's and master's to substitute for only 3 months 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. A 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. A 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 ~~analysis~~testing ~~(Module 6)~~ shall be a person with
   1) ~~successful completion of~~ eight (8) college, ~~and/~~or equivalent technical courses, in any combination of chemistry, physics, or equivalent scientific discipline,
   2) ~~with~~ an additional college, or equivalent technical course, ~~of~~in radiochemistry for each technology ~~in the area of responsibility~~for which the technical specialist will be responsible. ~~N~~ with no more than four (4) technology specific courses ~~are~~ 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) ~~. In addition, such a person shall have at least~~ two (2) years of experience in the radiochemical ~~analysis~~ testing of environmental samples. ~~A~~ master's or doctoral degree in chemistry, physics, or equivalent scientific discipline may be substituted for one (1) year ~~experience. Additional~~experience. ~~years of experience working in an environmental radiochemistry laboratory may be substituted for any required courses. One (1) year of experience shall substitute for one (1)~~

~~course. Multiple years of experience may be substituted for courses, but at least six (6) courses must be from actual college or equivalent technical training sources. Each year substituted must be related to the learning of and proficiency in a different technology.~~

4) Required courses in 1) and 2) may be substituted with additional years of experience working in an environmental radiochemistry 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 college or equivalent technical training sources. Each year substituted must be related to the learning of and proficiency in a different technology.

Commented [BD11]: Radiochemical testing, like in 3)?

~~d)~~e) Toxicity Testing (Module 7)

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

1) a 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, and

~~3)~~ 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. 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) The laboratory may seek an educational waiver if the proposed technical specialist meets the following experience criteria:

i. A technical specialist with an earned associate's degree 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 no degree shall have at least five (5) years of experience in representative technologies for which the technical specialist 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 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 an organization such as, but not limited to, the American Water Works Association (AWWA), the Water Environment Federation (WEF), or The NELAC Institute (TNI) shall be considered to possess the requisite qualifications.

~~d)~~

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 [BD12]: Expand to cover part of requiried coursework?

Commented [BD13]: Coursework?

Commented [BD14]: PA will not accept applicants with no degree nor will PA reciprocate accreditation from a state that allows this.

Commented [CNL(15)]: If this is just another educational waiver, this should become iii. under a) and change a) to end with just "criteria" instead of "experience criteria". However, in the previous standard this didn't require a waiver, it was an allowed exception.

Commented [KG16R15]: Agree with both points.

Commented [CNL(17)]: What accreditation?

Commented [KG18R17]: Should this say "waiver"

Commented [BD19]: From PA - since no credentialing currently exists, this should be removed.