Quality Management System Expert Committee (QMS)
Meeting Summary

June 13, 2022

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on June 13, 2022. Attendance is recorded in Attachment A – there were 14 voting members present. Associate members present: Kelvin Yuen, Brian Hulme, Debra Zeller, Kathleen Lloyd, Kristin Brown, Cindy Redmond, Nicole Van Aken, Hong Yu, Tammy Kreutzer, Brian Lamarsh, Alma McCammond, Linda ODonnell, Patricia Carvajal, Lizbeth Garcia, Jessica Jensen, Sushmitha Reddy, Jeanett Hernandez, Annmarie Beach, Tiffany Shaw, Ty Atkins, Cody Danielson, Eric Davis, Carl Kircher and Lisa Parks.

The April and May minutes were distributed by email. A motion was made by Earl to approve the April 11, 2022 and May 9, 2022 minutes as written. The motion was seconded by Nick and unanimously approved.

2. Definitions Workgroup

TheWorkgroup is working on a definition for "policy". They need to do some research in the ISO/IEC standard and other TNI documents for similar terms. This will help them to decide if the term is even needed.

Also still looking at "method validation" and "method verification".

3. SIR 433

Debbie provided the following information by email:

SIR 433 to QS, May 6, 2022

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. 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". A separate record is, however, required to record deviations from the SOP, per TNI V1M2 5.4.1 "…Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer." and TNI V1M2 5.10.3.1 "…test reports shall, where necessary for the interpretation of the test results, include the following:
a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions".

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
In most instances, a reference to the SOP is acceptable. Only those instances that fall under the requirements in 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)" require a record of the time of analysis.

3) 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)
In this instance, a reference to the SOP is not acceptable. These are observations, the confirmation of pH within a specified criteria. So, 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.", a record of this observation is required.

Comments by email:
Robert Waite's comment that Analysis Time be recorded (not the timed step, necessarily)
Dorothy Love's comment is to record time 'where a method stipulates a time for a particular step…'

Kathi commented that you want to know when extraction starts, but don't need to know timing on all steps other than making sure hold time is met.

Elizabeth gave other examples where time is needed. An example would be incubations.

Holquist – If it says a digestion should occur for 2 hours, the assessors expect to see this documented. If this documentation is no longer required, how do you train the ABs to not ask for this?

What are time critical steps? This would be extremely difficult to define.

Nicole asked if ABs expect to report 2 minute shakes? No. For solids analysis, they do expect a stop and start time. How do you decide when the documentation is needed and when it is not?

Carl Kircher commented that the Committee should be careful in responding to this. Only comment on what is being asked. The first paragraph is fine.

After further scrutiny of the draft language, the final suggested response is:

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. 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". A separate record is, however, required to record deviations from the SOP, per TNI V1M2 5.4.1 "…Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer." and TNI V1M2 5.10.3.1 "…test reports shall, where necessary for the interpretation of the test results, include the following:

a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions".

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

In most instances, a reference to the SOP is acceptable. Only those instances that fall under the requirements in 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)" require a record of the time of analysis.

3) 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). In this instance, a reference to the SOP is not acceptable. These are observations, the confirmation of pH within a specified criteria. So, 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." A record of this observation is required.

A motion was made by Ashley to respond to SIR 433 as written in italics above. The motion was seconded by Earl.

A roll call vote was taken:
Debbie – For
Kathi – For
Nicole – For
Michael – For
Carla – For
Nick – For
Earl – For
Jenna – Abstain

Zanetta – For
Amber – For
Amy – For
Ashley – For
Tony – Abstain

The motion was passed by a super majority. The response will be forwarded to the LASEC.

4. Conference

The following people expect to be at the conference in person: Zaneta, Earl, Nick, Kathi, Michael, and Debbie.

These members do not expect to be at the conference – Tony, Jenna, Carla, Ashley, Nicole, Amber, Amy.

There will be two QMS sessions at the conference. The following agenda items are being considered:

- Workgroup updates. Language update needed – Nicole can put together a summary. (Nick can do the update at the conference.)

- Definition update – Paul Junio – need to let him know when he is needed.

- Technical Manager Discussion

- Continue working on Standard Language. May look at more current SIRs.

Debbie will work with Ilona on the agenda to get to Jerry in the next week.

5. Crosswalk

The Committee continued to review the Crosswalk and inserting language into the DRAFT Standard starting at Section 5.8 (see Attachment C). They completed the review of the document.

The Small Laboratory Handbook won't be due for any updates until the Standard is complete. It will likely be a major re-write.

6. Technical Specialist/Expert

Debbie has not gotten a lot of comments back from the other modules. The Committee will probably need to have another meeting in July to review this information in order to prepare. Most people are available on the 29th – 1pm Eastern. An extra meeting will be held on the June 29, 2022.

(Addition: A special meeting was held on June 29, 2022 from 1 – 2:38pm Eastern. Attendance included: Debbie Bond, Tiffany Shaw, Rami Naddy, Jeanette Hernandez, Lizbeth Garcia, Eric Davis, Karna Holquist, Ty Atkins, Amber Ross, Ashley Larssen, Jenna Majchrzak, Cody Danielson, Justin Brown, Linda ODonnell, Michael Desmarais, Michelle McGowan, Debra Zeller, Jessica Jensen, Robert Waite, Amy Schraeder, Cindy Redmond, Douglas Kablik, Kathleen Lloyd, Joe Manzella, Tony Francis, Terry Romanko, Annmarie Beach, Patty Carvajal, Zaneta Popovska, Alma McAmmond, Dylan Lyon, Nicole Cairns, Robin Cook.

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

7. New Business

No new business.

8. Next Meeting and Close

The next regular meeting will be July 11, 2022 by teleconference/Webex at 1pm Eastern. A special meeting to discuss Technical Specialist/Expert will be held on June 29, 2022.

Debbie adjourned the meeting at 2:08pm 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 at 1:24pm**	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 **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 **Present**	PA DEP/Bureau of Laboratories	2025	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 **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's technical specialist(s), however named (e.g., Technical Manager, Technical Director, Technical Specialist, 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 test he/she is responsible for and at least a working knowledge of relevant quality system requirements in the TNI Standard. 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 the client.

b) serve as the key authority regarding all processes involved in generating data from a specific area (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) not be the technical specialist(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body

d) meet qualification requirements as specified in Section 5.2.6.1.

4.1.7.2 If the technical specialist is unable to fulfill their 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(s) to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing; and ….

5.2.6.1 Technical Specialist Qualifications

The laboratory must maintain records that demonstrates the technical specialist meets the qualifications defined below.

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. A technical specialist responsible for for 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

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Commented [BD2]: Where a degree is required, the Technical Expert must be able to provide a copy of the diploma which was awarded and the AB should verify that the diploma was issued from an institution accredited by an organization recognized by the US Department of Education or equivalent international organization, at the time the diploma was issued. Can we verify this is an AB requirement? How do we figure out what is an 'equivalent international organization'?

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Commented [MW3]: The CEC feels that "representative" allows for the addition of new methods and or emerging technologies.

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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 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 specialist of an accredited environmental laboratory engaged in radiological analysis shall be a person:

i. with 8 college and/or equivalent technical courses in any combination of chemistry and/or physics; and
ii. with 1 additional college and/or equivalent technical course of radiochemistry for each technology/method used in the laboratory, with a maximum of 4 courses required.
    i. For example, the technical manager of a laboratory performing only gas-flow proportional 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.
    ii. In the case where a new technology/method 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/method before accreditation is sought, accreditation for the new technology/method may be given based upon the demonstrated performance of the new method and PT performance (installation documentation, method validation, DOCs, PT performance, etc), with a maximum of one technology/method per year; and
iii. with two (2) or more years of experience in the radiological analysis of environmental samples.
    i. 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 radioanalytical laboratory may be substituted for 1 course in section a.i or a.ii.
    i. Multiple years of substitution may be utilized, but each year substituted must be related to the learning of and proficiency in a different analytical method/technique or instrumentation type. This will help ensure an increasing level of knowledge in radiochemistry analyses (preparation and/or instrumentation)

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Commented [BD4]: This paragraph covers emerging technologies, but without a bachelor's degree "**if they do have experience in that technology or experience as a TE, they could oversee emerging technologies. For example, you can't come in as a new TE without a bachelor's degree and with no method or TE experience and bring up an emerging technology method, but if you have been a TE for XXX years or have XXX years of experience in that technology, you can be a TE. If we require a bachelor's degree, someone who is currently a TE without that degree who does all other methods won't be allowed to bring on new methods at all, even if they have staff with tons of experience in that method.**"

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Deleted: of a laboratory engaged in microbiological analysis using methods that employ presence/absence tests; membrane filtration; multi-tube fermentation; multi-well culturing devices; or heterotrophic plate count techniques. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree.

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during that time period. No more than 6 courses total may be substituted – at least 6 courses must be from actual college and/or equivalent technical training sources.

d) [Similar language for asbestos]

e) Any technical specialist of an accredited environmental laboratory engaged in toxicity testing shall be a person with at least a bachelor's degree in life sciences, environmental sciences, natural sciences or environmental engineering and a minimum of four (4) college-level courses in fields of biological or environmental sciences from an accredited institution, and have at least two (2) years of experience in all parts of the analysis of toxicity testing of environmental samples representative of the analyses for which the laboratory seeks or maintains accreditation.

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 of the courses specified above. One year of experience shall substitute for 1 course. Multiple years of substitution may be utilized, but each year substituted must be related to the learning of and proficiency across the scope of accreditation. Experience must be recent without any lapse in related work history of greater than one (1) year.

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 the analysis of representative analytical 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 the analysis of representative analytical 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) 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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Commented [MW6]: Seems like an AB requirement needs to be in volume 2.

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