Quality System Expert Committee (QS)
Meeting Summary

August 9, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 9am Eastern by webinar on August 9, 2021 during the TNI Accreditation Forum. Attendance is recorded in Attachment A – there were 10 members present. Associate Members present: Justin Brown, Jessica Jensen, Carl Kircher, Michelle Wade, Paul Junio, Ashley Larssen, Marlene Moore, and Eric Davis.

2. Recap

Debbie provided a summary of what the Committee has been doing since the Winter meeting last January. (See Attachment B).

3. ISO/IEC 17025:2005 verse 17025:2017 Language

Debbie shared the crosswalk the Committee is using to track changes that need to be made to the Standard.

2005: Section 4.1.5.d – Debbie noted that the Committee still needs to look at whether policies and procedures are needed to avoid involvement in activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity. Marlene commented that the 2017 version requires the lab to have an analysis of the risk to its impartiality. It is ok to have a policy and procedure, but this is not required since it is more important for the lab to have done a risk analysis and determined how the risk is eliminated or minimized.

Debbie noted that the Committee is leaning towards keeping the Quality Manual requirements.

Comment: 2017 seems to be codifying the Quality Policy Statement. Including a Qual Policy Statement may be redundant in the QM.

Kathi emphasized that 2017 does not require a specific Quality Policy Statement. Jerry Parr
Commented that the Quality Statement is generally boiler plate language. Is this even auditable?

Nick noted that the 2017 does require that the lab have a policy, but it is not the same as the Quality Policy Statement from before. It is simplified. He pointed to Section 8.2.1 of the 2017 Standard. 8.2.2. also has a required policy.

Marlene noted that the lab has to have something that states their policy and objectives. It doesn't mean a manual specifically is needed. Could be on the lab website. She is OK with dropping the Quality Manual, but all the requirements in Section 8.2 still need to be followed.

2005: Section 4.3: Document Control

The concept of a "master list" is not in the 2017 language. Debbie noted the Committee thinks it should be kept because there needs to be a way to identify current documents.

Jerry commented that the document control procedure will be used to identify … You don't have to have a list … just need a way to control all the documents. Others agreed. Make sure there is a process, don't define.

2005: Section 4.3.2.3: 2017 document removed the requirement. 2017 moves more towards electronic documents. Marlene reminded everyone that there are labs that are not doing electronic.

2005: Section 4.3.3.3 - Drop hand changes because whether by hand or electronic … it needs to be identified.
Could clarify that amendments must be approved prior to use. Maybe there could be a procedure to know when an amendment requires an approval.

2005: Section 4.3.3.4 - Paul commented that it would be difficult to do this without a procedure. Section 8.3.2 looks good to Jerry and Paul. Marlene noted in 2017, a documented procedure is not required, but a process would be needed.

Nicole noted that the section before does talk about management system documentation. Points back to 8.2.1 and 8.2.2. – lab has to have policy and objectives. She thinks the requirements are still there, but they are not spelled out the same way in 2005.

BREAK

2005: Section 4.4 – Review of Requests, Tenders and Contracts

Nick asked to see note in 4.4.2. He noted there is a note in 2017 - 7.1.1.- Note 2. Will look to see if this note is more appropriate.

Sections 4.5, 4.6, 4.7, 4.8 - Overall. Looks good.

The Standard Update Workgroup is at Section 4.9, so Debbie stopped review at this point.

4. Summary of Changes to DRAFT Standard

Debbie shared the Summary document and noted that the Definitions Workgroup will be working on many of the definition related changes.

Section 5.8.7.1:
Addition requires that a lab have a procedure instead of just implementing verification of preservation. Change term "documenting" to "recording".

Section 5.10.11.c:
Jessica commented that if you claim accreditation across the board, you need to clearly identify what you are accredited for in your reports.

Nicole thinks that if we need a note about the statements on the website … maybe this belongs somewhere else in the Standard.

The reports are important, and it should be clear what the accreditation status is for each reported result.

Jerry pointed to a statement on the TNI website: https://www.nelac-institute.org/news.php?id=4254:

NELAP and California Proposition 65
Date Posted: 4-9-2020
TNI's National Environmental Laboratory Accreditation Program (NELAP) was established to accredit environmental laboratories that test environmental media (e.g., air, soil, water) for environmental contaminants using test methods published by the United States Environmental Protection Agency and other groups such as ASTM International and Standard Methods. Section 25900 of California's "Proposition 65" regulation contains a clause that among other entities, mentions laboratories accredited under NELAP. NELAP-accredited laboratories are not accredited to use test methods approved by the Consumer Products Safety Commission. The test methods these laboratories do use are specific to environmental analysis and are not appropriate for consumer products. TNI cautions all NELAP-accredited laboratories to not imply their NELAP accreditation has any basis for testing consumer products. TNI recommends those seeking to have consumer products tested use an accredited lab from the Consumer Products Safety Commission.

It was commented that some ABs are requiring showing accreditation status to the analyte results level on the report. A listing of what a lab is or is not accredited for is not being considered acceptable.

Section 7.11.2:
Debbie added to Section 7.11.2 – Commercial off the shelf software used without any configuration or modification may be used without further validation by the laboratory. This would be added as a requirement instead of Note 2. Instead, the group preferred that

this additional text be deleted and that a note about Note 2 being a requirement be used instead.

Section 8.3.1:
Section deals with “authorized editions”. Labs have to have copies of the Standard.

Section 4.13.3:
Look at DOD language.

Marlene asked if this section includes manual integration. Need to specify that electronic before and after records need to be maintained.

Section 7.5.2 is clear about this. It does not state that you need to note a reason for the change. A note may be needed? Or it would be easier to spell it out?

Possible DRAFT language: This system shall impact the quality and historical reconstruction of the resulting data, such as laboratory facilities, equipment, analytical methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification, and inter-laboratory transfers of samples and/or extracts.

Or make it a Note? Paul commented that traceability is critical. TNI does have a definition for traceability that Paul read to the group. It was commented that notes are an excellent way to ensure consistency between labs and assessors. I think we should use notes more for these types of things.

Comments:
- I see this section as a 'gotcha' item for assessors. Please consider what is actually necessary to ensure quality, rather than something that 'is just a good idea' or something an assessor is going to pull things out of the air.
- Quality and traceability of data.
- Or impact data quality.

Section 4.4.1.c:
Need a definition for customer. Entity requesting data? A person or organization that purchases services from a laboratory?

Comment: Remember, the contract review should include any regulatory requirements for the data. Thus, the end user/regulator's needs/requirements should already have been determined as part of the needs of the customer.

Debbie asked for any additional comments on anything discussed today. No comments.

Debbie confirmed that most are OK with having Quality Manual but get rid of Quality Policy Statement. She asked for comments. No comments.

5. New Business

No new business.

6. Next Meeting and Close

The next regular meeting will be on September 13, 2021 at 1pm Eastern by teleconference.

Debbie adjourned the meeting at 11:34pm 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
Lizbeth Garcia **Present**	Oregon Dept. of Environmental Quality	2022	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Stephanie Atkins **Absent**	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 **Absent**	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
William Ray **Absent**	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross **Present**	PA DEP/Bureau of Laboratories	2022*	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
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Quality Management Systems Module 2

Summer Conference Meeting
8/9/2021

1

Quality Management Systems Committee

Debbie Bond
Chair
dbond@southernco.com

Kathryn Gumpper
Vice-chair

2

Quality Management System Committee

Member	Organization	Representation
Nicole Cairns	NYSDOH	Lab
Michael Desmarais	SVL Analytical	Lab
Tony Francis	SAW Environmental	Other
Lizbeth Garcia	Oregon Dept of Env Quality	AB
Stephanie Atkins	Pace Analytical	Lab
Nicholas Slawson	A2LA	AB
Earl Hansen	Retired	Other
Jenna Majchrzak	NJ DEP	AB
William Ray	William Ray Consulting	Other
Amber Ross	PA DEP/Bureau of Laboratories	AB
Amy Schreader	UC Laboratory	Lab
Alyssa Wingard	NAVSEA LQAO	Other
Ashley Larsson	KC Water	Lab

3

Agenda

- Approve July minutes
- Update Action List
- Recap since winter meeting
- Begin ISO17025:2005 vs. 2017 missing items
- Summary of Changes items to Draft Standard
- Other new business

4

(Open July Minutes Word Doc)

REVIEW JULY MINUTES & UPDATE ACTION LIST

5

Quality Management Systems Module 2

Recap

- ISO 17025:2005 vs 2017 Workgroup
- Internal Audit language
- New Workgroups
- SIRS

6

Internal Audit Language

- Original Text

4.14.5 Additional Items

a) The laboratory shall have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results.

b) The laboratory management shall ensure that these actions are discharged within the agreed time frame.

c) The internal audit schedule shall be completed annually.

7

Internal Audit Language

- Draft Text

1. In addition to the requirements listed in 8.8.1 and 8.8.2, the internal audit program shall include:
   a. a pre-defined schedule covering a 2-year period
2. The interval for each audit shall be determined by the laboratory and shall not exceed:
   a. 24 months for methods/technologies on the scope of accreditation
      Note: Technologies are defined in the TNI Laboratory Accreditation Management System.
   b. 12 months for the elements in Module 2 of this standard
      Note: Laboratories must ensure they follow the most stringent requirements, where applicable.

8

New Workgroups

- Definitions Workgroup
  - Will evaluate and draft definitions for:
    - Annual
    - Quarterly
    - Support Equipment
    - Method Validation
    - Verification
    - Customer

9

New Workgroups

- Language Re-write Workgroup
  - Will consider language for the following sections:
    - 4.2.8.5, esp. f – sections for procedures listed are specifically for technical/analytical procedures, not administrative. All sections are not required in every tech/analytical procedure.
    - 5.8.5 – unique sample IDs on each sample bottle
    - ISO (2017) 8.8.2 d) – specify what is meant by "undue delay" for corrective actions from internal audits
    - 4.13.3 b) – clarify that a record must be retained for 5 years after last use

10

SIRs

Disclaimer

- The SIRs in the following slides are not complete. Responses described must be approved by LASEC and AC before they may be posted. They may change.

11

SIR 401

- 401 on section 5.5.13.1 e.i
  - The term "Microliter" is a trademark for Hamilton Company syringes. Are other brands and types of syringes acceptable, such as SGE MicroVolume, Hamilton GasTight, or Agilent syringes? If so, what is the definition of a glass microliter syringe (i.e. maximum volume, plunger construction, etc.). Thank you.

12

SIR 392

- 392 on section 5.5.8
  - The section of the Standard states "Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due."

    Most labs have interpreted that this requirement applies to support equipment such as balances and pipettors. Does this section apply to analytical equipment such as turbidimeters, spectrophotometers, pH meters, ICP-MS, etc?

13

SIR 378

- 378 on section 5.5.13 d)
  - d) Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available.

    Question: do reference thermometers need to be calibrated annually? These are traceable to NIST.

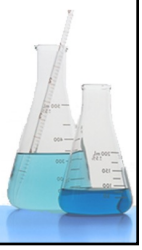
14

SIR 412

- 412 on section 5.6.4.2d
  - "All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date."
    If the reagent is from the same lot but came in multiple bottles, do they need a unique ID? For example, if a case of Methylene Chloride came in a pack of 4 bottles, can all 4 bottles share the same ID or do they need to be distinguished despite having the same manufacturer lot number?

15

Questions?



16