Quality Management System Expert Committee (QMS)
Meeting Summary

January 11, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 8am Central in San Antonio, TX on January 11, 2023. Voting members present: Debbie Bond, Michael Demarias, Tony Francis, and Nick Slawson. A quorum was not present, so the Committee was not able to do business, but could meet.

Debbie started the meeting by reviewing the presentation included in Attachment A.

2. Definitions Workgroup

See slides in Attachment A.

3. Language Workgroup - Nick

Nick noted that the Workgroup was given 5 sections of the Standard to work on. They have suggested language to the Committee for 4 sections to date. The Workgroup's goal was to reduce redundancy and streamline language.

The slides in Attachment A were reviewed.

Q: Define - readily available? A2LA defines it as available by the end of the assessment. Will send to Definitions Workgroup.

Q: Yesterday in Chemistry - How valuable is the iDOC record 10 years from now? Just working together on these types of issues so the Standard is consistent.

Q: Conflicts with General requirements to only keep records to 5 years. This is a change to this. It is being proposed that it is 5 years from use, not date.

Q: How do you know what Last Use is? When required to support current laboratory activities. Example would be iDOC. Analyst is doing work right now … so need to keep record.

4, Technical Specialist

Debbie quickly reviewed the language to date on screen, but did not go through it in detail. She wants to work mainly on exceptions today.

She reviewed each Module's Technical Specialist requirements.

Comments:
- Thank-you. Much more usable. Exceptions are acceptable.

- Make it if you meet one of the criteria. Don't have to have a plant operator's license.

Debbie noted in Section d), there is a good possibility that this section will not remain. TNI does not have any control of these other organizations and TNI doesn't have a credentialing system today. Ilona suggested bringing this up in the afternoon Credentialing meeting or bring it to their attention.

Comments:
- Is there a reason it is not bullet iv? It doesn't need a waiver?

- A2LA accredited credentialing organizations. Consider changing to accredited credentialing organizations.

- There were mainly labs in the room. Not a lot of ABs.

Debbie stepped back to each section to get comments:

- Texas AB: Technical Specialist for Multiple locations. ABs are not going to be happy with this language as it stands. Not clear. Lab can decide any schedule. Doesn't say the schedule has to be approved by the AB. Currently, a schedule is proposed and TCEQ currently receives it. There is concern thatd the ABs will not approve this language.

<u>Asbestos:</u> No comments.

<u>Chemistry:</u>
Q: What is experience? On instruments? Data review? More information needed.

Q: Its equivalency? Lab's? Need to show it is equivalent to what is listed. Remove "it's".

Q: Technology? Any analyte?

Q: ;Are these minimum? This was removed.

<u>Microbiology:</u>
Micro lite - there are more options than previously in this section? It was analyte based and now it is technology.

<u>Radiochemistry:</u>
Proficiency or competency here? Debbie will check on this?

Toxicity Testing: No comments.

Exceptions:
Replace Manager with Specialist.

5. Internal Audit

Debbie reviewed options for internal audits in the meeting slides (Attachment A), looked at the SIR 308 that discusses internal audits, and looked at possible language:

TNI V1M2, 3.1 Additional Terms and Definitions:
Technology: A specific arrangement of analytical instruments, detection systems, and/or preparation techniques.

Current DRAFT Internal Audit language:
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.

SIR 308: TNI V1M2 (2009 & 2016) 4.14.1 – Request:
Per Clause 4.14.1, the internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is unclear if all test methods need to be audited annually since 4.14 never uses the word "methods" but rather "areas" or "activities".
Can the test methods be grouped by technology (i.e. GC/MS, ICP/MS, ICP, Spectrophotometry, Gravimetry, Meters, Titrimetry, SFIA, etc.) or does every method have to be audited annually? If grouped by technology, can different test methods within each technology be scheduled annually? The schedule beyond one year would show that tests are rotated for internal audits over time.
Response:
No, not every method needs to be assessed annually in the laboratory's internal audits. Yes, different methods within each technology may be assessed on an annual basis.

Suggested language 1:
All methods under which the laboratory performs its accredited testing shall be assessed, as part of the internal audit program, within a three-year audit cycle. The audits of methods to be performed in a given year shall be specified in the predetermined internal audit annual schedule. The laboratory shall have procedures in place to ensure all methods are assessed within a three-year cycle and the internal audit annual schedule is completed.

Laboratory management shall ensure within the internal audit program that a representative sample of the methods are assessed on an annual basis. For example, not all methods within a laboratory with a large scope of accreditation have to be assessed annually as long as enough of the methods have been assessed to be representative of the entire laboratory. The representative sampling of the methods shall take into consideration matrices and method/technology combinations. It is recommended, that laboratories with a small scope of accreditation should have all tests assessed on an annual basis.

Suggested language 2:

1) The current DRAFT internal audit language essentially says that the lab shall audit all elements of Module 2 every 12 months. Could we use this same approach for all of the Technical Modules? The emphasis should be on auditing the lab to the standard, not necessarily just the methods. Maybe state: **"The laboratory shall audit all elements of applicable Technical Modules 3-7 annually using a representative selection of analytes, matrices, and methods that cover at least one-third of the laboratory's scope of accreditation."** This puts the emphasis on the standard requirements every year, encompasses more than just methods, and avoids technologies. It also ensures that one-third of the Scope is assessed every year within the 3-year cycle, but gives the lab flexibility. I know the word "representative" is still in there, not sure how else to say it more succinctly.
2) And what about Module 1? At what frequency should the lab audit the PT requirements? Maybe fit in with Technical Modules?

Comments:

- Likes second sentence better. Small scope? Is it clearly defined anywhere?

- Problem with word "representative." It is different for labs vs. ABs.

- Need to talk about risk. Debbie thinks boundaries need to be placed.

- Nick - 17025:2017 is risk based in regards to internal audits. He looks at PTs and that should help determine where you do internal audits. He likes setting 3 years to check everything, but up to lab how to do this.

- Tony – over 3 years audit all methods on your scope.

- AB Comment - liked language - what is a small lab? This addresses it. If your lab only does micro - do internal audit every year. Takes some of subjectiveness out of it.

- Has lab with 500 fields. Divide by 3 - can't do that in one year. Would have to hire someone. Would like to make this a risk decision. Think about it as methods on your scope? Need to look at it as technology instead.

- States are saying they want methods, but SIR says technology. You are going backwards. What are the technologies?

- Labs would like to see risk based established by the lab.

- Look at technology instead of methods.

BREAK

6. Defining Technology

Debbie reviewed the slide for Too Broad or Too Narrow in Attachment A.

Comments:

- Need a definition for Internal Audits if they get focused on technology instead of method.

- Read definition for Technology in Glossary.

- Method Selection - uses same technology in 1.4 - Is that a concept applied in the Standard … maybe a jump off.

- Tony - What if you figure out the determinative step - not the separation technique? Then you can combine more. What is the detector at the end?

- For Microbiology - preparative step might be the most important.

- For Microbiology - Thinks the same thing. Front end is the place to look. It might be possible to figure out other words to use that could be consistent. Come up with definition and then let the expert committees define the pairings.

- Are we looking for a definition? Or could we look at forming a list of technologies? A definition may still cause some confusion. A list may help with implementation.

- Simplest form of defining technology may be what is needed. That may make it too norrow. Then look at what you have and figure out how that relates to LAMS.

- Current definition for technology: A specific arrangement of analytical instruments, detection systems, and /or preparation techniques.

- Thinks it should be based on the science instead. What is it doing?

- Technology is also used in PTs.

- AB commented: Would not want to change how PTs are looking at technology. Also, ABs decide whether analytes can be added based on technology - so impacts ABs also.

- Debbie thinks we will need to understand LAMS use of Technology and go from there.

- A list should not be part of the Standard because it could change. Maybe reference LAMS for technologies? She shared a list from LAMS.

- Need to be able to figure out how to handle new technologies too.

- Need a definition to figure out how to group things together. Though it could be easier to work on lists and then form a definition. It may become clear if you start by listing.

- Groupings are in Standard Methods for Micro … that may help as a starting point.

- We know technology is used by Chemistry Expert, PT and QMS uses it for Internal Audits and Technical Specialist. Field of Accreditation also refers to technology. Ask Chemistry Expert and PT how they use Technology (not definition, but what they do with it). This might help.

- Do we want to separate prep from technology?

- Consider defining competency instead of using technology in Technical Specialist language.

- LAMS technology is pretty good.

Debbie asked for some feedback on how this should be addressed:

- List - 15
- Rely on definition - 0

Debbie thinks she will start with working on a list. Maybe this is a Task Force exercise since it impacts all of TNI. Debbie will discuss this Stacie Crandall (Chair, PTPEC) and Paul Junio (Chair, CSDP).

7. New Business

- None.

8. Next Meeting and Close

The next meeting will be by teleconference on February 13, 2023.

Debbie adjourned the meeting at 11:10am Central.

Quality Management Systems Expert Committee
Volume 1 Module 2

Winter Conference
1/11/2023

1

Quality Management Systems Expert 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
Carla McCord	Virginia	AB
Stephanie Atkins	Pace Analytical	Lab
Nicholas Slawson	A2LA	AB
Earl Hansen	Retired	Other
Jenna Majchrzak	NJ DEP	AB
Zaneta Popovska	ANAB	AB
Amy Schreader	UC Laboratory	Lab
Alyssa Wingard	NAVSEA LQAO	Other
Ashley Larsson	KC Water	Lab

3

Agenda

- Recap since winter meeting
- Update from Language Workgroup
- Technical Specialist language – exceptions feedback

Break

- Internal Audit language - feedback
- Defining Technology – ideas?

4

Quality Management Systems Expert Committee

2022 in Review

- ISO 17025:2005/2017 Crosswalk review
- Current Workgroups
- SIRs
- Technical Specialist language

5

ISO/IEC 17025:2005 v 2017 Crosswalk

- December 2021 to June 2022 – review by full committee
  - Review is complete!
  - Some requirements from 2005 were included in the Draft Standard, most were covered in some way in Rev. 2017
- Expert committee will review Quality Manual requirements later.

6

SIRs

- SIRs
  - SIR 422 (traceability of preservative used during sampling)
  - SIR 433 (SOP sufficient for historical reconstruction?)

Disclaimer

- The following SIRs are not complete. Any response described must be approved by LASEC and AC before it may be posted. The response may change.

7

SIR 422

- 422 on section 5.6.4.2
  - This section of the Standard specifies, "Documented procedures shall exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory."

    Question: What does the Standard mean by "technical operations of the laboratory"? Would a 1:1 HCl dropper used to acidify a VOC sample during sample collection require the documentation and labeling of paragraphs b) and/or d)? Do reagents that are used at collection fall under the definition of "technical operations of the laboratory"?

8

SIR 433

433 on Section 4.13.3

- 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?

9

Definitions Workgroup

- Workgroup members
  - Paul Junio (Chair), Northern Lake Service Lab (Lab)
  - Lizbeth Garcia, Oregon Dept of Environmental Quality (AB)
  - Jenna Majchrzak, NJ Dept of Environmental Protection (AB)
  - Amy Schreader, UC Laboratory (Lab)
  - Debbie Bond, Alabama Power General Test Lab (Lab)
- Mission
  - Evaluate requests for definitions of specific terms in V1M2 of the 2016 TNI Standard. Where a definition is needed, develop definitions that align with the Standard. Review TNI language use a consistent term when a written procedure is required. Present to the QMS Expert Committee for consideration

10

Definitions Workgroup

- Completed
  - Defined: Annual, Quarterly, Customer, Procedure, Corrective Action, Duplicate
  - Added info to 5.5.13.1: Support Equipment
- In Process
  - Validation/Method Validation, Verification, Policy
  - Standardize use of 'procedure,' 'policy,' and 'activity' in V1M2 to eliminate terms such as 'instructions,' 'measures,' etc., where possible.

11

Quality Management Systems Expert Committee

Language Update Workgroup Report

Winter Conference 2023

12

Language Update Workgroup

- Workgroup members
  - Nicole Cairns (Chair), NY-DOH (Lab)
  - John Gumpper, ChemVal Consulting (Other)
  - Lisa Parks, Jackson Family Wines (Lab)
  - Nick Slawson, A2LA (AB)
- Mission
  - To update language for specific clauses of Volume 1, Module 2 of the 2016 TNI Standard where clarification or changes are needed and to present the updated language to the QMS Expert Committee for consideration.

13

2016 V1M2 Assignments

- Clause 4.2.8.5 – Completed; presented at San Antonio conference
  - Clarify differences between analytical/technical and support/QMS documents
  - Clarify listed items are not a required outline of sections for procedures
- Clause 5.8.5 – Completed; presented at Crystal City conference
  - Evaluate use of word "unique" in sample identification
- 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"
- Clause 5.6.4.2 d) – from SIR 412
  - Clarification of unique ID for standards, reference materials and reagents

14

ISO/IEC 17025:2017, Clause 8.8.2

- Current Language – ***ISO/IEC 17025:2017, Clause 8.8 – Internal Audits***

8.8.2 The laboratory shall:

a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) ensure that the results of the audits are reported to relevant management;

d) implement appropriate correction and corrective actions without undue delay;

e) retain records as evidence of the implementation of the audit programme and the audit results.

15

ISO/IEC 17025:2017, Clause 8.8.2

- No change to *ISO/IEC 17025:2017, Clause 8.8*
- Proposed Language for *ISO/IEC 17025:2017*, Clause 8.7 – Corrective Action

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.

*This assumes that the QMS Expert Committee continues to require a procedure, as currently required in V1M2 4.11.6 of 2016 TNI Standard. If not, then ensure there is a requirement for the laboratory to document time frames for the implementation of corrective actions.

16

ISO/IEC 17025:2017, Clause 8.8.2

- Justification
  - New language added to corrective action section (8.7) to address all corrective actions, not just those arising from internal audits.
  - With this new language, no need to further clarify undue delay in the internal audit section, as a lab will have to begin the corrective action process as soon as practicable and will have to follow the timeframes they have defined for the implementation of corrective actions.

17

2016 V1M2 Clause 4.13.3

- Current Language

a) The laboratory shall establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation. This system shall produce unequivocal, accurate records that document all laboratory activities 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.

- Proposed Language

Delete entire clause

- Justification
  - Redundant with *ISO/IEC 17025:2017, 7.5.1 and 8.4.1*; does not add value and is poorly worded
  - *7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original..*
  - *8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.*

18

2016 V1M2 Clause 4.13.3

- Current Language
  b) The laboratory shall retain all records for a minimum of five (5) years from generation of the last entry in the records
- Proposed Language
  b) The laboratory shall retain all records for a minimum of five (5) years from the last use of the records. Records are considered "in use" when they are required to support current laboratory activities.
  Note: Examples of records that are required to support current laboratory activities include, but are not limited to, method validation records, training records of personnel, equipment installation and calibration records, and records of standard preparation.
- Justification
  - To ensure records are maintained 5 years beyond their use, not just last entry.
  - Many records, like a completed initial DOC record, may be needed well beyond 5 years after its completion if the analyst is still performing the same method and the initial DOC still applies.

19

2016 V1M2 Clause 4.13.3

- Current Language
  c) Records shall be available to the accreditation body.
- Proposed Language
  No Proposed Changes

20

2016 V1M2 Clause 4.13.3

- Current Language
  d) Records that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval.
- Proposed Language
  Delete entire clause
- Justification
  - Redundant with section *ISO 71025:2017 8.4.2*
  - *8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.*

21

2016 V1M2 Clause 4.13.3

- Current Language
  e) Access to archived information shall be documented with an access log.
- Proposed Language
  e) Access to archived records maintained in hardcopy shall be controlled.
- Justification
  - Re-worded for clarity and to allow for a laboratory-defined mechanism of control.

22

2016 V1M2 Clause 4.13.3

- Current Language
  f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory. (Includes subclauses i – xix; list of information to maintain)
- Proposed Language
  Delete entire clause and subclauses
- Justification
  - It is encompassed by "all laboratory activities" in *ISO/IEC 17025:2017, 7.5.1* and *8.4.1*
  - The list is not complete and missing activities, like sample receipt and data review/verification
  - Many of the subclauses are redundant with other parts of *ISO/IEC 17025:2017* or 2016 V1M2
- Possible Exceptions
  - Subclause xix. A record of names, initials, and signatures….; if retained, recommend moving to *ISO/IEC 17025:2017 6.2 Personnel*.

23

2016 V1M2 Clause 4.13.3

- Current Language
  g) All generated data, except those that are generated by automated data collection systems, shall be recorded legibly in permanent ink.
  i. An individual making corrections to records shall date and initial the correction.
  ii. Corrections due to reasons other than transcription errors shall specify the reason for the correction.
- Proposed Language
  g) All non-electronic data shall be recorded in permanent ink.
- Justification
  - Reworded for clarity.
  - "legible" is redundant with *ISO/IEC 17025:2017, 8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.*
  - Subclauses redundant with *ISO/IEC 17025:2017, 7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations*

24

2016 V1M2 Clause 4.13.3

- Current Language

  h) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business. In addition, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

- Proposed Language

  No Proposed Changes

25

PROPOSED TECHNICAL SPECIALIST LANGUAGE

26

Technical Specialist

- Formerly known as Technical Manager
- Background
  - The Competency Task Force provided acceptable language
  - Proposed language was reviewed and updated by Technical Module Expert Committees
  - QMS Expert Committee reviewed language and made additional edits
- The proposed language can be tweaked but the overall intent must remain.
- Feedback on Exceptions clause 5.2.6.2
  - See Technical Specialist 01052023 clean.docx

27

(Open Internal Audit options 01102023.docx)

INTERNAL AUDIT LANGUAGE & DEFINING TECHNOLOGY

28

Audit Frequency Options

- Define Technology and allow rotating audits by technology in a shorter time range (1-2 year audit schedule).
- Allow a longer time range to complete the audit schedule, but require each technology used for accredited testing be audited within the 3-year period.
- Allow a longer time range to complete the audit schedule, but require each accredited method be audited within the 3-year period.
- Other options?

29

SIR 308 – Clause 4.14.1 (rev 2009 & 16)

- Request
  - Per Clause 4.14.1, the internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is unclear if all test methods need to be audited annually since 4.14 never uses the word "methods" but rather "areas" or "activities".
  - Can the test methods be grouped by technology (i.e. GC/MS, ICP/MS, ICP, Spectrophotometry, Gravimetry, Meters, Titrimetry, SFIA, etc.) or does every method have to be audited annually? If grouped by technology, can different test methods within each technology be scheduled annually? The schedule beyond one year would show that tests are rotated for internal audits over time.

30

SIR 308 – Clause 4.14.1 (rev 2009 & 16)

- Final Response
  - No, not every method needs to be assessed annually in the laboratory's internal audits.
  - Yes, different methods within each technology may be assessed on an annual basis.

31

Defining Technology

- LAMS Technologies (114 defined) may be too narrow or too broad for Internal Audits, Technical Specialist experience, etc.
- Ideas on better definition?

Too narrow?

GC-AED	Gas Chromatography - Atomic Emission Detector	Organic Chemistry
GC-ELCD	Gas Chromatography - Electrolytic Conductivity Detector	Organic Chemistry
GC-ELCD-PID	Gas Chromatography - Electrolytic Conductivity/Photoionization Detector	Organic Chemistry
GC-ECD	Gas Chromatography - Electron Capture Detector	Organic Chemistry
GC-ECD-FID	Gas Chromatography - Electron Capture/Flame Ionization Detector	Organic Chemistry
GC-FID	Gas Chromatography - Flame Ionization Detector	Organic Chemistry
GC-FPD	Gas Chromatography - Flame Photometric Detector	Organic Chemistry
GC-FTIR	Gas Chromatography - Fourier Transform Infrared Spectrometer	Organic Chemistry
GC-MS	Gas Chromatography - Mass Spectrometer	Organic Chemistry
GC-HRMS	Gas Chromatography - Mass Spectrometer - High Resolution	Organic Chemistry
GC-NPD	Gas Chromatography - Nitrogen Phosphorus Detector	Organic Chemistry
GC-PID	Gas Chromatography - Photoionization Detector	Organic Chemistry
GC-MS-MS	Gas Chromatography - Tandem Mass Spectrometer	Organic Chemistry
GC-TCD	Gas Chromatography-Thermal Conductivity Detector	Inorganic Chemistry

Too broad?

GRAV	Gravimetry	Inorganic Chemistry
TITR	Titrimetry - Visual Indicator	Inorganic Chemistry
BioTox	Toxicity Testing	Toxicity Testing

32