Quality System Expert Committee (QS)
Meeting Summary

January 26, 2021
TNI Virtual Conference

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1pm Eastern by teleconference on December 14, 2020. Attendance is recorded in Attachment A – there were 10 voting members present: Amber Ross, Debbie Bond, Jessica Jensen, Kathryn Gumpper, Kristin Brown, Lizbeth Garcia, Michelle Wade, Nick Slawson, Shari Pfalmer, and Tony Francis. There were 157 participants attending the meeting.

2. Overview

Jessica shared a presentation to summarize committee membership, activities and goals (Attachment A).

Jessica reviewed the "Where do we go from here?" slide.

3. Summary of Proposed Changes

For the meeting today, Jessica shared the Summary of Proposed Changes (Attachment B) table that includes the new items added after the Public Webinar.

Comments:

- Support Equipment: It was commented that a balance can be an analytical piece of equipment and in some cases, it can be support equipment. Some would like to get rid of the list of support equipment examples and others would prefer to keep it because it helps explain what is meant. If the list is removed, define what support equipment is.
  - I like leaving this as a note - sometimes the language can leave someone unclear as to what exactly it means. Having an example is helpful.
  - I actually like the list because it provides examples and better helps understanding the standard.
  - I find that examples (lists) are helpful and that notes have value. If a note needs to be enforceable then it should be made into the standard, but notes should not be removed overall in the standard just because they are "notes".
  - Though it was commented that implementation guidance could be helpful, others did not like this concept: Please make the standard readable and understandable as a document without needing guidance and small lab handbooks.

- Notes are not enforceable, but they do provide background to support an interpretation of the standard. AB's might have to create a list of what constitutes support equipment in their own rules if list is removed.
- Others felt the list helps with consistency.
- Overall comments preferred to keep a list and that notes are OK in the Standard.

- Record Keeping (ISO/IEC 17025 Section 7.5.1 – See Attachment B)
  This one was originally an SIR. Committee thinks language is as clear as possible. Comments?

  - Record keeping is based on paper and electronic.
    It was commented that people are so used to having something on paper it makes it difficult to move to electronic. You think you still need something electronic. He commented that people need to understand that the same issues are there on paper (transcription) verses entry into the computer.
  - What if there are software changes? Can't go back because to old data. One person commented they kept the computer and old copies of the software.
  - Some people use dual entry systems for critical information to make sure the correct information is entered.
  - What about using portable devices to transfer data to LIMS? You can ask "how do you know people are recording the right numbers?" There is a level of validation that has to happen before you start using a system like this. Need to make sure the software works.
  - ISO 17025: 2017 addresses LIMs and electronic data.
  - CFR Part 11 is very restrictive and not required. We have to be able to retrieve and retract the records.
  - Summary – lots of concerns about electronic records. Need to make sure standard addresses this.

- SOP Requirements (ISO/IEC 17025 Section 4.2.8.5 – see Attachment B)

  - There was support for the changes QS is recommending.
  - DoD made a note that administrative SOPs can have different sections. Many assessors require the list. The "where applicable" is too vague. We'll never define "where applicable" fully enough ... I suggest leaving that alone.
  - There were other comments to use bullet points, but an assessor would prefer numbering to use it in their references for deficiencies.
  - Some components of the method SOP can be combined such as safety and pollution prevention; definition of terms relevant to the method should be included in the SOP; commonly used terms in the QM definition of terms.
  - Suggestion for this language: Each test method SOP should consider the following elements …
  - I think we need to be careful with the word method verses SOP. When we use the term method do we need to say test method or test SOP or support (administratvie) SOP.

- Need to make sure it is clear what applies to method SOPs and what applies to other SOPs.
- Debate over bullet and section numbers. Paragraph form may be helpful too.
- TCEQ has a nice list of admin SOPs , p12: https://www.tceq.texas.gov/assets/public/compliance/compliance_support/qa/tceq20132.pdf
- Ilona commented that you need to think about what you want? A list makes people think they need to use them as headers, but paragraph form makes you think you just need to cover it. It was asked how important is the citation? She doesn't think each has to be referenced individually.
- TNI standard should not put requirements on non-method SOP structure at all.
- I am not sure that changing the language is adding any clarity. Again, a lab can simply say NA to any section that does not apply. Having a standard format for an SOP is not a bad thing and can be uniform with an NA.
- If there are pieces that must be in an SOP – then don't use "where applicable".

- "Unique" ID (ISO/IEC 17025: Section 5.8.5 – See Attachment B)

  - Are we indicating "unique" to the client, the site, the process of collection (first or second bottle) or something else? "Unique" does cause confusion.
  - It means being able to uniquely identify doesn't necessarily have to be an ID number. Maybe the label contains the preservative and that is how you uniquely identify. It should depend on the lab. Maybe the requirement is that traceability needs to be in place – not uniquely identify.
  - In general, people were OK about removing the word unique. Maybe a better term could be ambiguous. Nick commented that ISO has moved to the term unambiguous.
  - Silky commented that unique has a connotation. She commented that if a lab is recycling numbers – that is an issue. Uniquely is used because the identification is only tied to that sample container. She thinks it needs to be unambiguous and unique. Jessica pointed out that other text in the section addresses the reason unique was originally used. Maybe use "identify"?
  - It was commented that you could have Discharge point 1, collected every day, and ID as DP1, but unique because of date. It was commented that NH ELAP would accept a date as unique identification in this example. This is a very common practice in municipal labs.-

BREAK

- Internal Audit Frequency (ISO/IEC 17025 Section 4.14.5 – see Attachment B)

  - There were a lot of negative comments on this during the public webinar, so the Committee is rethinking this.
  - It was asked if this could tie in with the need to define annually. Jessica responded that they would prefer not to use the word annually anymore.

- Suggestion made: The internal audit of all elements of the quality system and each technology/method must be scheduled and completed every calendar year (or 12 month-interval, as defined by the laboratory) and within 18 months of the previous audit of that element or technology.
- A suggestion was to make it 13 months. There needs to be an allowance to exceed 365 days.
- The problem with going with a terminology of every calendar year basically would allow an audit to be completed in January of one year, then December of the following year. This would not meet the intent of ISO/IEC.
- Not every method has to be audited annually. Some methods may be 2 years, but labs usually audit all the technologies each year. The important thing is that every method is looked at on a schedule and your AB is OK with that schedule. Ideally, frequency should be based on what is needed based on risk.
- Example language to consider: "Internal audits shall normally be performed at least once every 12 months or completed within a 12-month time frame for segmented (or rolling) internal audits. A documented decision-making process shall be followed to change (reduce or restore) the frequency of internal audits or the time frame in which internal audits shall be completed. Such changes shall be based on the relative stability and ongoing effectiveness of the management system. Records of decisions to change the frequency of internal audits, or the time frame in which they will be completed, including the rationale for the change, shall be maintained."
- I do not think method or technology audit should be stated but the lab must provide the justification for ensure that all activities are covered in the internal audit. Every technology needs to be audited annually. DW and DoD does need to be annual.
- The TNI Glossary Workgroup is looking at: "Unless otherwise clearly stipulated, occurring at a frequency of every 12 months (+/- 2 months)".

- ISO/IEC 17025 Section 5.8.7.1 – see Attachment B: No new comments. OK

- ISO/IEC 17025 Section 5.10.11.c – see Attachment B

  - Much more clear. Someone asked about why parameter was added. Important for WET, Asbestos, pH, etc.
  - It was commented to move the end of the sentence to the beginning.
  - Jessica commented that if a lab claims they are accredited on their website and don't share the accreditation Scope … they need to make it clear what they do and what they are not accredited for. It was noted that many labs think this just relates to reports, but it also relates to websites.
  - Comment received that most labs are not thinking about a claim of accreditation tying back to the website. Need to include that to make it clear. Jessica suggested that claims are made in any way – she added it.
  - Would like TNI to move towards ISO/IEC 2017 language … claims of accreditation. In the new ISO/IEC 17025:2017- Section 5.3. Lab needs to define

what they are accredited for. Report needs to be clear what you are and are not accredited for. Document range for what you are conforming to the standard for.
  - There is a past example where a lab analyzed Cr6 in consumer products and the client assumed it was covered under NELAP. 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. See the following link: http://nelac-institute.org/news.php?id=4254. Matrix is important.
  - Could accreditation on website be resolved by requiring a lab that puts claims of accreditation on their website, they also have to upload their accreditation cert showing what method/analytes they're accredited for?
  - Not a fan of marking what is accreditted. Too many notations and clients won't like. Better to mark what is not accredited if you are going to do something like that.
  - I think I agree with what the last speaker just said, either call out what is not accredited, or call out what is accredited, depending on what is more sensible for the lab to do. As long as it's transparent.

- Quality Manual – see Attachment B
  - I think the SDWA requires a quality manual so don't we need a quality manual statement in the TNI standard.
  - Suggested Language: Add Note to ISO/IEC 17025:2017 Section 5.5 stating "A Quality Manual is an effective way to meet these requirements."
  - If this is left up to the states to decide then there may be several different types of QMs with varied degrees of information and content. I recommend moving forward to a universal QM, this would be helpful for auditors who perform audits.
  - Couldn't you change the citations for Quality Manual to Quality Management System documents?
  - ORELAP rules "a quality manual (QM) that includes all elements as set forth in the TNI Standards".
  - For SDWA, a separately prepared text could be a listing of all QMS documents that address each required topic in the drinking water program. NH ELAP Rules: The laboratory shall prepare and maintain a quality systems manual that meet the requirements specified in Volume 1, Module 2, Sections 4.2.8.3 and 4.2.8.4 of the TNI standards.

Jessica thanked everyone for all the comments. Update from the discussion today are included on the table in Attachment B.

6. Next Meeting and Close

The next regular meeting will be on February 8, 2021 by teleconference at 1pm Eastern. Ilona will distribute Webex invites for screen sharing the morning of the meeting. Jessica adjourned the meeting at 1 pm Eastern.

Quality Systems - Module 2
Open Forum for Standard Modification

Winter TNI Virtual Meeting
01/26/2020

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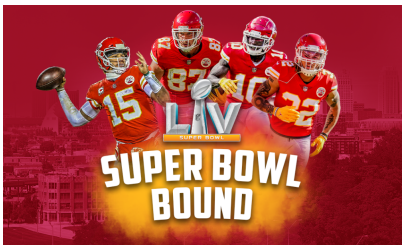

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Quality Systems

Labs (4) – Jessica Jensen (Chair), Debbie Bond (Chair Elect), Shari Pfalmer, Michael Desmarais,

ABs (5) – Kristin Brown, Lizbeth Garcia, Nicholas Slawson, Jenna Majchrzak, Amber Ross

Others (6) – Kathi Gumpper (Vice Chair), Bill Ray, Tony Francis, Michelle Wade, Alyssa Wingard, Earl Hansen

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Quality Systems - Module 2 Revision

2020 Recap

- Suggested Changes sheet
- Webinar
- Comments from webinar
- SIRS

4

Quality Systems - Module 2 Revision

Documents

Suggested Changes Chart

Webinar Comments

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Where do we go from here?

- Review language from ISO 2005, What do we want to keep?
- Determine a goal for completing a Volume 1 Module 2 Voting Standard.
- Continue working through controversial topics:
  - Internal Audit time frame
  - Technical Manager (coordinate with other committees)
  - Document/record retention
  - Quality Control currently listed in the standard and determine when it is appropriate
  - Addressing requirements dropped in ISO/IEC 17025:2017
    - Need for a Quality Manual and SOPs (and what they must include)
    - Quality policy (and general usage of the term policy in the standard)
  - As additional controversial topics arise, expand this list and pursue TNI stakeholder input.
- Review Charter.

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Questions?

Jessica Jensen
No Longer Chair – Quality Systems Committee
KC Water
Jessica.Jensen@kcmo.org
Debbie Bond
Now serving as Chair- Quality Management Systems Committee
Dbond@southernco.com

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Attachment B: Module 2 Standard Update - Summary of Suggested Changes – 1/26/21

Original Text	Suggested Change	Justification
Include reference and language.	*Don't need to work on specific language - just summarize change needed.*	*Why does this need to be changed/updated?*
6.4.6 ISO 5.5.13.1 Support Equipment This Standard applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).	The list should either be removed or included as a note. Provide a definition of what support equipment is if the list is removed. Implementation guidance for the support equipment. If list is removed, some ABs may add the list into their regs.	The list is not all-inclusive and does not need to be in the standard. There may need to be a guidance document created for this section. There is a section in the small lab handbook that discusses support equipment. Whenever lists are presented in the Standard, they cause issues because people incorrectly look at them as an all-inclusive thing. How can we better make use of lists in the Standard?
7.5.1 ISO 4.13.3 Additional Requirements 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.	No Change suggested	Audit trail is mentioned in 4.13.2.1 Gray area does exist, however the language is as clear as we can make this. We are open to suggestions for changes.
7.2.1.2 ISO 4.2.8.5	Clarify that paragraph f is not a required outline, all topics must be covered when	SOPs can be written in any format that includes all of the information necessary

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a) Documents that contain sufficient information to perform the tests, do not need to be supplemented or rewritten as internal procedures if the documents are written in a way that they can be used as written. Any changes, including the use of a selected option, shall be documented and included in the laboratory's records. e) The laboratory shall have and maintain an SOP for each accredited analyte or method. f) The SOP may be a copy of a published or referenced method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each method shall include or reference the following topics where applicable: i. identification of the method; ii. applicable matrix or matrices; iii. limits of detection and quantitation; iv. scope and application, including analytes to be analyzed; v. summary of the method; vi. definitions; vii. interferences; viii. safety; ix. equipment and supplies; x. reagents and standards; xi. ……	applicable but exact wording of headers and specific order is not required. Modify the language from F to clarify that it applies to method procedures and add G for "administrative" SOPs Work on language for the final sentence of f) Clarify the difference between types of procedures for instance: administrative SOP and Method/Analytical SOP may not require all of the same components listed. Some would like to see the list in bullet points, this makes the list harder to assess to as you can reference individual bullet points. Also commented to put the list with comma, so that the headers do not look like they must be used in that exact wording. Suggested wording for final sentence of f) Each test method SOP must address the following if applicable: Do we need to have separate list for something that MUST be in the SOP then we can have a list for areas that are not always applicable.?	to accomplish what is defined in the standard. The formatting and language needs to be modified so laboratory understand there are many ways to accomplish this requirement. Again, this is a list. Not all of these items are required, and since this list is written for methods, these bullets don't apply to non-method SOPs
7.4.2 ISO 5.8.5 Additional Requirements – Documentation	Look at the word unique and whether the word should just be removed.	Identifying the sample and being able to track it through the quality systems do

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	The following are essential to ensure the validity of the laboratory's data. a) The laboratory shall have a documented system for uniquely identifying the sample containers that hold samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates. b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned to each sample. c) The laboratory ID code shall be placed as a durable mark on the sample container. d) The laboratory ID code shall be entered into the laboratory records and shall be the link that associates the sample with related laboratory activities such as sample preparation.	**VOA vials need to be individually identified for it to be traced back to show which one was used for the analysis.** **Taking out the word uniquely does not change the sentence, due to the second part there can be no confusion regarding the identity of such samples at any time.**	not necessarily require every container to be uniquely identified. A unique identifier is required for each sample, and sub-samples need to be tied back to the sample. These are two different requirements
8.8.2 ISO 4.14.5.	c) The Internal audit schedule shall be completed annually,	Remove "schedule" .Remove the word annual/quarterly and insert language for the specific time frame intended Suggested Language: ~~Instead of annually use every 12 months not to exceed 18 months or Internal audit must be performed every calendar year not to exceed 18 months~~ This language was negatively received during the webinar.	There does not seem to be a uniformity in what annually means. We need to clarify this statement.

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	Every technology must be audited within a calendar year (Jan-Dec), not to exceed 18 months between audits.	
5.8.7.1 The laboratory shall implement procedures for verifying and documenting preservation.	Change from implement to have and implement.	This change is to insure that procedures are documented and not just implemented.
5.10.11 c) Any non-accredited tests shall be clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables.	Any results issued to the client for non-accredited analytes and parameters shall be clearly identified as such in the analytical report and in the supporting electronic or hardcopy deliverables when claims of accreditation to this Standard are made. New suggested language 01/26/2021 When claims of accreditation to this Standard are made in any way, any results issued to the client not under the scope of accreditation shall be clearly identified as such in the analytical report and in the supporting electronic or hardcopy deliverables. When claims of accreditation to this Standard are made in any way, the report needs to clearly identify the status of accreditation for any results.	The rewording is to clarify that this only applies when claims of accreditation to this standard are made. Suggest mentor session on what defines a claim of accreditation.
Multiple references to Quality Manual, the first is 1.1 introduction	Remove the requirement of a Quality Manual Reevaluate the requirements for a quality manual in both the TNI and ISO 2005 standard. Currently nine requirements within TNI 2016 standard. Within current language we state the policies must be included within the quality manual. Maybe we need to let go	Hold off on this change, as many states require it in their regulations. Work towards this goal. It's possible to have all of these items in multiple places, especially as more information is stored on-line or in 'the cloud'. If the Quality Manual went away, it wouldn't mean that the requirements contained in it would go away

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	of the word quality manual and just say that the documented procedures for laboratory activities. Change Quality Manual to quality management systems documents this would allow for the 'manual' to be a road map to all other documents that address the requirements of a quality manual Drinking water still requires a laboratory quality plan which is a more stringent requirement for a seperatly prepared text but can be reference to other documents. Volume 2 7.2.2 b requires the accreditation body to require a copy of the labs quality manual, this needs to be looked at before any changes can be made. Not in the new version.	
ISO 8.8.2 d) implement appropriate correction and corrective actions without undue delay;	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.
4.13.3 b) The laboratory shall retain all records for a minimum of five (5) years from generation of the last entry in the records.	Change the word entry to use or add a part in the section about personnel training and initial demonstration and or all training records on the analyst until 5 years after they leave the company. If we change the language to use this would take care of CRM and IDOC as the initial record would be 'used' every time the standard is reference or a CDOC is done.	Training records are different than other laboratory records and need to have clarification within this section. Make a guidance document for records and time frames that are required for keeping (IDOC, maintenance records on instruments)
4.4.1 c) the appropriate test and/or calibration method is selected and is capable of meeting the	No change suggested	The customer however named is the end user of the data

customers' requirements (see 5.4.2).	Add a definition for customer in the standard	
ISO **7.8.2.1** Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse: f) identification of the method used; n) additions to, deviations, or exclusions from the method **ISO 7.8.3.1** In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following: b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);	Additional Language needs to be added on what is required in the reports: Prep methods- Different for every state so should be up to the end users, not part of the standard Need to add more language to expand on requirements in 7.8.2.1 Need more language to make sure that laboratories are identifying the revision of the methods. – The reason to require this is to show that the report mets the original request or requirement. This could be a customer driven items, but would support the data integrity. Paul states that this should be a customer request and not part of the standard as its not required by the AB. Method should match what is on your Scope. Prep methods are not required on PT due to not being in table, but are required on final report by most Abs PT executive committee looking at adding Prep methods to table. This is no longer true Qualifiers	The ISO language needs to be expanded for the specific requirement within an environmental laboratory.

	Should this go under final reports or non-conforming work. 5.10.3.2 f is language from 2005 iso standard, replaced with 7.8.2.1 n, where it talks about deviations from the method. Additional language needs to be added for data qualifiers.	
ISO 7.11.2 NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.	Instrument Software Note in 17025 needs to be added as requirement. – Has always been a note and has not been an issue. Therefore, it should be left as a note.	Instrument software- verification and validation is done by using the equipment, so analytical performance would count as the instrument software validation. DOD requires that the calculation on the instrument be validated with a known set of data and run in through the program to do some manual math checking. Should TNI follow this thinking? This is based on old thinking, so maybe we should let it go. Need to consider before making Note 2 a requirement, laboratories do not want the same requirements for LIMS to be applied to off the shelf software, unless it has modification made by or for the laboratory.
5.6.4.2 a) The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity	No Suggested Change	Possible guidance document here Note: C of As only available on the vendor website are by definition

(if available), the date of receipt, and recommended storage conditions.		uncontrolled record for which labs can't ensure record retention requirements are met without some level of contractual agreement with the vendor.
ISO 3.8 and 3.9 Definitions	No Suggested Change	Data validation/verification is already a requirement of the standard, however named.
5.4.2 Selection of Methods	No Suggested Change	Language is ISO language and may need guidance but does not need additional language.
ISO 8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document. ISO 8.3.2 d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;	Language needs to be added from the current standard 'authorized editions'	There needs to be language added to ensure that accredited laboratories have an authorized copy of the standard for which they have accreditation.
5.5.13.1 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.	No Suggested Change However we determine to handle annually needs to also be addressed here.	Open to suggested language
Continuing Operations Plans	No suggested Change	This would fall under the risk and opportunities clause.
Method validation and verification	Leave up to the technical modules to define.	The QS module needs to state that validations and verification must occur using current ISO language, how they are completed would be up to each technical module.