Quality System Expert Committee (QS)
Meeting Summary

February 4, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 8am Pacific in Newport Beach, CA on February 4, 2020. There were 6 members present (Jessica Jensen, Kathi Gumpper, Bill Ray, Shari Pfalmer, Kristin Brown and Michelle Wade). There were also 3 new members present that will start their term after the conference: Nick Slawson and Michael Desmarais.

2. Open Forum – Summary of Suggested Changes

Jessica continued to review SIRs to determine if there are more changes needed to the Standard. Changes noted were summarized on the Summary of Suggested Changes table.

- Standard Interpretation Requests (SIRs)

  SIR 119 – Add to change table. Address under reporting. Qualifiers on analytes.

  SIR 169 - No

  SIR 175 – Do we need to add "outside source" or "second source"? This is a Module 4 issue.

  It was noted that these types of definitions would be a good idea. A definition would leave no doubt what is needed.

  Ray said outside source is used 4 times in the Standard – Micro and WET only. It was removed from Chemistry.

  SIR 180 – The language in the 2016 Standard is all ISO/IEC 17025:2005. Did it change for 2017 version? Do we need to add language to clarify? Added to the change table.

  It was noted that contracts may still require an old method. Bill Ray noted that TNI and labs don't control what method needs to be used. The new 2017 Standard says to use new method as appropriate (2017 ISO/IEC Standard - 7.2.1.3). Sheri suggested adding a note along the lines that it is not appropriate to use a method the client did not request.

  Paul Junio noted that there is another SIR that relates to this. "Most recent version" was previously addressed in SIR 166. The link to the response is here: https://nelac-institute.org/content/load_sir.php?SIR=10005. The key is the italicized phrase from

5.4.2 (The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so.). The latest edition of a method must be used unless it is not appropriate or possible to do so. Therefore, if a method from an earlier edition of a published document (such as Standard Methods) is mandated for use by a regulatory agency, then it is not appropriate to use the most recent method.

SIR 192 – Similar to issue discussed yesterday about electronic manuals. Will be added to change summary. Is electronic CoA OK? Is manufacturer's site only OK? Jessica gave an example of a chemical that was no longer offered, and it was no longer on the vendor site. She had to call to have them find it. Might have been better to have saved it when she originally purchased the item.

SIR 304 – Not added.

SIR 308 – Relates to Section 4.14.1 – which was read. There is no difference between 2009 and 2016. There is a change in the 2017 language. (Section 8.8). It uses terms like frequency.

The language in 2017 no longer has an annual requirement. This is an opportunity to move forward with risk based, but ABs in the audience yesterday felt it should still be more defined.

The lab gets to decided how to do the Internal Audit – but you do have to cover the entire system. Assessors will look more closely at the internal audit if they are seeing lots of system issues. Why weren't these things caught by the lab?

There are SIRs related to Technical Manager, but these will not be discussed at this time. They have been reviewed and comments on Technical Manager have been received and will be further discussed this afternoon.

SIR 328 – this is already covered on the Change Summary. Jessica read through the response for this SIR. It was turned into Implementation Guidance – 9-8-2019.

SIR 363 – Legitimate copy of the TNI Standard. This will be added to the Change Summary.

It was noted that NJ requires you have to have a copy of the Standard or they won't schedule the audit.

It was asked if a lab needs more than 1 copy in the lab – can they have more than one copy that is uncontrolled. It depends on what the lab purchased.

Response to the SIR:

4.3.1 General: The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.
4.3.2.2 The procedure(s) adopted shall ensure that: a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

Because the TNI standard contains specific requirements that laboratories must address, and because these requirements are not universally available from other sources, yes, an authorized edition of the appropriate TNI standard revision under which the lab holds accreditation must be available within the laboratory's controlled document system. (The highlighted sections contain the language upon which the interpretation stands.)

BREAK 10-10:30am

Jessica asked for any additional areas of the Standard that need to be changed or added:

- Support Equipment – 6.4.6, 5.5.13.1 (2016)

- Support Equipment and Audit Trail – 7.5 4.13.3 a). and 4.13.2.1 (duplicating language – not in combined Standard – it is now ISO language – 7.5.1).

- SOP headers – 7.2.1.2 (4.2.8.5 d) – 2016)

- Unique identifiers – 7.4.2 (5.8.5 a) -

  It needs clarification. When you take a sample through the process, is it clear that the sample can't get mixed up.

  Look at d) – original code is used. Digestate does not need another unique ID. It was suggested to look at from a storage stand point. Any container that the sample is stored in should be labeled.

  Paul Junio – The unique ID needs to be put on container where there is a potential for mix-up. Need a method to get back to the original sample ID.

  Kathi – ISO language specifies this better than the old language.

  Need enough of the original sample number to uniquely identify it when putting it in the analysis container. System needs to keep the record from getting confused.

- Internal Audits – 8.8.1, 8.8.2 (4.14.5 c) – 2016)

- Time Frames

  It was suggested that the actual time frame be put in the Standard instead of trying to find a definition that works universally. If TNI does this, it also doesn't matter how states define these words because we won't be using them in our Standard.

  It was noted that a lab defines quarterly, annually etc in the lab's documents.

  AB – assessments need to be completed within 24 months. The wording is important because it affects how things can be done. One day after … it is a finding.

3. Technical Manager

   It was asked if a brief summary about technical manger could be shared. Jessica reviewed the latest DRAFT of the language. She noted that each expert committee is being asked to write their own requirements and submit it to the Quality Systems Expert Committee for compilation and review.

   CA is exempted from 6.2.6 requirements because they are not a NELAP AB. It was noted that CA is still in proposal phase. CA proposed language can be found on the CAL ELAP website. Look at proposed rule language. If an onsite assessment is done by a TNI AB, the audit can be used for CA. Just need to turn in an application. (Click on Regulations – Complete Rulemaking File – Text of Originally proposed regulations).

   All the technical manager requirements will still be in Module 2. Asbestos did not provide separate language.

4. Meeting Close

   The meeting adjourned at 12pm Pacific. The next meeting will be by teleconference on February 10th at 1pm Eastern.