Quality System Expert Committee (QS)
Meeting Summary

February 3, 2020

1. Roll Call:

Jessica Jensen, Chair, called the meeting to order at 1:30pm Pacific in Newport Beach, CA on February 3, 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, Tony Francis and Michael Desmarais.

2. Open Forum – Summary of Suggested Changes

Jessica asked people to let the Committee know about areas of the Standard that have caused issues and need clarification or better wording. Jessica reviewed the list of suggested changes from the 1-13-20 minutes. Technical Manager will not be discussed today. A Summary of Suggested Changes table was used to capture the suggestions.

- Support Equipment vs. Analytical equipment – related to an issue in WET. Same equipment cannot be both.

- Technical modules need to clarify if there are needed differences to Module 2. Some modules think they don't need to follow Module 2. This needs to be spelled out in the expert committee modules. This is more of a comment for Program Administrators and expert committee chairs.

- SOP categories – Would prefer to see "as applicable". Re-do order too.

- Aren't assessors trained to do assessments? Why is there so much inconsistency? Labs are afraid to push back. He has used the process to contest a finding and sometimes it works in his favor and sometimes it doesn't.

- It was noted that not everyone understands the complaint process. This should be shared with labs. (Maybe could be a mentor session topic?)

- New Jersey is adding definitions to their state regulations … so we want to work on these definitions quickly.

- A number of states have their regulations open right now. They are implementing the Standard.

- Define Annual.

It was commented that annual should not be defined as 12 months. This means you really have to do it every 11 months.

A suggestion was made to look at all the time terms used. Is it really what you want? Provide flexibility.

Quarterly is only used once in Module 2. More in other modules. Should the labs define the terms?

Lab will "periodically" – does it say annual? It is further down in the Standard.

AB – When he reads the Standard, it does not mean that you just need to make a schedule every year.

Annual is defined in his laboratory. If it is January, it just needs to be done sometime in January.

- Internal Audits

Nick – He pointed out how internal audits are looked at in ISO/IEC. The point is to do a good audit.

Kathi – Many labs spread the internal audit over a period of time.

Ilona commented that this may be an opportunity to look at risk based. Similar to what Nick mentioned.

A lab puts a schedule together and each audit stands on its own. They don't leave them all open. They do not hold the audit until the end.

Ilona commented that TNI has internal audit classes. One item that is emphasized is to talk to your AB ahead of time. Send them your schedule and see what they think.

AB – Be careful about how you approach risk based. You may get stuck with it being more proscriptive.

The problem with risk based is that the ABs are resistant.

A lab is being audited to the 2017 Standard. Need to provide guidance to the lab.

Jessica noted that there are some risks going too far into risk based because there are some labs that will take advantage of this when they have problems. Not all labs are equal.

Kathi – It will be a balancing act.

Perhaps it's not as important to get an internal audit finding … if they are having an issue it will be seen in the external audit.

One AB is looking at a small subset. They think issues should be found in an internal audit.

A lab was told to make sure they look at technology every year.

Jessica noted that the Committee is not writing a standard just for states and they are not writing just for labs. They have to mesh this.

BREAK 3-3:30pm

The Committee continued to add items to the Summary of Suggested Changes table.

- Should Module 2 include overarching concepts for DOCs? Jessica said NO.

- Document retention – 5 years. What should retention be for DOCs? 5 years after last use … so this works with thought that you must keep it until 5 years after person leaves.

- Why are we keeping DOCs? This should help you determine the time frame. Her city makes it a 10-year requirement.

- Work on request for tenders. They have a captive audience. Clarify what is needed.

- Keep in mind the client may not always be outside of the laboratory or organization. It might be the person who is requiring the work.

- It was noted that ISO uses term customer instead of client. It has some good things on this topic.

- How much traceability is really required? Do you really need to state which pipet you use, etc ….

- Ilona pointed out implementation guidance – Quality Systems -9-8-19

- Review of Standard Interpretation Requests (SIRs)

  Jessica moved on to look at SIRs to see if more should be added to the Change Summary.

  - 22) and 79) are already on the list.

- 93 – revision number of methods on reports - This makes sense to do a guidance document instead – need to update SIR Summary.

- Add to table. Does a lab need to include their prep method on final report?

- 101 – Need to require this in the Standard. It is currently a note.

- 180 – Do the same thing as 93.

- 246 - Already in change table.

- Issue came up about using standards from other lots. There have been issues where the vendor has used some of the same lots or within a lot some of the analytes between standards were from the same lot while other analytes were different lots. Ilona asked if this relates to the Task Force being formed to looking at Consumables. An AB mentioned that it is important to know whether the vendor had to do something to the item before it went out.

- You run PTs, so if there is a problem with Standards … wouldn't it be found?

- It was asked whether TNI defines what a day is. It is an AB question? Maybe a data user question? TNI can't address this.

- With many equipment manuals now online … how do we control a document we don't have control of. You print a copy or take the risk that a system could be down or a company goes out of business. The Standard does not require it. It was noted that there are a lot of things that are electronic. You need to decide your risk. Sometimes the online versions are updated and it may not be applicable to the device you have.

3. Meeting Close

   The meeting adjourned at 5pm Pacific and will continue tomorrow morning at 8am Pacific.