

Quality System Expert Committee (QS) Meeting Summary

March 23, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 11:30am by teleconference. Attendance is recorded in Attachment A – there were 11 members present. Associates members on the call included: Elizabeth Turner, Carl Kircher, Aurora Shields, Bill Ray, Eric Denman and Meera Neb.

The committee spent the first 15 minutes of the meeting becoming familiar with the use of Webex for committee meetings so documents can be worked on live.

The meeting minutes from the 3/9/15 will be reviewed and approved at the next regular meeting in April.

2. Small Lab Handbook

Ilona sent a number of documents to committee members to help the committee get started – Handbook, original Handbook (Tom's), a presentation Jerry Parr and Chuck Wibby did as an overview of the Standard many years ago, information on past lab deficiencies, FAQs being developed by LASEC, a link to the SIRs, etc. Everyone was asked to review this information and put something in writing on thoughts of how to move forward, how to organize the Handbook revision, what should the content be, etc. The committee members were asked to submit this before the meeting so Ilona could compile it into one document.

Paul pulled the comment summary document up on Webex for everyone to review together. He thought there were a lot of good comments. He pulled up Matt's comments first since he was concerned about diverging requirements. The two audiences are not the same and they have different needs. Is the committee being asked to do two things that are counter active?

The majority of the users of the document historically have been people just starting out. Paul does not think a brief document would be appropriate for this audience.

Elizabeth would prefer more detail in the handbook to help people who are using it. This is consistent with Paul's comments.

Silky commented that the current version leads people astray in a few areas and so this update needs to be done.

Introduction

The current document needs the new TNI disclaimer. The committee also wants to include information from Tom's introduction. Everyone especially liked the bold red text: **Read the standard!**

Aurora asked about what the difference is between this document and what Advocacy is working on to help laboratories with implementation. They are updating an old EPA guidance manual that provides guidance to labs on topics like personnel, quality, etc... It might be described as Good Laboratory Practices. Aurora questioned why they two groups are not working together on some of this.

Paul described the history of how QS came to work on the Handbook. He then noted that this document is specific to the standard. The EPA guidance document would not necessarily address the same things. He does not think they need to coincide.

Outline

Ilona suggested the committee take a step back and look at Patty's outline as a whole so the group can come up with the outline and then start going through specific sections such as the Introduction.

The Committee decided to build on Patty's outline and incorporate the comments other people sent to Ilona. The Committee went through each bullet point. (See Attachment D for a copy of the final Outline based on today's meeting.)

The committee worked on a comprehensive list of reference documents. It was pointed out that TNI is working on a methods compendium that will have links to public access methods. Standard Methods will still need to be purchased.

The committee talked about access to various reference documents and the need to have copies that are still available when the internet goes down. Some auditors have concerns about web based reference documents because links change, databases go down, etc. Paul commented that he pulls copies of the web based documents and keeps them on his server.

The committee also talked about providing links to helpful websites that contain copies of many reference documents.

Chris commented that in ISO– it is noted that a laboratory has to document its policies, systems, programs, procedures and instructions ... it states that the master list contains internal and externally derived documents. He would not have a problem with a document on an internal server, but web based would be a problem. Others agreed.

Would it have to be a physical copy or internal server? Or is it OK to go to a website that is not owned by the lab. If you do not have control over the link – you don't have control

over the document. This discussion will be continued when the committee works on this section, but the information has been added to the outline so it will be considered.

Ilona suggested taking some of the initial bullet points and lumping them under a common bullet of First Steps.

Dale likes the current version of the Handbook because it references the standard. He does not think it needs to be in the same order. There were no objections.

Module 2 should be first – Quality Systems General Requirements. Then Module 1 – Proficiency Testing.

CSDP is working on a common list of terms, definitions and acronyms. This can be referred to in the Handbook.

Paul highlighted that people working on this project need to have a copy of the standard with the ISO language. Ilona noted that TNI no longer distributes a copy of the Standard without the ISO language.

Under Module 1 bullet – Corrective Action, Complaint Resolution and Reinstatement after suspension or revocation are part of Module 1. Paul's thoughts are that not much time needs to be spent on this because these are not issues for someone first applying. There was general agreement and this will be handled more lightly.

The appendices need to be moved up. Paul noted that Asbestos, Radiochemical and Toxicity are usually not used by small labs – so these may only include a reference to the standard and further guidance may not be developed.

The committee worked on additional items to add to the Prepare for the First Onsite Assessment section. These additions included providing pre-audit documents, training lab personnel on audit protocol, etc.

Paul will forward the document the committee worked on today. This will be the starting point for the next call on April 13th. People should continue to forward comments to Ilona by the Thursday before meetings so she can compile all information into one document for the call.

Ilona suggested that people look at the comments below the Outline and see what else needs to be added or deleted on the outline.

3. Action Items

A summary of action items can be found in Attachment B.

4. New Business

- None.

5. Next Meeting and Close

The next meeting will be April 13, 2015 at 1pm Eastern. Ilona will send out a conference and Webex invitation.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Paul adjourned the meeting. The meeting ended at 1:01 pm EST (motion – Silky, Second – Shannon Unanimously approved.)

Attachment A
Participants
Quality Systems Expert Committee (QS)

Members (Exp)	Affiliation	Balance	Contact Information	
Paul Junio (2018) (Chair) Present	Northern Lake Service	Lab	262-547-3406	paulj@nslab.com
Michelle Wade (2016) (Vice-chair) Absent	Wade Consulting and Solutions	Other	913-449-5223	michellefromks@gmail.com
Katie Adams (2016) Present	USEPA Region 10	Other	360-871-8748	Adams.Katie@epa.gov
Kristin Brown (2016) Present	Utah DOH	AB	801-965-2530	kristinbrown@utah.gov
Patty Carvajal (2017*) Present	San Antonio River Authority	Lab	210-227-1373	pmcarvajal@sara-tx.org
Chris Gunning (2018*) Present	A2LA	Other	301-644-3230	cgunning@a2la.org
Jessica Jensen (2018*) Present	A&E Analytical Laboratory	Lab	316-618-8787	jessica@aelabonline.com
Silky S. Labie (2018) Present	Env. Lab Consulting & Technology, LLC	Other	850-656-6298	elcatllc@centurylink.net
Shari Pfalmer (2018*) Present	ESC Lab Sciences	Lab	615-773-9755	spfalmer@esclabsciences.com
Dale Piechocki (2017*) Present	Eurofins Eaton Analytical	Lab	574-472-5523	DalePiechocki@eurofinsUS.com
Matt Sowards (2017*) Present	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Shannon Swantek (2017*) Present	Oregon Public Health Division	AB	(503) 693-4130	shannon.swantek@state.or.us
Janice Willey (2018) Absent	NAVSEA Programs Field Office	Other	843-794-7346	Janice.willey@navy.mil
Ilona Taunton (Program Administrator) Present	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – QS Executive Committee

	Action Item	Who	Expected Completion	Actual Completion
1	Review the two handbooks – Tom’s and the version currently being sold. Also review information sent by Ilona (SIRs, FAQs, Assessment Findings). Prepare an outline of how you think the handbook should be organized and comment on any key elements of design or content that should be considered. Send to Ilona by Mon, Mar 2 nd .	All	3/2/15	Extended. Comments due 3/19/15.
7				
8				

Attachment D – Updated Outline from Summary Document

Laboratory Handbook Outline

I need a copy of the outline we finished up with after our meeting.