

**Quality System Expert Committee (QS)
Meeting Summary**

September 12, 2016

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference on September 12, 2016. Attendance is recorded in Attachment A – there were 8 members present. Associate Members: Eric Davis (30 min), Eric Denman, Reed Jeffery, Tyler Sullens, and Carl Kircher.

The meeting minutes from June 13, 2016 were reviewed. A motion was made by Patty to approve the June 13, 2016 minutes as written. The motion was seconded by Janice and unanimously approved.

The meeting minutes from July 22, 2016 were reviewed. A motion was made by Dale to approve the July 22, 2016 minutes as written. The motion was seconded by Shari and unanimously approved.

There was no meeting in August.

2. Committee Membership

Paul distributed Jacob Oaxaca's resume and information for membership consideration on the committee. Dale motioned to add Jacob to the committee by email and the motion was seconded by Patty. There was no further discussion on the call today. Individual vote:

Paul – For
Jessica – For
Janice – For
Dale – For
Shari – For
Patty – For
Kristin – For
Sara – For

The motion passed and he will be added to the committee. There are now 6 laboratories, 4 ABs and 3 Other.

3. Orange County Meeting

Paul thought the training went well. It was interesting hearing about the concerns from California laboratories. He's had follow-up with a number of labs.

ISO 17025 is being revised. Carl is on an international committee on conformity assessment. This committee is an ANSI group. The committee is working on comments and then they will issue a DRAFT International Standard that will be up for vote. Carl provided Paul with a DRAFT of the current document and he shared this with the committee through Webex. Ilona noted that Jerry is checking into getting copies of the DIS that the committee will use to begin review of the Standard.

Carl noted that the format of ISO 17025 has changed. They are trying to get all of the international standards to look similar in format. A lot of the previous standard has been rearranged and there is more on risk assessment, impartiality, confidentiality, etc ... Previously there were 5 sections ... now there are 8. Paul thinks there is more detail added. He asked about Option B in Section 8. Carl noted this relates to labs that are ISO 9001 accredited and outlined what is being considered.

The structure of the TNI Standard will need to change in the next update. TNI can start working on this update once the DIS is complete. Ilona noted that the non-governmental AB's noted that the Standard does not change very much after the DIS is completed. This is not expected for at least another 9 months.

Paul scrolled down to Section 8 of the ISO 17025 Draft. There is a lot of familiar information, but there is also some new information. He also gave people a chance to look at some of the other sections.

Carl has done a crosswalk between the current TNI Standard and this Draft ISO standard. He also compared it to the 2003 TNI Standard.

Technical Director and Laboratory Director requirements were discussed outside of meetings in Orange County. Shari asked if there are states that have specific requirements for Technical Directors or Laboratory Directors in their rules. Carl noted that New York and Minnesota do. There are also other states outside of TNI ABs that have requirements. Shari noted that Massachusetts's has requirements for quite a few Chemistry hours (thirty hours) and this excludes many people from being a Supervisor. In many cases the Laboratory Director has to be noted as the Supervisor because the Supervisor has a biology degree and not enough actual chemistry hours. The organization charts going to Massachusetts's look different than what goes to everyone else. Pennsylvania requires an email from secondarily accredited labs when there is a Technical Director change. Carl noted that Florida expects the same.

It will be difficult to deal with the Technical Director requirements in the next Standard update if so many states have different requirements. This will be a big task.

Carl noted that he believes the NELAP AC will be accepting Module 2 for NELAP implementation.

4. Small Laboratory Handbook

Iлона talked to Jerry about timing for the Small Handbook. Our original goal was to have it complete by December, but it can be extended to March. Iлона can also provide more staff support to meet this deadline.

Paul has not had an opportunity to further work on Handbook since the last meeting. He asked if there should be short calls to work on specific sections. Should more people be called in to help with this process?

Dale sent out a copy of the information sent by Radiochemistry. It does not follow the newer format discussed with Microbiology. Paul noted that there should be one format for all the sections. He pulled up what Dale sent and a copy of the format the committee decided on. Everyone agreed there should be one format and the preference was to use a more narrative form like what Radiochemistry used. The bullet points were not conversational and looked too much like the Standard. Paul will pass the Radiochemistry example on to Robin for Microbiology and request that they use this format.

Dale asked about the “What Do I Do?” section. Has this been eliminated? This is the same as including examples. Everyone agreed that examples should be included where helpful.

Dale asked if each section has to have the same headings. Do you have to have Keypoints, Discussion and Example in each section? Everyone agreed that there might be sections that don't need discussion or example.

Paul will reach out to everyone to continue progress on the Handbook. Jerry mentioned that they are thinking about having some lab session similar to what was done in Orange County. This gives labs an opportunity to just attend these sessions at a discount. Paul thought one of these sessions might give valuable feedback for the Handbook. The committee will need to push to have something prepared for the Houston meeting. Everyone liked that idea.

Paul has reached out to the Chemistry Expert committee, but needs to continue to follow-up. He also thinks this could be done within the QS Committee if there is an issue.

5. Action Items

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

6. New Business

None.

7. Next Meeting and Close

The next meeting is planned for October 10, 2016. Ilona will send out conference call and Webex invitations.

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

Paul adjourned the meeting at 1:55 pm Eastern.

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
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*) Absent	A2LA	Other	301-644-3230	cgunning@a2la.org
Sara Hoffman Present	Kansas Health and Environmental Laboratories	AB	785-291-3162	shoffman@kdheks.gov
Jessica Jensen (2018*) Present	A&E Analytical Laboratory	Lab	316-618-8787	jessica@aelabonline.com
Silky S. Labie (2018) Absent	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*) Absent	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Lizbeth Garcia (2017*)? Absent	Oregon Health Authority	AB		lizbeth.garcia@state.or.us
Janice Willey (2018) Present	NAVSEA Programs Field Office	Other	843-794-7346	Janice.willey@navy.mil
Ilona Taunton (Program Administrator) Present (1-1:45pm)	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – QS Expert Committee

	Action Item	Who	Expected Completion	Actual Completion
9	Look at the Handbook Table of Contents and volunteer for sections.	All	8/10/15	
23	Check with Richard Burrows regarding their committee doing the update on the Handbook.	Paul	3/14/16	Follow-up needed.
24	Summarize format for Handbook and send to committee members and other Expert Committee Chairs.	Paul	6/10/16	Follow-up needed.
25	Follow-up with Bob Wyeth and Jerry Parr about experience vs. course hours for Technical Directors.	Paul	TBD	
26	Provide in writing, thoughts regarding options for Technical Director approval.	Robin	TBD	
27	Send new Handbook format to Robin.	Paul	9/30/16	
28	Follow-up with Expert Committees to prepare a section of the Small Lab Handbook. Radiochemistry is complete and Microbiology has started.	Paul	9/30/16	

