Quality System Expert Committee (QS)
Meeting Summary

December 11, 2017

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 1pm Eastern on November 13, 2017 by teleconference. Jessica (Vice-Chair) helped lead the meeting. Attendance is recorded in Attachment A – there were 6 members present. Associate Members: Kathy Gumper, Gil Dichter, Eric Davis and Carl Kircher.

A motion was made by Silky to approve the minutes from the 11/13/17 meeting. The motion was seconded by Jacob and all in attendance voted "For". The vote will be completed by email or at the January meeting. (For: Paul, Sara, Jessica, Silky, Jacob, Matt).

(Addition: Vote will be completed at the 1/8/18 meeting.)

(Addition: Additional votes received at the 1/8/18 meeting: Chris, Kristin, Shari and Lizbeth. The motion passed.)

2. Membership

The following applications have been received:
Michelle Wade – Other
Stacie Crandall – FSMO
Maggie Cangro – FSMO

Janice recommended Alyssa Wingard from her organization. Paul will follow-up on this.

Kathy Gumpper is interested in joining the committee. Ilona will send a link to the application.

Jessica and Ilona will pull together resumes and applications for the committee members to consider at the next meeting on the 8th of January.

3. Standard Interpretation Request (SIR)

SIR #246
Jessica read the SIR.

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2

Section (eg. C.4.1.7.4)	5.8.5.a
Describe the problem:	Question: Do labs have to uniquely identify sample containers when received at the lab? The 2009 standard states: "The laboratory shall have a documented system for uniquely identifying 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." The 2003 standard stated the same but also added: "The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample." Since the 2009 standard dropped the wording above in the third paragraph, some are interpreting this to mean the labs do not need to uniquely identify sample containers anymore. However, since the 2009 standard does still include sample containers in the last sentence of the second paragraph, above, some are interpreting that sample containers must be uniquely identified. I have heard this may be addressed in the upcoming standard, but I don't know that absolutely.
Comments:	The comments received from the AC confuse the requirements. Samples must be uniquely identified. A sample may consist of many bottles. The requirement to have a unique sample ID (which applies to samples) is not equivalent to having a unique ID for each sample container. The word container was specifically removed from the 2003 Standard for this reason. A laboratory would likely have a listing of the required preservatives for a given analysis. That would indicate which preservative would be used for a given analysis. The specific sample bottle used for analysis is NOT a requirement of the Standard. If that is something required in a Project Plan or due to memories of the 2003 Standard, that is beyond the scope of the 2009 Standard.
Response:	The laboratory shall assign a unique identifier to each sample received. Each sample container need not contain an additional identifier beyond the unique sample ID. The laboratory shall have a system that

describes how it addresses multiple containers of the same sample.

An email from Lynn on 12/6/2017:
AC comments (9 negative votes):

- *The 2009 standard section includes "sample containers" as part of what needs to be uniquely identified. If each container itself does not have a unique ID how do you know which container was used for testing if questions on results occur.*

- *I am against the response based on VIM2 5.8.2 and VIM2 5.8.5 a. The lab must have identifying test items. The system shall be designed and operated to ensure that items cannot be confused physically or when referred to in records or other documents and the laboratory shall have a documented system for uniquely identifying the samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time.*

- *The response is brief, confusing and doesn't address the issue of 3 VOA vials which seems to be of some concern.*

- *The standard clearly states, "This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates." V1M2: 5.8.5.a.*

- *The response doesn't really answer the question. The standard is clear that the lab needs to have a system for identifying samples but it is up to the lab as to how they accomplish it.*

The 2009 Standard was reviewed and there is additional language in 5.8.5 d) that implies unique ID.

Since TNI is going back to the unique container in the 2016 Standard – Paul feels the lab has to have a unique ID. The way it is written, it could be interpreted either way.

Carl Kircher noted that if lab receives 10 sample containers from the same site, is there a way to confirm the proper bottle was used for the analysis and that it had the proper preservation. This is what he looks for in a lab.

Change to response:
The laboratory shall assign a unique identifier to each sample received. The laboratory shall use a system for how it uniquely identifies multiple containers of the same sample. The system must be able to track the sample container from receipt to report.

4. Small Laboratory Handbook (SLH)

Ilona provided an update on the SLH. The committee needs to review the Acronym list that Jessica prepared that Ilona distributed by email to the committee. We are still waiting

for Chemistry to finish up the guidance documents that are part of the Handbook. Kristin and Sara are still working on the Common Findings Appendix.

Silky noted these need to be added:
% relative error (%RE) and % relative standard error (%RSE)

Everyone was asked to send additions and changes to Paul and Ilona.

5. Action Items

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

6. New Business

Registration for the conference and hotel are now open.

7. Next Meeting and Close

The next meeting is planned for January 8, 2017 at 1pm Eastern by teleconference. The meeting will include a discussion on SIR #246 and the new ISO language.

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

Paul adjourned the meeting at 2:26pm Eastern. (Move: Matt Second: Silky 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@nlslab.com
Kristin Brown (2016) **Absent**	Utah DOH	AB	801-965-2530	kristinbrown@utah.gov
Chris Gunning (2018*) **Absent**	A2LA	Other	301-644-3230	cgunning@a2la.org
Sara Hoffman **Present**	Kansas Health and Environmental Laboratories	AB	785-291-3162	Sara.hoffman@ks.gov
Jessica Jensen (2018*) **Present**	Meridian Analytical Labs	Lab	316-618-8787	jessica.j@meridiantesting.com
Silky S. Labie (2018) **Present**	Env. Lab Consulting & Technology, LLC	Other	850-656-6298	elcatllc@centurylink.net
Jacob Oaxaca (2019*) **Present**	CA Water Board	AB	916-323-3433	Jacob.oaxaca@waterboards.ca.gov
Shari Pfalmer (2018*) **Absent**	ESC Lab Sciences	Lab	615-773-9755	spfalmer@esclabsciences.com
Dale Piechocki (2020) **Absent**	Eurofins Eaton Analytical	Lab	574-472-5523	DalePiechocki@eurofinsUS.com
Matt Sowards (2020) **Present**	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Lizbeth Garcia (2019*) **Absent**	Oregon Health Authority	AB	503-693-4115	lizbeth.garcia@state.or.us
Janice Willey (2018) **Absent**	NAVSEA Programs Field Office	Other	843-794-7346	Janice.willey@navy.mil
Bill Ray (2020*) **Absent**	William Ray Consulting, LLC	Other	925-352-5205	Bill_Ray@williamrayllc.com
Ilona Taunton (Program Administrator) **Present**	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
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	
33	Review SLH to date and send comments to Paul.	ALL	4/6/17	Complete
38	Continue SIR 246 and 296 discussions.	All	TBD	
40	Get PT root cause analysis example from Scott Hoatson.	Paul	8/31/17	
43	Work on secondary accreditation language to update Ch 1 of the SLH.	Kathy Gumper and Paul	11/20/17	Complete
44	Silky will review PT section and send any needed updates to DW language.	Silky	11/20/17	Complete
45	Review Ch 1 Application section for the use of “shall” and “may”. Are uses correct?	Paul, Sara	11/20/17	
46	The committee should continue review of the SLH and send comments before completion of the Final DRAFT.	ALL	11/20/17	
47				
48				

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Update charter in October 2016.	n/a	Delayed. Waiting for format from Policy Committee.