Quality System Expert Committee (QS)
Meeting Summary

June 12, 2017

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference on June 12, 2017. Attendance is recorded in Attachment A – there were 5 members present. Associate Members: Kristin Mosher, Carl Kircher, Trinity O'Neil, Eric Davis, Patty Carvajal, Eric Denman and Tyler Sullens.

The May minutes were distributed by email. A motion was made by Bill to accept the May 8, 2017 minutes as written. The motion was seconded by Kirstin and unanimously approved.
Votes:
Bill – For
Kristen – For
Sarah – For
Dale – For
Paul – For

The vote will be completed by email.

(Addition:
Chris – For (Email 6/12/17)
Shari – For (Email 6/13/17)
Lizbeth – For (Email 6/13/17)
Jessica – For (Email 6/13/17)
Jacob – For (Email 6/13/17)
Janice – For (Email 6/13/17)
Matt – For (Email 6/22/17)

The motion passed and the minutes will be posted on the TNI website.)

2. Standard Interpretation Requests

Paul noted that there were a few SIRs that still need to be completed by the committee and they have been added to the agenda for review.

SIR 246

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.

DRAFT 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.

Discussion:
Kristin thinks the response clarifies it, but is not sure she agrees with it. Sara noted that the NELAP AC talked about VOA vials and how you would a lab know which one was actually tested. Paul asked if it matters since the vials are supposed to be the same sample. Perhaps this can be addressed in an SOP? Paul asked if the Standard states that the containers have to be uniquely identified. The labs look at a sample and choose a container of a sample for analysis. A comment was made that with water samples, some come with containers that are specifically preserved a certain way for a specific method.

Paul thinks this is handled through SOPs because they state what sort of container or preservative is needed to run a method. The correct container is pulled.

An interpretation cannot add a requirement to the Standard. It does not say “container”, so it is not required.

How do multiple containers compare to subsampling?

Do you have to identify each container by giving it a unique identification on a label or does the process only need to be set-up in a way to identify each container uniquely? The process would be documented. A date or name could help uniquely identify a container.

The 2003 Standard used “container” and it was clear the containers needed to have a unique code. This was removed in 2009.

Paul looked at the preservation requirements. The lab shall document procedures for verifying and documenting preservation.

Ilona asked how the assessors on the call assess this section of the Standard. Carl relies heavily on the word “document”. The lab needs a documented system. How does he know the lab will select the correct sample container for the test? The lab needs a documented system for determining that.

Kathy noted that the QSM for DoD requires that the containers be identified. When she does work for a state AB, she checks with the state and what their expectations is. There are differences between the state expectations.

Sara assesses similarly to Carl. They look for a documented system. Some labs use stickers to identify the different preservatives to make it obvious which container should be used.

The group agreed with the DRAFT response after the discussion above.

Sara asked if a line could be added to state the lab needs a system to handle multiple containers for a sample. Paul added: The laboratory shall assign a unique identifier to each sample received. Each sample container need not contain a unique identifier beyond the sample ID. The laboratory shall have a system that describes how it addresses multiple containers of the same sample.

Paul will send this DRAFT response to the rest of the committee for comment.

SIR 108

This SIR is still being looked at.

Section (e.g. C.4.1.7.4)	5.4.13.1
Describe the problem:	In the description of internal audits, it states "The internal audit program shall address all elements of the quality system, including the environmental testing activities." Does this mean that every method has to be audited yearly? For Labs that are running 300 or more methods this doesn't seem reasonable.
Comments	Section 5.4.2.1 states 'The laboratory shall establish implement and maintain a quality system based on the required elements in this chapter and appropriate to the type, range and volume of environmental testing activities it undertakes.' It isn't too high a standard to expect that each method would be audited once per year. It is possible that there wouldn't be a complete, exhaustive audit if there are no problems in the past. There could be more than a review of SOPs to qualify as a method review, and it is likely that a more in depth review would be required if issues were uncovered. The laboratory must determine how it will conduct its assessment of its environmental activities, and the lab must establish its procedure for doing this.
Response	The Internal Audit that is required in 5.4.13 is of the laboratory's quality system. It is possible to assess a laboratory's quality system without auditing to every SOP.
Revise Response	No, every method need not be assessed annually in the laboratory's internal audits.
Comment – not a response	Are elements equivalent to just methods? Are elements PT samples, analytical SOPs, non-method SOPs, training records, management statements…. Can this be reflected in technologies (i.e., ICP/MS, GC/MS), so that you catch all analytes over two years? All methods may not have the same in-depth annual internal audit (this may be an analyst interview, observation of the method, or some other assessment), but all methods are fully assessed over a set timeframe. The laboratory is obligated to expand its assessment schedule if

	issues are identified during its internal audit.

Another topic being discussed in TNI is whether an AB needs to assess all methods or just a sampling.

It was noted that TNI is working on this issue. Ilona commented that this SIR should be tabled if another committee is looking at establishing a policy on this topic. Paul will send a message to Lynn to figure out what the status is.

(Addition: Response from Lynn Bradley 6/12/17:
This is essentially the same as #230, and LASEC recently kicked that one out, saying that an interpretation cannot answer it. I think I should take it back to LASEC and see if we can get a similar revised opinion for 108.

The policy under development won't address internal audits at all, only AB assessments, ... for now, sit tight on 108. I'm sorry it's taken so long to sort this out, but really, after all this time, I think we've got the answer! Saying what methods an internal audit should cover (or what methods an external assessment must cover, for that matter) simply is not within the purview of the standard, as written. When they get around to requiring "assessment plans" for each lab, I'll raise the issue that those should address how to select the methods....)

SIR 296

Describe the problem:	The 2009 standard, below (b), no longer contains the wording "environmental" analysis in the area of experience. Since it now states "such analysis" does this pertain to any type of laboratory experience in chemical, physical or environmental sciences (not just environmental)? b) Any technical manager of an accredited environmental laboratory limited to inorganic chemical analysis, other than metals analysis, shall be a person with at least an earned associate's degree in the chemical, physical or environmental sciences, or two (2) years of equivalent and successful college education, with a minimum of sixteen (16) college semester credit hours in chemistry. In addition, such a person shall have at least two (2) years of experience performing such analysis. And on the same topic, the 2009 standard for (c) below for limited microbiological analytes also no longer contains the wording "environmental" and just states "microbiological analyses", so may this also be interpreted as any microbiological laboratory analyses and not just environmental? c) Any technical manager of an accredited environmental laboratory engaged in microbiological or biological analysis shall be a

	person with a bachelor's degree in microbiology, biology, chemistry, environmental sciences, physical sciences or engineering with a minimum of sixteen (16) college semester credit hours in general microbiology and biology and at least two (2) years of experience in the environmental analysis of representative analytes for which the laboratory seeks or maintains accreditation. A master's or doctoral degree in one of the above disciplines may be substituted for one (1) year of experience. A person with an associate's degree in an appropriate field of the sciences or applied sciences, with a minimum of four (4) college semester credit hours in general microbiology may be the technical manager(s) of a laboratory engaged in microbiological analysis limited to fecal coliform, total coliform, E. coli, and standard plate count. Two (2) years of equivalent and successful college education, including the microbiology requirement, may be substituted for the associate's degree. In addition, each person shall have one (1) year of experience in microbiological analyses.
Committee Comments:	Section 4.1.7.2 b) also states that the Technical manager 'be experienced in the fields of accreditation for which the laboratory is seeking accreditation."
Response(s):	The terms "such analysis" indicates that the technical manager shall have experience in the fields of accreditation for which the laboratory is seeking accreditation. The experience required is of environmental analysis in the first question, and environmental microbiological analysis in the second. In both cases, the Standard requires that the analyses performed which would qualify as experience are those that would be performed by the laboratory at which a person would be the technical manager.
Revised Response	The terms "such analysis" indicates that the technical manager shall have experience in the fields of accreditation for which the laboratory is seeking accreditation. The Standard requires that the analyses performed which would qualify as experience are those that would be performed by the laboratory at which a person would be the technical manager.

Paul reviewed the issue raised in the SIR. Ilona reviewed the note Lynn sent when this SIR was returned to the committee: The *LASEC* subcommittee is concerned that re-inserting the term "environmental" into the response is actually changing the standard. Even though it may seem as if it's being changed back to what it was, that's beyond an interpretation of the existing language. Please provide a modified response to this SIR.

Kathy asked if the word "representative" analyses could be added. Carl didn't think it

could be added to an SIR, but should be considered in future Standard development.

Paul will send the revised response out to the committee for review and comment.

3. Small Laboratory Handbook (SLH)

The new Chapter 2 information still needs to be inserted. The PT module has been revised in the SLH and has been added to the SLH. There are additions to the Chemistry section and Paul hopes to have this done in the next few days. Paul reviewed the text regarding removal of points in an initial calibration. He noted that the Standard is referenced in some sections so all the information does not need to be reproduced.

Paul asked that the committee continue to review the SLH and send comments.

4. Action Items

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

5. New Business

- Conference registration for DC is open.

- Ilona suggested that people plan to attend the ISO meeting on Thursday afternoon.

6. Next Meeting and Close

The next meeting is planned for July 10, 2017 at 1pm Eastern by teleconference.

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

Paul adjourned the meeting at 2:28pm Eastern. (Motion: Dale Second: Sara. 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) **Present**	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*) **Absent**	Meridian Analytical Labs	Lab	316-618-8787	jessica.j@meridiantesting.com
Silky S. Labie (2018) **Absent**	Env. Lab Consulting & Technology, LLC	Other	850-656-6298	elcatllc@centurylink.net
Jacob Oaxaca (2019*) **Abent**	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) **Present**	Eurofins Eaton Analytical	Lab	574-472-5523	DalePiechocki@eurofinsUS.com
Matt Sowards (2020) **Absent**	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*) **Present**	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
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	Complete – Paul is working on the section and Chemistry Expert Committee will review his work.
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	
32	Send SIR #308 Response to LASEC.	Paul	3/27/17	
33	Review SLH to date and send comments to Paul.	ALL	4/6/17	Ongoing
34	Complete email votes for Minutes and Charter by email.	Paul	5/8/17	Complete
35	Check with Advocacy about Assessment findings and Assessment Preparation documents.	Paul	6/8/17	
36	Send SIR 246 and 296 to committee members to review DRAFT responses and comment.	Paul	7/9/17	
37	Send SIR 108 question to Lynn Bradley/LASEC.	Paul	7/9/17	

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.