Quality System Expert Committee (QS)
Meeting Summary

November 9, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference. Attendance is recorded in Attachment A – there were 10 members present. Associates members on the call included: Eric Denman, Tyler Sullens, Bill Ray, Reed Jeffrey, Carl Kircher and Eric Davis.

The meeting minutes for September were reviewed. Paul commented that the definition of "lot" does not need to go through the Standard update process because it was already reviewed and approved through the PT Standard. It is only an editorial change in the QS Standard. Janice made a motion to approve the 9/14/15 minutes. The motion was seconded by Silky and unanimously approved.

The meeting minutes for October were reviewed. Shannon made a motion to approve the 10/12/15 minutes as distributed. The motion was seconded by Silky. Vote: For – 9, Against – 0, Abstain – 1 (Michelle was not present and wanted to abstain).

2. SIRs (Attachment D)

Paul noted that these are older SIRs that may have been discussed previously. LASEC shows them as still being in our committee. The committee will review them and see if the response needs to be changed and then they will be returned to LASEC.

<u>SIR 229:</u>

It is based on the 2009 Standard in Module 4.

Paul asked the ABs on the call to see if they remember what the issue was with the response. Unfortunately they were not familiar with the issue.

Janice noted that if a MS fails, the LCS is looked at. The issue with the MS could be matrix related. Tyler noted that this is different than the question being asked.

Paul read through the standard language in Module 4: 1.7.3.2.3.

Silky noted that the intent of letting labs use matrix spikes was to reduce the amount of QC a labs would have to run. It was not intended to let the lab pick and choose.

Jessica noted that this section applies to situations where a lab is not running an LCS. When they are run at the same time, you can't pick and choose. A failed LCS is a failed LCS.

Final Response:
The standard does allow a laboratory to run an MS instead of an LCS. An MS may not be used to replace a failing LCS.

A motion was made by Jessica to approve the Final Response (above) to SIR #229. The motion was seconded by Dale and unanimously approved.

SIR #230 (and #108)

This is a continuing discussion from the last meeting. Paul and Ilona met with the NELAP AC and received feedback on an internal audit scenario such as the following:

The laboratory performs internal audits of its management system annually. The lab has a listing of methods and a schedule over a 3 (or 2?) year time frame for each method to undergo an in depth audit. Factors such as PT results, SOP reviews, previous audit findings, and general knowledge about the risks of the method are taken into consideration in developing this schedule. If an issue surfaces through the year or during a management systems audit, a method in depth audit is performed even if one is not scheduled for that year. The year(s) a method is not assessed in depth, the method is generally touched on during the management systems audit because systems such as PT, training, reporting and documentation are reviewed annually. It is recommended that a review of all technologies occur each year. It would not be beneficial to audit Inorganics one year and then Organics the next.

Paul plans to write up a detailed discussion on this issue and incorporate some of the feedback received during the NELAP AC meeting. He will send this out before the next meeting.

The DRAFT response to #230 currently reads: *All methods may not have the same in-depth annual internal audit (this ma 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.*

The committee will continue to discuss SIR #108 and 230 at the next meeting.

SIR #232

Paul suggested looking at the new language in the Standard and using this language as part of the response. Ilona asked if the new language is a clarification or if there is new language. Paul believes it clarifies, but there are some additions.

Paul asked what the difference would be between a mechanical or non-mechanical volumetric dispensing device. The word "mechanical" was removed in 2009 and some thought that meant mechanical devices were exempted. Paul clarified that it was dropped because there should be no difference and the word "mechanical" was dropped. Mechanical should be checked.

Final Response: Yes. Graduated cylinders, glass to-deliver pipets, and other garden-variety glassware, which are not Class A, must be checked quarterly.

A motion was made by Michelle to approve the Final Response (above) to SIR #232. The motion was seconded by Silky and unanimously approved.

SIR #274:

Paul suggested stating that Class A is required to be glass, so Class A Plasticware is not the same thing. It would be considered non-Class A. This is based on the ASTM definition.

Final Response: By definition, Class A plasticware does not exist. So, something that is called Class A plasticware would be required to meet the same requirements as non-Class A labware.

A motion was made by Shannon to approve the Final Response (above) to SIR #274. The motion was seconded by Michelle. Discussion:

Dale would like to look at this language in connection to risk of the volume changing. Paul and Ilona noted that an SIR cannot change the Standard. The new language being voted on right now should take care of the issues being raised, but it cannot be changed now. Dale is concerned about the additional work labs have to do.

Michelle commented that some labs may throw the glassware into a muffle furnace because they don't know any better. The current wording accounts for some of this.

Vote: For – 8 Against – 2 (Dale and Matt) Abstain – 0. The motion passed.

There are 2 more SIRs that need to be addressed at the next call. Paul will send the final responses agreed upon to Lynn.

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 December 14, 2015 at 1pm Eastern. Ilona will send out a conference call 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 2:11 pm Eastern. (Motion: Shannon Second: Jessica 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
Michelle Wade (2016) (Vice-chair) **Present**	Wade Consulting and Solutions	Other	913-449-5223	michellefromks@gmail.com
Katie Adams (2016) **Absent**	USEPA Region 10	Other	360-871-8748	Adams.Katie@epa.gov
Kristin Brown (2016) **Absent**	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*) **Absent**	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) **Present**	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
8	Send new wording for Section 5.5.13.1 to Cathy Westerman and get input.	Paul	7/13/15	10/11/15
9	Look at the Handbook Table of Contents and volunteer for sections.	All	8/10/15	
11	Send Standard language changes to SRC so any recommendations can be discussed at the next meeting.	Paul	9/21/15	Complete
12	Send update to Lynn regarding SIR #290.	Paul	9/21/15	
14	Send SIR 144, 172 and 175 back to Lynn (LASEC) for consideration.	Paul	10/15/15	Complete
15	Send note about SIR 108 to Lynn and ask for input.	Paul	10/15/15	Complete
16	Prepare detailed Summary on status of SIR 108 and 230 based on reread of the Standard and information gained at the NELAP AC meeting.	Paul	12/11/15	
17				
18				

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Update charter in October 2015.	n/a	

Attachment D. SIRs Reviewed At Meeting

SIR #229

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	EL-V1M4-2009:
Section (eg. C.4.1.7.4)	1.7.3.2.3
Describe the problem:	2009 Standard states in 1.7.3.2.3... Note: The matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. Is it the intent of the standard that when evaluated by the same criteria, a passing MS replace the LCS in its totality or can an individual target compound failure in the LCS be replaced by an individual acceptable result in a matrix spike sample? Thank you.
Response	OLD RESPONSE: It is the intent of the standard to allow a laboratory to run an MS instead of an LCS. The MS is not normally meant to demonstrate method performance. However, a laboratory may choose to use the MS in place of an LCS, as the matrix of a real world sample would make this allowance a more stringent demonstration of method performance. If this option were to be used, it should be specified in the laboratory's quality control documents (i.e., analytical SOP, Quality Manual) PRIOR to being invoked. It is not the intent of the standard to allow the laboratory to run both an LCS and an MS, and decide after the fact which quality control indicator they intend to follow in terms of demonstrating method performance. NEW RESPONSE: The standard does allow a laboratory to run an MS instead of an LCS. An MS may not be used to replace a failing LCS.

SIR #232:

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

Section (eg. C.4.1.7.4)	5.5.13.1.e
Describe the problem:	How encompassing is the universe of "volumetric dispensing devices (except Class A glassware and glass microliter syringes)" needing quarterly checks for accuracy? Specifically, do graduated cylinders, glass to-deliver pipets, and other garden-variety glassware, which are not Class A, need to be checked quarterly? NELAC 5.5.5.2.1.e read, "Mechanical volumetric dispensing devices including burettes (except Class A glassware) shall be checked for accuracy on a least a quarterly use basis." The introductory paragraph to NELAC 5.5.5.2.1.e includes "… volumetric dispensing devices (such as Eppendorf or automatic dilutor/dispensing devices)." Both of these examples are mechanical volumetric dispensing devices and supported "mechanical" in NELAC 5.5.5.2.1.e. TNI V1M2-5.5.13.1.e does not include the word "mechanical" which previously appeared in NELAC 5.5.5.2.1.e. However, the introductory paragraph to TNI V1M2-5.5.13.1 is identical to that in NELAC 5.5.5.2.1 (i.e., continues to includes two examples of mechanical volumetric dispensing devices).
Interpretation/Response:	OLD RESPONSE: Any volumetric dispensing devices (with the noted exception of Class A glassware and glass microliter syringes) must be verified on a quarterly basis when the volume delivered is used quantitatively to meet the accuracy of the analysis. NEW RESPONSE: Yes. Graduated cylinders, glass to-deliver pipets, and other garden-variety glassware, which are not Class A, must be checked quarterly.

SIR #274:

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.5.13.1
Describe the problem:	The standard states "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Would class A plasticware be considered the same as Class A glassware ie - you do not need to check it on a quarterly basis? Or would Class A pastic ware be considered the same as non-class A labware? The same question for V1M5 section 1.7.3.7 iii.2 "2. equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample

analysis vessels) shall be verified once per lot prior to first use. This verification may be volumetric or gravimetric."
Would you need to check Class A plasticware once per lot?

RESPONSE: By definition, Class A plasticware does not exist. So, something that is called Class A plasticware would be required to meet the same requirements as non-Class A labware.