Quality System Expert Committee (QS)
Meeting Summary

October 12, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1:15pm Eastern by teleconference. Attendance is recorded in Attachment A – there were 7 members present. Associates members on the call included: Carl Kircher, Bill Ray, Robin Cook and Tyler Sullens.

There were not enough members on the start of the call to review the minutes. They will be reviewed next month.

2. SIRs

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.

SIR 108:

Paul does not think "elements" means all methods. It would be beneficial to give examples of the elements of the quality system. Examples would be SOPs, training records, etc ... The Standard does not say that all methods must be audited every year.

Shannon looked up the actual language and commented that Oregon has interpreted this to mean every method or at least the grouping of technologies that covers the aspects of every method.

Paul commented a previous lab he worked with clearly stated that all methods were audited within a two year time window. There are many other labs that do this also and all these labs are accredited.

Silky interpreted the language to mean technologies could be looked at. For example, each metal has its own method, but you can look at ICP and apply it to the metals. You can audit a technology that might relate to multiple methods and the goal is to make sure each technology is looked at each year and each method within that technology is looked at over two years. Shannon commented that they do allow for such groupings, but they would look to see that if there is a problem with the technology … all methods will be looked at as part of the corrective action. She also questions whether the limits should be looked at for each method each year.

ESC does something similar to what Silky described. They do the Quality System's audit and technologies every year and ensure all methods are checked every two years.

Tyler's lab's looks at technologies because they combine methods in one SOP under a technology heading … so they do check all methods annually.

Chris noted that for ISO a lab can set up their own time frame as to how often all methods need to be looked at. Since TNI makes the comment about an annual audit … he interprets that to mean all methods need to be looked at annually. DoD clearly says that the method can be spread out over a two year period. The Food Program also allows for two years. If it must be done annually, perhaps the question is to what depth the methods have to be audited annually? All methods are looked at each year through the course of the internal audits (data audits, limits, etc), but they are required to be looked at in depth over a period of 2 years? Chris said the labs have a specific schedule that lists the methods and the level of depth. It is clear that each method is looked at in depth every two years.

Shannon commented that she would like it to be clear that the lab needs to continually assess. She is asking whether they would be looked at in depth frequently enough.

Ilona asked if this level of detail is beyond what should be in an SIR response. Giving directions on how audits should be done and at what frequency seems inappropriate. Perhaps it would be more appropriate to provide this information as guidance.

SIR 108 is somewhat similar to 230. There are many assessors out there that are equating "elements" to requiring all methods.

Shannon said Oregon does look for all methods – but they are not requiring a separate checklist for each method. If the lab is doing a full systems audit the methods should be getting looked at at some level every year. They are not asking for a 200.8 checklist and a 6020.

Carl noted that he is happy when he sees an internal audit at all. If all the methods and SOPs are not addressed, it does introduce a risk of meeting the TNI requirements.

There are some assessors that look for all methods and others that are not. There is no consistency.

Paul pulled up the guidance provided on the NELAP site and did not find any topic related to this discussion.

Paul summarized the discussion today. SIR 230 and 108 are related. He will summarize in comments and then send a note to Lynn to find out how to handle where the committee is at this point.

SIR 144 (see Attachment D)

Paul pulled up the language of this SIR. Ilona noted it was responded to back in 2011 and then it was resent to QS on 11/30/13. The committee responded to it in April 2014 with a revised response. He shared this response with the committee.

The committee did not have any further response, so Paul will resubmit this to Lynn.

SIR 172 (see Attachment D)

Ilona noted it was sent back to the committee back in June 2013 because of a concern about the last sentence.

Paul was able to find the original response and the committee looked at the last sentence:
Since the composition of the blank is "different", follow the requirements outlined in 5035.

A motion was made by Silky to drop the last sentence of the previous response. The motion was seconded by Patti and unanimously approved.

SIR 175 (see Attachment D)

Ilona noted it was sent back to the committee back in June 2013.

There was a note sent by Lynn on April 23, 2013:
The two that QS needs to address are SIRs 158 and 175 -- these are essentially the same question, and it would be nice 'n neat if they had the same answer, so LAS asks that QS revise the answer so that the same wording will respond to both requests.

Paul remembers this one. There is a false assumption that they are same and they are not. The committee will address SIR 175 independently.

Matt noticed there is another SIR that is related to the same section of the standard. Paul took a look on the TNI website. He will take the language and use it to help respond to this SIR.

Paul asked if what he typed below is the response:

> *The term outside source is not equivalent to the term secondary source.*
>
> *The term outside source is referenced in the requirements for Demonstration of Capability and in Whole Effluent Toxicity. The outside source cited in C.1 a) meant a source other than calibration standards. This is consistent with the definition of Quality Control Sample, which may be a Certified Reference Material, quality system matrix fortified by spiking, or actual samples fortified by spiking. The term outside source referenced in Whole Effluent Toxicity meant that organisms are purchased by the laboratory rather than being bred in-house.*

Tlyer commented that it seems like the lab is asking - Can they use their primary source to determine their LOD and LOQ or do they need do they have to use a secondary source?

Paul agreed this is what they are looking for, but the question is whether outside source is the same as secondary source?

Paul was concerned that though he agreed with Tyler, the committee needs to answer the actual question. Ilona suggested that Lynn can go back to the inquirer to get clarification on their question.

A motion was made by Shannon to accept the language Paul proposed above in italics. The motion was seconded by Silky and unanimously approved.

The meeting time has ended and the committee will pick up at the same spot next month. Paul will send the three responses on to LASEC and get some input on SIR 108.

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 November 9, 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 2:30 pm Eastern. (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@nlslab.com
Michelle Wade (2016) (Vice-chair) **Absent**	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*) **Absent**	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*) **Absent**	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
8	Send new wording for Section 5.5.13.1 to Cathy Westerman and get input.	Paul	7/13/15	
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	
12	Send update to Lynn regarding SIR #290.	Paul	9/21/15	
13	Find SIR responses for missing SIRs on the summary table sent by LASEC (Ilona).	Paul	10/8/15	Complete
14	Send SIR 144, 172 and 175 back to Lynn (LASEC) for consideration.	Paul	10/15/15	
15	Send note about SIR 108 to Lynn and ask for input.	Paul	10/15/15	

Attachment C

Backburner / Reminders – QS Executive Committee

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

Attachment D. SOPs To be Forwarded to LASEC After Meeting

#144

Standard	2003 NELAC Standard
Section (eg. C.4.1.7.4)	5.5.10
Describe the problem:	Regarding test reports, is it required that they list the limit of detection with relation to the limit of quantitation? The standard states that the level of uncertainty should be included, but does that mean that the LOD and LOQ must be expressly included and with relation to each other?
Comments	
Revised Response	The Standard does not require that the relationship between the limit of detection and limit of quantitation be listed on the test report, with or without regard to any estimate of uncertainty.

#172

Standard	2003 NELAC Standard
Volume and Module (eg. V1M2)	2003 Standard: Quality Systems
Section (eg. C.4.1.7.4)	Appendix D, section D.1.1.1.C)
Describe the problem:	The composition of a method blank shall consist of a quality system matrix that is similar to the associated samples and known to be free of analytes of interest. No reference could be found in SW-846 Methods 5035, 8000, and/or 8260 that require a VOA method blank to contain a solid matrix. In fact, in method 5035 section 8.2 it is stated before processing samples to analyze an organic-free water method blank.... Nothing about adding a solid matrix is mentioned. Adding a solid matrix to a VOA method blank would only potentially add contamination and not be reflective of the cleanliness of the analytical system. Also if one adds a solid matrix (even if it does not contain analytes of interest) to a

	VOA method blank, should not the same solid matrix be added to all the samples as well? Basically, is it necessary to add a solid matrix to a VOA method blank when analyzing low level soil samples? Is it the intent of NELAC's definition of a method blank to override what is presented in the method? Thank you for your response.
Comments	
Response	A blank is required to be free of the analytes of interest. Therefore, an appropriate blank for a solid matrix should not contribute contamination. 5.9.3 c) provides the following statements concerning the difference between 5035 and TNI: "The laboratory shall ensure that the essential standards outlined in Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed."

#175

Standard	2003 NELAC Standard
Volume and Module (eg. V1M2)	V1M4 1.5, 1.6
Section (eg. C.4.1.7.4)	C.1.a, C.3.1, C.3.2
Describe the problem:	A laboratory in our program has requested clarification that the term "outside source" has the same or a different meaning from the term "secondary source." The laboratory understands that a "secondary source" should be used for instrument calibration per NELAC 5.5.5.2.2.1.d but this is not required for demonstration of capability or determination of LOD or determination of LOQ. The question is "Is 'outside source' the same as 'secondary source'?" Thank you for your assistance.
Comments	
Response	The term outside source is not equivalent to the term

	secondary source. The term outside source is referenced in the requirements for Demonstration of Capability and in Whole Effluent Toxicity. **The outside source cited in C.1 a) meant a source other than calibration standards. This is consistent with the definition of Quality Control Sample, which may be a Certified Reference Material, quality system matrix fortified by spiking, or actual samples fortified by spiking. The term outside source referenced in Whole Effluent Toxicity meant that organisms are purchased by the laboratory rather than being bred in-house.**