Quality System Expert Committee (QS)
Meeting Summary

October 15, 2018

1. Roll Call:

Paul Junio, Chair, called the meeting to order at 12:30pm Eastern on October 15, 2018 by teleconference. Attendance is recorded in Attachment A – there were 11 members present. Associate Members present: Nick Haring, Eric Denman, Chaney Arend, Amber Ross, Carol Barrick, and Silky Labie.

The next meeting is on Veteran's Day. Paul asked if people would be interested in meeting on the 19th instead. He will follow this up with an email to the missing committee members and confirm the date of the next meeting by email.

2. SIR #329

Paul reviewed the status on the SIR 329 response. The committee has worked on this the past two meetings and through email.

He reviewed the response suggestions received so far and after further discussion the committee decided on the following language:

> Glass microliter syringes and Class A glassware are exempted from any traceability requirements as it relates to individual results because they need only be verified as required in 5.5.2 prior to first use. With that noted exception, all other calibrated support equipment is required to be traceable to individual results.
>
> Additional information - Support equipment verification requirements vary in their timeframes. Where something must be verified prior to each day of use, that verification would apply to any data from that day. Where the verification is prior to first use, then it would apply to any data associated with that use.

A motion was made by Earl to approve the language above and the motion was seconded by Dale.

Vote:
Jessica – Wait for Email
Kristin – For
Chris – For
Earl – For
Jenna – Wait for Email
Shari – For
Dale – For

Michelle – Against
Alysssa – For
Matt – Wait for Email

The vote will be completed by email.

(Addition: Paul distributed the following email to all committee members on 10/15/18 – Attached is the language from today's call. I have reproduced our response below. Note that we decided that requirements for verified equipment are NOT the same as for calibrated equipment.

Glass microliter syringes and Class A glassware are exempted from any traceability requirements as it relates to individual results because they need only be verified as required in 5.5.2 prior to being placed into service. With that noted exception, all support equipment requiring calibration must be traceable to individual results. Any support equipment requiring only verification then would not need to be traceable to individual results.

Support equipment verification requirements vary in their timeframes. Where something must be verified prior to each day of use, that verification would apply to any data from that day. Where the verification is prior to first use, then it would apply to any data associated with that use. The laboratory must retain all records necessary to establish an audit trail and allow the history of the samples to be followed through its documentation and records. To accomplish this, the laboratory must establish links to various activities such as equipment calibrations or verifications, standards source and preparation, sterilization checks etc. These links may or may not be in a single record – it is up to the laboratory to ensure that the record system design meets the audit trail and history requirements of 4.13.2.1 and 4.13.3.a.

We have already exempted glass microliter syringes and Class A glassware from any ongoing verification. They must be verified prior to use. It stands to reason that they shouldn't need ongoing tracking in their usage, as we have said they don't need tracking.

Please provide an e-mail vote by end of day Friday, October 19.

The final vote:

Vote:
For – Paul Junio, Jessica Jensen, Kristin Brown, Chris Gunning, Earl Hansen, Shari Pfalmer, Dale Piechocki, Bill Ray, Alyssa Wingard
Against – Jenna Majchrzak, Matt Sowards, Michell Wade, Lizbeth Garcia, Kathi Gumpper
Abstain – None

The motion passed.

Lynn contacted Paul after she reviewed the response and invited him to an LASEC SIR Subcommittee meeting to discuss the SIR. Paul sent the following message to the committee on 10/23/18:
During this call (LASEC SIR Subcommittee), we agreed that we would ask the submitter of this SIR to request that it be withdrawn with the understanding that Implementation Guidance would be written to address the question asked in the SIR. As an aside, this will likely help us with previous SIRs regarding support equipment.

I will write the Implementation Guidance over the next month or so and pass it along when it is done for review/comment. I'm glad that this response that didn't have substantial agreement will be addressed in another manner. Feel free to contact me if you have questions.)

3. SIR Summary Table

The committee finished going through the SIR Summary Table (Attachment D). Comments can be found in the table.

Ilona noted that SIR 246 is now being voted on by the NELAP AC. SIR 105 was determined to not be an SIR and was closed out in January 2018. It is not on the SIR website.

The committee's conclusions recorded in the table will be considered during the Standard update.

4. Action Items

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

5. New Business

None.

6. Next Meeting and Close

The next meeting will be planned by email due to the holiday. Ilona will send a Webex invitation the morning of the meeting.

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

Paul adjourned the meeting at 1:48pm Eastern. (Earl - motion Jessica – second, unanimous approval).

Attachment A

Participants
Quality Systems Expert Committee (QS)

Member	Organization	Expiration	Representation	Email
Paul Junio (Chair) **Present**	Northern Lake Service	2019	Laboratory	paulj@nlslab.com
Jessica Jensen (Vice Chair) **Present**	Meridian Analytical Labs	2021	Laboratory	jessica.j@meridiantesting.com
Kristin Brown **Present**	Utah DOH	2021	Accrediting Body	kristinbrown@utah.gov
Lizbeth Garcia **Absent**	Oregon Dept. of Environmental Quality	2019*	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Kathi Gumpper **Absent**	ChemVal Consulting	2021*	Other	kgumpper@chemval.com
Chris Gunning **Present**	A2LA	2021	Accrediting Body	cgunning@a2la.org
Earl Hansen **Present**	Retired	2021*	Laboratory	papaearl41@hotmail.com
Jenna Majchrzak **Present**	NJ DEP	2021*	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Jacob Oaxaca **Absent**	California State Water Board	2019*	Accrediting Body	Jacob.Oaxaca@Waterboards.ca.gov
Shari Pfalmer **Present**	ESC Lab Sciences	2021	Laboratory	spfalmer@esclabsciences.com
Dale Piechocki **Present**	Eurofins Eaton Analytical	2020	Laboratory	DalePiechocki@eurofinsUS.com
William Ray **Absent**	William Ray Consulting	2020*	Other	Bill_Ray@williamrayllc.com
Matt Sowards **Present**	ACZ Laboratories, Inc.	2020	Laboratory	MattS@acz.com
Michelle Wade **Present**	Wade Consulting	2021*	Other	michelle@michellefromks.com
Alyssa Wingard **Present**	NAVSEA LQAO	2021*	Other	alyssa.wingard@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 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	
38	Continue SIR 246 and 296 discussions.	All	TBD	
40	Get PT root cause analysis example from Scott Hoatson.	Paul	8/31/17	
45	Review Ch 1 Application section for the use of "shall" and "may". Are uses correct?	Paul, Sara	11/20/17	
51	Send example of Shari's report to NELAP AC to confirm format of listing all certifications without logo's is an acceptable process to report certifications for work being done.	Shari Paul	5/11/18	
53	Look into CWEA certification requirements.	Nick Jacob	7/9/18	
56	Reach out to Marlene Moore for additional information on Class A glassware.	Paul	7/9/18	
57	Look into status on labware SIR.	Paul	7/9/18	
58	Look into SIR 154 Response. Incorrect response may be posted.	Paul/Ilona	9/10/18	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Review charter in November 2018	Ongoing	Ongoing

Attachment D: SIR Summary Table

#	Date Submitted	2003	2009	2016	Paul Comments	Outcome
158	2/9/11		4.1.7.2 and 5.2.6.1 (a)	4.1.7.2 and 5.2.6.1 (a)	I disagree that this is an SIR. This is an AB, possibly more than one, who has used a term on their application and certificate that TNI has not defined. The root of this question is 'who is our Lead Technical Director', and TNI doesn't ask that question. I don't feel that this requires addressing in our revision.	committee agreement that this need not be addressed in revised Module 2
13	07/22/08	5.4.12.2.2	4.13.2	4.13.2	4.13.2.1 of ISO refers to retaining original records. One can't retain an original record if only a generic statement is made. 17025-2017 covers this in 7.5.1 (Original observations, data and calculations shall be recorded at the time they are made and shall be identifable with the specific task). I don't feel that this requires addressing in our revision.	committee agreement that this need not be addressed in revised Module 2
70	6/15/09	5.4.13.1	4.14.1	4.14.1	17025-2017 covers this in 6.2.3 (The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.) I don't feel that this requires addressing in our revision.	committee agreement that this need not be addressed in revised Module 2
108	1/27/10	5.4.13.1	4.14.1	4.14.1		see 308
308			4.14.1	4.14.1		The committee agrees that this needs to be addressed for clarity in Module 2

#	Date Submitted	2003	2009	2016	Paul Comments	Outcome
230	2/8/13	5.4.13.1	4.14.1	4.14.1		see 308
64	5/8/09	5.4.2.6	4.2.8.1	4.2.8.1	address	The committee agrees that this needs to be addressed for clarity in Module 2
22	08/07/08	5.5.4.1.1	4.2.8.5	4.2.8.5	This relates to SIR 323 which was rejected as an SIR. There needs to be clarification that the Standard DOES NOT apply where it has not been requested or where it isn't the regulation of the land. As it relates to this SIR, a laboratory can't be expected to have a procedure for a process that it doesn't perform.	start here
154	1/13/11		4.2.8.4.r		This response was not what QS submitted - it was the response to a different SIR. The submitted response was: Comment - 4.2.8.4 r) The quality manual shall contain or reference: policy addressing the use of unique electronic signatures, where applicable 4.13.3 Additional Requirements f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory. viii) analyst's or operator's initials/signature or electronic identification; See V1:M2 4.2.8.4(r) Response: Electronic signatures are acceptable (see references above). Note: a signature must be unique to the individual. Some states may have regulatory requirements pertaining to the use of electronic signatures. The laboratory should ensure that state requirements are met.	

#	Date Submitted	2003	2009	2016	Paul Comments	Outcome
101	12/1/09	5.4.3.1	4.3.1	4.3.1	17025-2017 8.3.1 has a note to address this. QS should identify the note as a required list and add these items (instrument manuals and equipment manuals) as among the required items.	
18	08/05/08	5.4.3.2.2.b	4.3.2.2.b	4.3.2.2.b	address - 17025 addresses the outcome of, not the timeframe between, assessments	
115	3/15/10	5.4.5.4	4.5.4	4.5.4	address	
82	8/13/09	5.5.5.2.1 b	5.5.2.11	5.5.2.1	5.5.13	
79	8/5/09	5.5.10	5.10.11	5.10.11	address	
16	07/31/08	5.5.10.2(i)	5.10.11 (b)	5.10.11 (b)	maintain the language from 5.10.11 b) in its new location (possibly within 7.8.3.1)	
93	10/2/09	5.5.10.2	5.10.2	5.10.2	start here - How would a NOTE be received indicating that reporting requirements to this level are not addressed by the Standard, but should be verified with the end user? Talk to the AC for advice. Capture the scope of accreditation	if requested or required, the revision number however specified
296	11/6/15		5.2.6.1	5.2.6.1	come back to this one	
212	5/29/12		5.2.6.1 a and b	5.2.6.1 a and b	This strikes me as a complaint about Technical Manager requirements more than an SIR.	
302	5/23/16		5.2.6.1.c	5.2.6.1.c	Bulleting each of the requirements into separate points would clarify each of these as requirements.	

#	Date Submitted	2003	2009	2016	Paul Comments	Outcome
180	8/31/11		5.4.2	5.4.2	Has this been addressed in an FAQ or through Technical Advice? If so, that language should be added for clarity (2003 maybe?) There are 2 different SIRs relating to 5.4.2	
21	08/07/08	5.5.4.4; 5.5.4.5; C3.3b)	5.4.4 and 5.4.5	5.4.4 and 5.4.5	This should not be an SIR, but a method interpretation	agreed
66	5/18/09	5.5.4.6.1	5.4.6	5.4.6	17025-2017 7.6 addresses uncertainty in greater depth than the previous Standard. I don't feel that the Committee intends to reply with a how-to document.	agreed
270	8/15/14		5.5.13.1	5.5.13.1	We should add language addressing single use items as needing to be checked once per lot. EDIT SINCE NEW ORLEANS - we already did this	done
274	9/22/14		5.5.13.1	5.5.13.1	If we were to change the term glassware to labware, it would put the onus on the laboratory to prove that an item of plasticware is Class A. It would also alow for the concept of risk to be used to address how frequently and for what types of labware this might be necessary. Consumables as single use items - verify before use	
304	10/12/16		5.5.13.1.3	5.5.13.1.3	there seems an obvious difference between a microliter and non-microliter syringe	
206	4/6/12		5.5.13.1.b	5.5.13.1.b	This has been addressed in a modification to the Standard and needs no further discussion or changes	
290	7/13/15		5.5.13.1.b	5.5.13.1.b	This problem appears to be a technical issue and not a request for interpretation of the Standard.	

#	Date Submitted	2003	2009	2016	Paul Comments	Outcome
232	2/26/13		5.5.13.1.e	5.5.13.1.e	'garden variety glassware' is not equivalent to volumetric despensing device, which is where the requirement lies.	work to be done on support equipment requirements
39	11/09/08	5.5.5.5	5.5.5	5.5.5	electronic requirements - it may be addressed	
73	7/8/09	5.5.5.8	5.5.8	5.5.8	support equipment needing clarification	