

**Quality System Expert Committee (QS)**  
**Meeting Summary**

**July 12, 2021**

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on July 12, 2021. Attendance is recorded in Attachment A – there were 10 members present. Associate Members present: Christopher Fuller, Cindy Redmond, Debra Zeller, Eric Denman, Jeanette Hernandez, Jessica Jensen, John Gumper, Joe Manzella, Karna Holquist, Katie Strothman, Kelvin Yuen, Kristin Brown, Linda O’Donnell, Paul Junio, Rachel Van Exel, Renee Jernigan, Rob Waite, Tiffany Shaw, Tom Widera, and Ty Atkins.

The May minutes were sent by email and shared on Webex. On July 12, 2021, Tony made a motion to approve the May 10, 2021, minutes as written. The motion was seconded by Jenna. There was no further discussion, and it was unanimously approved.

The June minutes were sent by email and shared on Webex. Kathi made a motion to approve the June 14, 2021, minutes as written. The motion was seconded by Bill. There was no further discussion, and it was unanimously approved.

2. New Member Introduction

Ashley Larssen briefly introduced herself.

3. SIR 412

Discussion began regarding Nicole’s e-mailed comments about the proposed response. Prepared, not purchased, may be the key. A suggestion was made to use the language from SIR 251 and tweak it to better fit this request. Concern was offered that the Standard doesn’t refer to “prepared in the lab”, so the Committee has to be careful about adding any requirements. This may be the historical reason for the differentiation between items b and d of the cited section, but it doesn’t explicitly say that. Final response as follows was motioned for approval by Lizbeth, seconded by Bill, and approved by all present.

**Response:** The use of the solvent at analysis requires that all data necessary for the historical reconstruction of the data be available (see 4.13.3 f). The lot number is created at a point in time when the reagent, standard or material is prepared and is unique to that preparation. Housing the prepared standard, reference material, and reagent in multiple containers does not require assigning each container a unique ID, but they must each bear the assigned identifier of the preparation.

Debbie will send the response to LASEC.

#### 4. Internal Audits

A brief discussion regarding internal audits ensued. There was some discussion to re-set how the committee had arrived at the possible language regarding internal audits, trying to achieve consensus that involved risk and assessability. Following discussion regarding whether the internal audits need to be planned or completed, the previously supported Option 1 was modified in item 2 as shown below (by deleting planned – it was determined that ‘interval’ captured the timeframe that the Committee supported, while the addition of ‘completed’ didn’t add anything substantive):

2. The interval for each audit shall be determined by the lab and shall not exceed:
  - a. 24 months methods/technologies on the scope of accreditation
  - b. 12 months for the elements in Module 2 of this standard

#### 5. Summary of Change Table

Debbie re-organized the Summary of Changes table, and it broke down nicely into (1) terms that needed defining; (2) language that needed tweaking; and (3) work needing the input of the entire Committee. Debbie will solicit volunteers to work on Definitions and Language. A few volunteers spoke up during the meeting.

#### 6. Definitions / Changes

Included in the discussion regarding Internal Audits was a discussion of the term ‘annual’. For reasons including risk and assessability, there was a proposal to change that term to something like ‘a timeframe not to exceed 13 (or some other number of) months. Also suggested were ‘at least once every 12 months’ and ‘once per calendar year’. Both of those would mean that 1 day outside of that window would be a Finding. Following some discussion, a suggestion was made to define annual in such a way that consensus could be reached. A proposed definition of ‘once per 12 months, not to exceed 13 months’ was generally agreed upon. It offers leeway without being excessively long. Following this general agreement, a proposed definition for “quarterly” was offered as ‘once per 3 months, not to exceed 4 months’. While the ‘not to exceed’ portion of quarterly is the same length of time in comparison to that for annual, the wording of the definition is cleaner than trying to set a number of weeks (such as 2) for the ‘not to exceed’ timeframe. There was general agreement, but this definition will be taken back to various constituencies for feedback.

#### 6. SIR Information

Paul Junio, the Chair of the Consensus Standards Development Executive Committee, shared some information regarding SIRs. There have been some instances where people have taken SIR discussions and acted on them prior to the SIRs being finalized. Paul reminded those in attendance that once an Expert Committee approves its response to an

SIR, that response must be approved by LASEC, and then approved by the AC. Once those steps occur, the SIR is posted to the website at which point it is final. Paul cautioned everyone to wait for all of the steps to occur prior to making any changes on the basis of SIR discussions.

#### 7. Next Meeting and Close

The next meeting will be on August 9, 2021 at 9am Eastern during the virtual portion of the TNI summer meeting.

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

Debbie adjourned the meeting at 2:24pm Eastern.

## Attachment A

**Participants**  
**Quality Systems Expert Committee (QS)**

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) <b>Present</b>	Alabama Power	2023*	Lab	dbond@southernco.com
Kathi Gumpper (Vice-Chair) <b>Present</b>	ChemVal Consulting	2024	Other	kgumpper@chemval.com
Nicole Cairns  <b>Absent</b>	NYSDOH	2024	Lab	nicole.cairns@health.ny.gov
Michael Demarais  <b>Absent</b>	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis  <b>Present</b>	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Lizbeth Garcia  <b>Present</b>	Oregon Dept. of Environmental Quality	2022	Accrediting Body	LIZBETH.GARCIA@dhsosha.state.or.us
Stephanie Atkins  <b>Absent</b>	Pace Analytical	2024*	Lab	<a href="mailto:stephanie.atkins@pacelabs.com">stephanie.atkins@pacelabs.com</a>
Nicholas Slawson  <b>Absent</b>	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen  <b>Absent</b>	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak  <b>Present</b>	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
William Ray  <b>Present</b>	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross  <b>Present</b>	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Amy Schreader  <b>Present</b>	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard  <b>Present</b>	NAVSEA LQAO	2024	Other	<a href="mailto:alyssa.wingard@navy.mil">alyssa.wingard@navy.mil</a>
Ashley Larssen  <b>Present</b>	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) <b>Absent</b>	The NELAC Institute	n/a	(828)712-9242	<a href="mailto:Ilona.taunton@nelac-institute.org">Ilona.taunton@nelac-institute.org</a>

## Attachment B

### Action Items – QS Expert Committee

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
63	Consider starting a list of items to add to the small laboratory handbook.	All	TBD	
83	Determine Goal for Completing Volume 1 Module 2 Standard Update.	All	TBD	
84	Add a definition for “method validation” to the definitions section of Module 2.	All	TBD	
85	Continue working on controversial Standard updates within Committee meetings. Examples: Internal Audits, Technical Manager, Document/Record Retention, QC, need for Quality Manual and Quality Policy, and Equipment Calibration tags.	All	TBD	Ongoing
87	Send SIR 412 response to LASEC.	Debbie	7-19-21	
88	Develop Definitions and Language Workgroups to help with the Standard Update	Debbie	8/9/21	
89	Share the proposed definitions for “annual” and “quarterly” to get feedback.		9/13/21	

