

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

December 18, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1:50 pm Eastern by teleconference. Attendance is recorded in Attachment A – there were 8 members present. This is a special meeting to vote on items discussed during the 12/14/15 meeting.

2. Interim Standard

Paul distributed the final language for both the VDS Voting and Comment Summary and the Interim Standard (see Attachment D).

A motion was made by Silky to move the Standard on to an Interim Standard – the changes being proposed are non-controversial. The motion was seconded by Chris and a roll call vote was taken:

Paul – For
Katie – For
Silky – For
Dale – For
Chris – For
Kristin – For
Shannon – For
Michelle – For

Addition: Email votes: Matt – For (12/18/15), Jessica – For (12/18/15). The motion passed with 10 affirmative votes out of a possible 13.

A motion was made by Dale to approve the Interim Standard as sent by Paul on 12-14-15 and included in Attachment D. The motion was seconded by Kristin and a roll call vote was taken:

Paul – For
Katie – For
Silky – For
Dale – For
Chris – For
Kristin – For
Shannon – For

Michelle – For

Addition: Email votes: Matt – For (12/18/15), Jessica – For (12/18/15). The motion passed with 10 affirmative votes out of a possible 13.

A motion was made by Michelle to approve the comments and status of each comment included in the VDS Voting and Comment Summary sent by Paul on 12/14/15. The motion was seconded by Shannon and a roll call vote was taken:

Paul – For
Katie – For
Silky – For
Dale – For
Chris – For
Kristin – For
Shannon – For
Michelle – For

Addition: Email votes: Matt – For (12/18/15), Jessica – For (12/18/15). The motion passed with 10 affirmative votes out of a possible 13.

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 January 11, 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 2:15 pm Eastern. (Motion: Shannon Second: Michelle 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@nslab.com
Michelle Wade (2016) (Vice-chair) Present	Wade Consulting and Solutions	Other	913-449-5223	michellefromks@gmail.com
Katie Adams (2016) Present	USEPA Region 10	Other	360-871-8748	Adams.Katie@epa.gov
Kristin Brown (2016) Present	Utah DOH	AB	801-965-2530	kristinbrown@utah.gov
Patty Carvajal (2017*) Absent	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*) 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*) Absent	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	10/11/15
9	Look at the Handbook Table of Contents and volunteer for sections.	All	8/10/15	
12	Send update to Lynn regarding SIR #290.	Paul	9/21/15	
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	Send final language for Interim Standard and final language for the VDS comment summary to committee members for review and vote on Friday, 12-18-15.	Paul	12/14/15	Complete
18	Paul will contact the missing members on the 12/18/15 call to get their votes. He will ask them to email their votes to Ilona.	Paul	12/18/15	

Attachment D. Interim Standard

5.5.13.1 Support Equipment

This Standard applies to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and mechanical volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).

- a) The results of any calibration or verification shall be within the specifications required of the application for which this equipment is used. The laboratory shall define the specifications for acceptability if none exist in method or regulation. If any equipment fails to meet the specifications for acceptability:
 - i) the equipment shall be removed from service until repaired; or
 - ii) the laboratory shall maintain records of established correction factors to correct all measurements.
- b) The laboratory shall maintain all support equipment in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.
- c) On each day the equipment is used, balances, ovens, refrigerators, freezers, incubators and water baths shall be checked and documented. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.
- d) Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available.
 - i) If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;
 - ii) If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.
- e) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, the laboratory shall verify volumetric measuring devices as follows:
 - i) Glass microliter syringes and Class A glassware are exempt from any verification requirements beyond what is stated in Section 4.6.2;
 - ii) Disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use;
 - iii) Mechanical devices shall be verified prior to first use and on a quarterly basis. Mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device;
 - iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.

- f) All other support equipment shall be calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use.
- g) Raw data records shall be retained to document equipment performance.