Quality System Expert Committee (QS)
Meeting Summary

July 31, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1:05pm Eastern by teleconference. Attendance is recorded in Attachment A – 8 members were present.

Minutes will be reviewed during the regularly scheduled conference call in August. The purpose of this extra meeting is to work on language for the Standard.

2. Working Draft Standard

SUPPORT EQUIPMENT

Paul reviewed the changes made to the Standard based on meeting input in Chicago and a conversation with Marlene Moore after the meeting.

Silky commented that the manufacturer often has specifications. Perhaps the language should include a reference to the manufacturer specification and that the lab needs to set this if there aren't any. If the glassware is verified and there is a problem meeting the stated accuracy, there is a problem.

Paul asked if a note pointing to 4.6.2 would alleviate Silky's concern:
Section 4.6.2: The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

Paul suggested some additional language pointing to Section 4.6.2 and 5.5.7 in the note he originally included.

Paul realized the language regarding quarterly checks has been deleted. He will add this in as point iii) and the current iii) will move to iv). He pulled the language directly out of the 2012 standard.

After further discussion, Paul suggested the following language:

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 are exempt from any verification requirements;
ii) Disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use;
iii) Mechanical volumetric dispensing devices shall be checked for accuracy on a quarterly basis.
iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.
NOTE: Section 4.6.2 requires that materials must comply with standard specifications or requirements defined by methods. Section 5.5.7 indicates that materials that have been mishandled shall be re-calibrated prior to re-use.

Chris asked if this supercedes 4.6.2 in regards to microliter syringes. It was commented that the lab only needs to retain any documentation that comes with the syringe, but this is not what the wording above states. It says it is exempt.

The committee worked through various language options to define the use of microliter syringes.

It was asked if all Class A glassware will need to be checked – even that already in use. Is there a way of grandfathering in old Class A glassware?

Silky commented that a number of labs are now buying Class A glassware to not have to deal with all the checks.

Paul considered the discussion and feels that perhaps nothing should change until it is proven there really is a problem with Class A glassware. He is now suggesting the following:

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 volumetric dispensing devices shall be checked for accuracy on a quarterly basis.
iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.
NOTE: Section 4.6.2 requires that materials must comply with standard specifications or requirements defined by methods. Section 5.5.7 indicates that materials that have been mishandled shall be re-calibrated prior to re-use.

There was additional discussion to ensure that the requirements for microliter syringes and Class A glassware are clear and not open to multiple interpretations. Similar concerns were raised for mechanical dispensing devices.

Paul provided the following update:

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 volumetric dispensing devices shall be checked for accuracy at each point of use. These checks shall be performed prior to first use and on a quarterly basis;
iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.

NOTE: Section 4.6.2 requires that materials must comply with standard specifications or requirements defined by methods. Section 5.5.7 indicates that materials that have been mishandled shall be re-calibrated prior to re-use.

Based on Silky's concern, Paul moved the information in the Note into the introduction text.

Ilona noted that iii) is in conflict with itself. The intent was to note that it needs to be checked at volumes of use. Paul asked if this wording has been addressed by DoD. Chris Gunning looked up DoD language. DoD is daily before use within specifications outlined in the requirements.

New version from Paul:

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). Section 4.6.2 requires that materials must comply with standard specifications or requirements defined by methods. Section 5.5.7 indicates that materials that have been mishandled shall be re-calibrated prior to re-use.

Etc …

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 volumetric dispensing devices shall be checked for accuracy at each volume of use. These checks shall be performed prior to first use and on a quarterly basis;
iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.

Ilona asked if the paraphrasing on 4.6.2 and 5.5.7 is accurate. Paul asked everyone to confirm as he read the language in each section. Ilona is concerned about the paraphrasing and how this will work with the audit checklist. The paraphrasing does not do justice to the language in these sections. It should be deleted or left in a note.

After additional discussion, the committee agreed on the language in Attachment D.

Katie is still concerned about the language requiring every point of use. Paul suggested looking at how many volumes this would be in her situation and what the ranges would be. Katie will get back to the committee by email.

Chris asked how many measurements need to be taken to check accuracy? This is spelled out in the DoD standard (3x). It is not spelled out in our standard, so there is no requirement that a lab must do more than one. Silky thinks most labs do at least 3 measurements. The committee agreed it does not want to be prescript.

Chris made a motion to accept the final language emailed by Paul during the meeting (Attachment D). The motion was seconded by Silky. Paul will distribute this to committee members to complete the vote by email.

(Addition:
Voting results:
Paul – For (9/14)
Michelle – For (7/31)
Chris – No vote
Dale – Against (8/3)
Janice – No vote

Jessica – No vote
Katie – Against (8/4)
Kristin – No vote
Matt – Against (8/10)
Patty – Against (8/10)
Shannon – No vote
Shari – Against (8/10)
Silky – Against (8/5)

Final vote: 2 – For, 6 – Against, 0 – Abstain. No votes: 5. The motion did not pass.)

LOT DISCUSSION

Following the morning NEMC Session on Certified Reference Materials, it was suggested that a definition of "Lot" could be added to Module 2 to help avoid issues regarding second source standards. There was initial talk of that definition going into Module 4, but since this definition would apply to more than just the Chemistry Module, it needs to be added to our section. There will be a webinar scheduled to discuss this, and I hope that this passes quickly.

Paul heard back from Shawn that the lot itself is the unique designation. Adding the language suggested by Silky would be redundant.

The following language is proposed:

3.0 TERMS AND DEFINITIONS

> ***Lot:*** *A definite amount of material produced during a single manufacturing cycle, and intended to have uniform character and quality*

A motion was made by Silky to accept the definition for Lot as defined above. The motion was seconded by Matt. The vote will be completed by email.

(Addition:
Voting results:
Paul – For (9/14)
Michelle – For (7/31)
Chris – No vote
Dale – For (8/3)
Janice – No vote
Jessica – No vote
Katie – No vote
Kristin – For (8/10)
Matt – For (8/10)
Patty – For (8/10)
Shannon – No vote

Shari – For (8/10)
Silky – For (8/5)

Final vote: 8 – For, 0 – Against, 0 – Abstain. 5 – No vote. The motion passed and the language will be passed on to the Standards Review Committee before the QS Committee votes this language in as the Voting Draft Standard.)

3. Action Items

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

4. New Business

Paul reviewed the draft Tulsa schedule with the committee. There were some concerns expressed about meeting on Tuesday morning against the Assessment Forum. Looking at other options, the committee would like AB involvement, so they don't want to move to Wednesday. No requests for a change will be made.

5. Next Meeting and Close

The next meeting will be August 10, 2015 at 1pm Eastern. Ilona will send out a conference and Webex invitation. The SIRs will be discussed at the following meeting.

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.

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) **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*) **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*) **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*) **Absent**	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	
10				

Attachment C

Backburner / Reminders – QS Executive Committee

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

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 volumetric dispensing devices shall be checked for accuracy at each volume of use. These checks shall be performed prior to first use and on a quarterly basis;
   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.

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If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, volumetric dispensing devices shall be checked for accuracy on a quarterly basis;

Volumetric containers that are used at a single point shall be calibrated or verified at that point prior to or in conjunction with first use;

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The results of such calibration or verification, whether daily or annually, shall be within the specifications required of the application for which this equipment is used or:

the equipment shall be removed from service until repaired; or

the laboratory shall maintain records of established correction factors to correct all measurements.

If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis.