Quality System Expert Committee (QS)
Meeting Summary

December 14, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference. Attendance is recorded in Attachment A – there were 10 members present. Associates members on the call included: Robin Cook, Bill Ray, Reed Jeffrey, Carl Kircher and Eric Davis.

The meeting minutes for November were reviewed. Jessica made a motion to approve the 11/9/15 minutes as distributed. The motion was seconded by Patty and unanimously approved.

2. SIRs

Paul forwarded the SIRs worked on at the last meeting and 5 out of the 6 have been posted to the NELAP AC SIR voting site. There was an issue on #274. From our last meeting:

SIR #274:

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.5.13.1
Describe the problem:	The standard states "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Would class A plasticware be considered the same as Class A glassware ie - you do not need to check it on a quarterly basis? Or would Class A pastic ware be considered the same as non-class A labware? The same question for V1M5 section 1.7.3.7 iii.2 "2. equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels) shall be verified once per lot prior to first use. This verification may be volumetric or gravimetric."

Would you need to check Class A plasticware once per lot?

RESPONSE: By definition, Class A plasticware does not exist. So, something that is called Class A plasticware would be required to meet the same requirements as non-Class A labware.

There were LASEC members that believe they have plasticware with Class A stamped on it. There are also multiple definitions for Class A – so perhaps the committee needs to state which definition it is using. Paul suggested that this response not be finalized until after the Tulsa meeting where someone from ASTM will be speaking on this topic. There was agreement.

3. Voting Draft Standard Comments

Paul distributed all the votes and comments to the committee. Paul removed the identity of the commenters from the file. There were 3 negative votes with comment and 2 affirmative votes with comments.

Comment #1: Negative with Comment

5.5.13.1 Section 5.5.13.1 is good as it stands currently. The TNI Standard should not require how labs verify their thermometers and mechanical pipets. What is proposed is a good rule of thumb, but every lab is different. There needs to be flexibility to allow labs to decide what is best for them, their program, and how to best serve their customers.

Final Conclusion:

Non-Persuasive -
The committee feels that the Standard should clarify when bracketing is required, and clarify what needs to be done. As such, the Committee feels that clarification is better explained than in the previous version of the Standard.

Paul confirmed that all were in favor of the response, but will not be taking an official vote until all of the comments have been reviewed and responded to.

Comment #2: Negative with Comment

5.5.13.1 I have serious concerns about proposed change relative to pipetting

The quarterly requirement is removed in 5.5.13.1. sections e) i) and section e) iv). Fixed volume pipettors are lumped into a category which is exempted from any ongoing monitoring after the equipment is taken into service.

Backing away from quarterly checks is very ill-advised. Quarterly checks are already questionably weak (see comment below). While dropping the check frequency to less than quarterly assumes that the risk of ongoing failure is very low, requiring only a one-time check (at first use) unrealistically assumes that the risk of ongoing failure is zero. Mechanical measuring equipment not only goes out of calibration, it also fails under use, from normal wear and tear, abuse, neglect, or accidental mishandling. It is for this reason that maintenance, service and replacement parts are available for pipettors and that laboratories need to buy replacement pipettors from time to time.

Some might argue that the decreased frequency is adequate since batch QC monitoring will identify problems. Batch QC is not capable to reliably detect bias/uncertainty on the order of 1-5% (even with trending). If one were to accept this logic, there would be no need to recalibrate or run a CCV on primary instrumentation until an LCS fails.

Also, the range over which pipets may be checked is problematic. Suggest limiting the use of the pipet to the actual range checked similar to that this is required for other equipment.

Reed Jeffery provided some possibly language that I think might be good: "Mechanical volumetric devices, such as pipets and burets (whether fixed-volume or adjustable), shall be checked for accuracy, prior to first use and on at least a quarterly basis, in a manner that brackets the range of use."

Comment (not part of the negative) - I realize that going against quarterly check frequency, which is currently in the standard, may be swimming upstream. I would personally advocate more frequent checks (daily or weekly). People forget that it is not only the equipment that is of concern, but that the analyst is a crucial part of the delivery system. At my lab, each analyst checked each pipet each day prior to their using it either across a range or at the volume being used.

Discussion: Robin agreed that at face value, the commenter is correct in their concern.

You need to consider whether you are excluding fixed pipets from mechanical pipets. A fixed mechanical pipet would fall under #4. Eric thinks there is a typo in the comment.

Part of how the wording was chosen for this section was based on comments received that stated that checking volumetric support equipment quarterly was an onerous requirement on the labs and ABs thought it would be difficult to track all of it on a lab.

The committee looked at the language and discussed various options for changing the language of the VDS.

It is no longer just mechanical pipets used at multiple volumes – single volume mechanical pipets also need to be checked.

Robin looked at the 2003 Standard and felt the requirement to check mechanical dispensing devices was in there. Paul pointed out that it was part 4 that was the concern. Some thought every beaker in the lab needed to be checked quarterly.

Number 3 was just written poorly in the VDS. The intent has not changed, but the wording is not clear. The language needs to be cleaned up.

Reed thinks the language needs to be expanded to include mechanical burets. An example is bottle top dispensers. Paul asked if they are used for exact measurements. Carl said they are sometimes used for Hexane extraction, etc … Silky thinks they are included. The word pipet might eliminate them, so the word device is better.

Katie asked about the cases where the 10% does not work. There is an Eppendorf from 0.5 to 2.5 – so 10% does not work. Carl suggested looking at the term "range of use". Bracketing would reduce the checks to two points. Paul suggested bracketing and at the mid-point.

Final language: 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;

There was agreement with the wording change. A formal vote will be taken at the end of the review.

Final Conclusion:

Persuasive
The Committee agrees that quarterly checks of mechanical devices are warranted. Committee cleaned up language to reflect that issue. Re-word e iii) as 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;

There was general agreement and a formal vote will be taken at the end of the review.

Comment #3: Affirmative with Comment

5.5.13.1 and 5.5.13.1e)	In the first paragraph under 5.5.13.1, there is no mention of volumetric labware used to measure or contain volumes (as opposed to those used to deliver volumes). An example would be a Class A Volumetric flask or a beaker. Recommend including reference in this paragraph to "volumetric measuring devices" or something similar, as the only volumetric equipment mentioned in this section are mechanical dispensing devices. Section 5.5.13.1 e) includes the term "volumetric measuring devices" and includes requirements for this type of non-mechanical equipment, so use of similar lanaguage and inclusion in the opening paragraph may be beneficial.

Discussion: The list is not exhaustive.

Final Conclusion:

Non-Persuasive
The list is preceded with 'to include, but not limited to', meaning it isn't exhaustive.

Comment #4: Affirmative with Comment

5.5.13.1 e) iii)	No reference of how often to verify single volume mechanical pipettes, only multi-volume.

Discussion: Changes have already been made above. This comment would be persuasive.

Final Conclusion:

Persuasive
Language has been clarified to address this point.

Commment #5: Negative with Comment

5.5.13.1 e) iii) and e) iv)

Most of the changes will improve the quality of laboratory analyses, but I have serious concerns about two of the proposed changes.

Section 5.5.13.1. e) iii):
1. The proposed check of mechanical pipets at 10% of the volume is unenforceable. Our lab uses Eppendorf(R) pipets with a manufacturer-specified range of 0.5 uL to 2.5 uL, and checking these pipets at 0.25 uL is impossible. Replacing this requirement with a requirement to bracket the range of use would make more sense and be enforceable.

2. The midpoint check (50%) is unnecessary and has little value. So far as I am aware, the typical range of mechanical pipets is 1 order of magnitude or less. If ranges were 1 1/2 to 2 orders of magnitude, I could see the value of a midpoint check, but with such a narrow range, bracketing the range should be sufficient.

Section 5.5.13. e) iv):
3. Dropping the requirement for quarterly checks of fixed-volume mechanical pipets and all mechanical burets is ill-advised. Mechanical devices are subject to wear and will also go out of calibration due to misuse or neglect. Quarterly checks should be a minimum requirement for these devices.

For these reasons, the following revision of section 5.5.13.1. e) iii) is proposed.

"Mechanical volumetric measuring devices, such as pipets and burets (whether fixed volume or adjustable), shall be checked for accuracy, prior to first use and on at least a quarterly basis, in a manner that brackets the range of use."

Discussion: The new language above has a midpoint check. Matt noted that the manufacturer's of the devices have different recommendations. Some recommend a two point check and others recommend a three point check.

The committee discussed putting some rules into place for when a mid-point check is needed, but there was concern about confusing things.

A greater number of committee members wanted the mid-point left in. There was only two members who preferred out. The committee agreed with leaving it in at this point.

Final Conclusion:
Persuasive

Committee feels that the midpoint check is a worthwhile inclusion when a device is used over a range. Committee agrees that quarterly checks of mechanical devices are warranted.

The committee now needs to review the comments placed into the VDS summary table and vote to approve the comments and status – persuasive vs. non-persuasive.

The committee will also need to decide and vote whether the changes to the Standard will make it a Modified Voting Draft Standard or an Interim Standard. Everyone agreed the changes made were non-controversial and that they would like to see it move to an Interim Standard. The changes are only clarification.

The committee will need to vote on the changes made to the VDS – for or against.

Paul will make the changes to the Standard and clean-up the comment table. He will then distribute these documents to the committee for final review. He would like to set-up a meeting on Friday to vote on the three voting topics above. Ilona will send out a Doodle to set-up a time to meet.

4. SIR #296

The SIR was received mid November. Paul prepared a proposed response for the committee to consider (see Attachment D).

Silky agreed with Paul's response.

A motion was made by Silky to approve the response prepared by Paul to SIR #296 and send the response back to the LASEC. The motion was seconded by Michelle and unanimously approved.

Paul will send the response to Lynn Bradley.

5. Action Items

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

6. New Business

- Rooms for the Tulsa meeting need to be booked by January 12, 2016.

7. 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 2:30 pm Eastern. (Motion: Shannon Second: Jessica 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) **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*) **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 (1:20pm)**	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) **Present**	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	
18				

Attachment C

Backburner / Reminders – QS Executive Committee

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