Quality System Expert Committee (QS)
Meeting Summary

August 10, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1pm Eastern by teleconference. Attendance is recorded in Attachment A – there were 9 members present. Associates members on the call included: Eric Denman, Elizabeth Turner, Jennifer Blossom (LCRA) and Carl Kircher,

2. Standard

Paul sent the following proposed language to the committee for consideration:

Section e)

a) 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 pipets shall be checked at all dispensing volumes used. If more than three volumes are used, the laboratory shall check the volume at the most frequently used volume and two others which are rotated among the other volume points that are used for dispensing volumes. The intent is that all volume points used for dispensing are checked over a two-year period**

OR

iii) **Mechanical pipets shall be checked at 10%, 50%, and 100% of the nominal volume, where nominal volume is the max volume of the pipette**;
iv) All other volumetric support equipment shall be checked for accuracy prior to or in conjunction with its first use.

Elizabeth and Katie prefer the second option. Dale thinks it should be 10, 50 and 100% of the maximum volume. First use and quarterly basis.

The committee decided on: Mechanical pipets used at more than one volume shall be checked at 10, 50 and 100% of the maximum volume of the pipet. These checks shall be performed prior to first use and on a quarterly basis.

A motion was made by Patty and seconded by Dale to move the standard on to a Voting Draft Standard with the new language above. *(Addition: This will be voted on at the 9-14-15 meeting.)*

The language for Lot comes from one of the PT Modules. They are looking for consistency between this Module and the PT Volume.

Paul asked everyone to finish up the email vote on the "Lot" definition.

3. Standard Interpretation Requests (SIRs)

SIR 230

Original request:

Sec. 5.4.13.1 The laboratory shall periodically, in accordance with a predetermined schedule and procedure, and at least annually, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Standard. The internal audit program shall address all elements of the quality system, including the environmental testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.

The standard states that "The internal audit program shall address all elements of the quality system, including the environmental testing activities." We are unclear as to what is expected in reference to "Environmental Testing Activities." For example, if we have 10 methods used for environmental testing are we required to audit each of those specific test methods yearly, or is acceptable to audit the laboratory as a whole is operating under the quality system.

QS Response Info: It may not be necessary for every method to be audited by the laboratory on an annual basis. If the laboratory's Quality System is operating correctly, an audit of a representative number of analytical methods might suffice. The laboratory should describe in its internal audit plan and predetermined schedule how all elements of the quality system will be addressed. The results of laboratory management reviews, preventive action assessments, improvement opportunity identifications, and audits by external bodies could indicate whether or not the laboratory's approach to internally auditing its entire quality system annually is sufficient.

Carl commented that this SIR may be addressed by something the LAB Expert Committee worked on. He believes it has been addressed by a policy currently being reviewed by the LASEC. Paul asked Carl to send the language to him. Paul sent the language to all committee members by email (Attachment D – SIR and information from Carl Kircher).

Paul reviewed the information Carl sent to evaluate whether it is relevant to SIR 230. People needed time to review this information and it will be discussed at the September meeting. Paul will attempt to put a DRAFT response together before the meeting.

SIR 290

SIR #290, referred to Quality Systems Expert Committee July 24, 2015

Standard	2009 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.5.13.1.b
Describe the problem:	Our laboratory is required to calibrate all thermometers annually against a NIST traceable thermometer, bracketing the range of use. If the 2 temperatures that the thermometer is calibrated produce different correction factors, which correction factor is used?

Matt commented that this is difficult to respond to because more information would be needed. Dale noted that it should be checked at the temperature of use. The correction factor may be different at different parts of the thermometer scale. Many labs use thermometers for a single use purpose. If a lab uses a thermometer at multiple temperatures, it should check it at multiple temperatures.

Janice read a document from NIST and there is a requirement that any variance has to be within the Uncertainty of the thermometer. If it is beyond that, it should not be used. NIST Publication #819. Paul distributed a copy of this document to all committee members by email. Janice would like to research this a little more.

Paul pulled the publication up on screen. It does not explicitly say you shouldn't use the thermometer.

Ilona noted that the committee can go back to the inquirer and ask questions. The committee would like to ask:
Which temps used for bracketing?
What were the correction factors?
Range of use of the thermometer?
What temp is the thermometer being used at?

Paul will send a request to Lynn Bradley to respond to the inquirer with these questions.

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 September 14, 2015 at 1pm Eastern. Ilona will send out a conference 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 2:02 pm Eastern. (Motion: Matt Second: Kristin 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) **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*) **Absent**	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) **Absent**	Env. Lab Consulting & Technology, LLC	Other	850-656-6298	elcatllc@centurylink.net
Shari Pfalmer (2018*) **Present**	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*) **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	
9	Look at the Handbook Table of Contents and volunteer for sections.	All	8/10/15	
10	Send request regarding SIR #290 to Lynn.	Paul	8/15/15	
11				

Attachment C

Backburner / Reminders – QS Executive Committee

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

ATT D:	
Standard	2003 NELAC Standard
Volume and Module (eg. V1M2)	2003 NELAC
Section (eg. C.4.1.7.4)	Sec. 5.4.13.1 The laboratory shall periodically, in accordance with a predetermined schedule and procedure, and at least annually, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Standard. The internal audit program shall address all elements of the quality system, including the environmental testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.
Describe the problem:	The standard states that "The internal audit program shall address all elements of the quality system, including the environmental testing activities." We are unclear as to what is expected in reference to "Environmental Testing Activities." For example, if we have 10 methods used for environmental testing are we required to audit each of those specific test methods yearly, or is acceptable to audit the laboratory as a whole is operating under the quality system.
Response	It may not be necessary for every method to be audited by the laboratory on an annual basis. If the laboratory's Quality System is operating correctly, an audit of a representative number of analytical methods might suffice. The laboratory should describe in its internal audit plan and predetermined schedule how all elements of the quality system will be addressed. The results of laboratory management reviews, preventive action assessments, improvement opportunity identifications, and audits by external bodies could indicate whether or not the laboratory's approach to internally auditing its entire quality system annually is sufficient.

ATT D (continued) From Carl Kircher:

NELAP Policy on Laboratory On-Site Assessments (Re-assessments)

The NELAP Accreditation Council (AC) highly recommends that all the accredited laboratory Fields of Accreditation be covered and addressed during the regular on-site assessments that are conducted at the accredited Conformity Assessment Body (CAB, environmental testing laboratory) every two years, plus-or-minus six months (as re-assessments).

The applicable Standard in ISO/IEC 17011 Clause 7.5.6 (and TNI V2M3, 6.3.5) says that the assessment team needs to "witness a representative number of examples." The reader should not automatically or necessarily equate "examples" with accredited test methods, to imply that not all test methods need to be covered during on-site assessments. Analytes might also be considered as "examples." Further examples that could be witnessed on a representative basis would be laboratory analysts, test reports, data packages, continuing demonstrations of capability, limits of detection and verifications, and test method standard operating procedures. Taken together, it could be that not all accredited methods will be covered during a CAB's reassessment. However, 100% of the laboratory Quality System must be addressed during the re-assessments of each accredited CAB.

This Standard also specifies "sampling (if applicable)," and there may be instances where sampling only a representative number of methods and analytes during a reassessment is not applicable. An example of this circumstance would be US EPA's expectations for a State Accreditation Body (AB) to maintain Primacy for the Safe Drinking Water Act. Laboratory client expectations, project requirements, and other factors should be taken into account.

With the Standard as currently worded, while all methods of all technologies, test methods, and analytes do not necessarily have to be assessed during the reassessment, the AB is obligated to assure the performance of the laboratory. While the Standard is not prescriptive about how that must be accomplished, the Standards are clear about what the end result must be.

V2M1, 3.7 NOTE: Assessing the competence of a CAB involves assessing the competence of the entire operations of the CAB, including the competence of its personnel, the validity of the conformity assessment methodology, and the validity of the conformity assessment results.

V2M1, 4.2.1: The … operation of an accreditation body shall be such as to give confidence in its accreditations.

V2M1, 4.2.2: The accreditation body … shall be responsible for its decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending, and withdrawing of accreditation.

V2M1, 7.7.2: The accreditation body shall establish procedures and plans for carrying out … reassessments at sufficiently close intervals to monitor the continued fulfillment by the accredited CAB of the requirements for accreditation.

If the Accreditation Body considers that reassessments should be identical with initial assessments (rather than "similar"), then the following Standard is also applicable:

V2M3, 6.9.1: The assessment team shall conduct the assessment of the conformity assessment services of the CAB at the premises of the CAB … to gather objective evidence that the applicable scope the CAB is competent and conforms to the relevant standard(s) and other requirements for accreditation.

V2M3, 6.13.2 also requires that the AB's procedures and plans for laboratory assessments be at sufficiently close intervals to monitor the accredited laboratory for continued fulfillment of the requirements for accreditation. Thus, if not all methods and analytes are covered during the routine reassessment, the laboratory may need reassessments at intervals more frequently than every two years plus or minus six months.

Each recognized Accreditation Body on the NELAP Accreditation Council (AC) should consider that confidence in its laboratory accreditation decisions needs to be instilled in many affected parties, inclusive of laboratory clients, officials making environmental protection and public health decisions, users of laboratory test results, the laboratory community seeking competent subcontractors, NELAP AC members granting secondary accreditations, and (last but not least) The NELAC Institute.

Notice of Consensus Standard Development (ELS Volume 2, Modules 1 and 3)

Pursuant to The NELAC Institute's SOP 2-100 on consensus standard development, notice is hereby given that the Laboratory Accreditation Body Expert Committee (hereinafter called Lab AB Committee) seeks to consolidate Modules 1 and 3 in Volume 2 of the Environmental Laboratory Sector (ELS) standards into one module.

Modules 1 and 3 were formerly the responsibility of two separate expert committees. However, the former On-Site Assessment Committee is now merged with the Lab AB Committee, so that the latter-named committee now has responsibility for both modules.

The existence of separate modules has created some confusion and problems for the NELAP Accreditation Bodies (ABs) that are recognized by TNI when evaluated to these standards. Overlapping requirements are found in both Modules 1 and 3, while some key requirements are found in Module 3 but not Module 1, and visa versa.

Volume 1, which is applicable to the accredited environmental testing laboratories, has benefitted from having all the quality management system requirements in ISO/IEC 17025 incorporated, in order, into Module 2. The proposed combined module for Volume 2 will thus benefit NELAP ABs by having all the ISO/IEC 17011 requirements incorporated, in order and in one place, along with the additional normative requirements added by TNI.

The Lab AB Committee actively seeks input from stakeholders and stakeholder groups who may subsequently adopt this standard as accreditation bodies, be accredited to the standard, or use data from accredited entities. This Committee also has several openings for interested TNI Members to nominate themselves and be seated as voting members on the Committee.

Further information about this proposed consensus standard development may be directed to the Lab AB Committee Chair, Carl Kircher, at phone number 904-791-1574 and through e-mail "carl.kircher@flhealth.gov."