

Quality System Expert Committee (QS) Meeting Summary

March 9, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1:08pm by teleconference. Attendance is recorded in Attachment A – there were 9 members present. Associates members on the call included: Bill Ray, Jennifer Blossom, Robin Cook

The meeting minutes from the 2/4/15 meeting in VA were reviewed. A motion was made by Dale to approve the minutes. The motion was seconded by Silky and unanimously approved. They will be forwarded to TNI for posting.

2. Chair and Committee Member Training

Paul reminded all committee members to watch the online committee training referenced in the agenda. When the training is completed, send a message to Paul so he can track who still needs to take it.

3. Standard Conflict

There is a conflict between Mod 2 and Mod 5 (Microbiology). A summary of the issue is included in Attachment D. The Microbiology Expert Committee provided language in their Standard for a single point calibration, but Module 2 requires a range of use calibration.

There has been a SIR on the topic of single point calibration checks. People in the past thought it was acceptable and historically most ABs have accepted it in the past.

Paul worked on the language based on the discussion and provided the following language:

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 volumetric dispensing devices (such as Eppendorf® or automatic dilutor/dispensing devices).

a) All support equipment shall be maintained in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.

- b) Raw data records shall be retained to document equipment performance.
- 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) The results of such calibration or verification shall be within the specifications required of the application for which this equipment is used or:
 - 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.
- f) 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.

Ilona reminded the committee of Richard Burrow's email comment to change "may" to "are not". Paul made the change.

Aaren Alger had asked why a 10 degree limit? Paul responded with:

It seem like a number that could work. My concern would be for allowing too broad of a range, so it had to be narrowed somehow. 10 degrees should encompass coolers and incubators as well as ovens for solids. It wouldn't allow for a single point verification if you use one thermometer for multiple disciplines, nor for an expected wide range of use such as for flashpoint.

Bill looked at the NIST website and they only calibrate at one temperature unless told to do something different.

Silky had some questions:

If this change can go through a TIA – she thinks that would work. She does not want to open the entire standard. Robin was asked if she could take the reference to Module 2 out of Module 5. Robin commented that she thinks Module 2 would still apply without the reference. Ilona pointed out that Module 5 can have a difference as long as it is specifically addressed that the Module 2 reference is not applicable. If the committee

takes this approach, the issue can be addressed in Module 2 using normal standard procedure.

Paul said the TIA process is being called into question by ANSI. They may no longer be letting TNI use this process. This is the first time TNI has had to deal with a conflict in this process, but Ilona reminded everyone that Module 5 has not been submitted as a Voting Draft Standard yet – thus, it is not a formal conflict yet.

Paul would like to find a way to change the language in Module 2.

Silky – Isn't there a policy on opening the entire Standard, not just a portion of it?

Robin – Also thought that you could open just a portion of the Standard. CSDEC has been working on a revised SOP for Standard Development that addresses that issue.

Paul – part of the reason for being able to open just a portion of the Standard is to avoid people only looking at changes just before the end of the process, and derailing things by taking one last shot at changes.

During this discussion, it was noted that assorted versions of what seem to be the same policy or SOP are accessible on the TNI website – there seems to be an issue with revision control.

Matt – Could you bracket the range of use within 10°C of the endpoints?

Bill – Isn't there a threshold requirement rather than bracketing? Thresholds are generally where temperatures are concerned, in terms of not exceeding some level.

Robin – That's what's addressed in the Microbiology Standard.

Paul – The biggest issue, in his opinion, is with multiple use thermometers. The purpose of picking a range of 10°C was in case someone used a thermometer at temperatures such as 0 AND 100°C. Some lab might try to just verify at one temperature within that range, and that doesn't feel right, thus the limit at a range of use of 10°C.

Matt – Using Flashpoint as an example, if a thermometer is used at 30-100°C, could you allow for a 10°C range for bracketing, so that you could check it at, for example, 25°C and 105°C?

Dale – When anyone determines their range of use – there will always be a +/- involved. If it is outside of the 10 degree range of use being proposed – the range of use of the thermometer still needs to be checked.

Ilona commented that the issues being raised are the same issues labs deal with today. They are outside of whether to use a single point or range of use calibration check. Do these other issues need to be resolved to decide how to deal with the Module 2 and 5

conflict? There was general agreement that the other issues did not have to be solved today.

Silky motioned that the QS Expert Committee support the concept defined in Paul's document with Richard's language change (Att D). Matt seconded the motion. There was no further discussion and the motion was unanimously approved.

Paul will attend the CSDP meeting on Thursday and present the proposed language and get back to the committee. NOTE – At CSDP it was decided that Section 5.5.13.1 would be proposed as a Working Draft Standard, to be published for 30 days comment.

Silky commented that some labs don't have a thermometer that is calibrated in 1 degree increments. Paul noted that given there are procedures that are currently being done – leave it as is and this can be worked on during the next standard update. There are things that can be done better, but that is not the current issue. Leave as is.

4. Small Lab Handbook

No one was able to make comments on the documents sent by Ilona.

Paul will forward both copies of the handbook – the current one being sold today and Tom's version. This will help people with their homework.

Ilona will set-up an additional call for this month to discuss the handbook. The call will be on Monday, 3-23-15 at 11:30 Eastern. Comments need to be sent to Ilona by Thursday, 3/19/15.

5. Action Items

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

6. New Business

- None.

7. Next Meeting and Close

The next meeting will be March 23, 2015 at 11:30 am Eastern.

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 2:23 pm EST (motion – Silky, Second – Shannon 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) Absent	Wade Consulting and Solutions	Other	913-449-5223	michelle@michellefromks.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) 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*) Present	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 D – Information Distributed about Standard Language Conflict

EXECUTIVE SUMMARY – I'm trying to address a conflict in the language between Modules 2 & 5 before it arises, and in the process, include in the Standard the single point verification of thermometers. If I have missed anyone who needs to be in this discussion, please reply-all and include them

All – There is a conflict between the language in the proposed Module 5 (Microbiology) and Module 2 (Quality Systems). The conflict involves thermometer verifications, and is as follows:

Module 2, 5.5.13.1 b) - All 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.

The recently advanced language in Module 5 reads as follows: Temperature Measuring Devices

Temperature measuring devices such as liquid-in-glass thermometers, thermocouples, or platinum resistance thermometers shall be used to assess and document equipment temperatures and shall be the appropriate quality to meet specification(s) in the method.

The graduation and range of the temperature measuring devices shall be appropriate for the required accuracy of the measurement. Temperature measuring devices shall be verified to national or international standards for temperature. Verification shall be performed at least annually (see TNI Volume 1, Module 2, Section 5.5.13.1). This verification may be accomplished by a single point provided that it represents the method mandated temperature and use conditions.

So Module 5 now refers to a single point verification of thermometers, but refers back to Module 2 where the requirement is to bracket the range of use (i.e., two points of verification).

Previously, SIR 206 asked for clarification on this point, asking to extend the 'single point exception' that was allowed in the 2003 Standard (no such exception existed). Quality Systems responded "An exemption for narrow range use thermometers is not described in the 2003 NELAC Standard and historical data does not provide that an exemption was made on an organizational level. The use of a single point calibration/verification check for the narrow use range thermometers exemption is not described in the 2009 TNI Standard".

The Accreditation Council has said that it would not be opposed to a single point verification.

I feel that the language below would clarify the requirements of support equipment as they relate to calibration, and would eliminate the conflict between Modules 2 & 5. Once these Modules undergo their review by the Standards Review Council, or LASEC, is this something that can be done?

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 - e) The results of such calibration or verification shall be within the specifications required of the application for which this equipment is used or:
 - 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.
 - f) 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.
- Question received** – Why 10°C?

Answer - It seemed like a number that could work. My concern would be for allowing too broad of a range, so it had to be narrowed somehow. 10 degrees should encompass coolers and incubators as well as ovens for solids. It wouldn't allow for a single point verification if you use one thermometer for multiple disciplines, nor for an expected wide range of use such as for flashpoint.

Support from Aaren Alger (AC), Judy Morgan (LASEC), Richard Burrows (Chemistry), Robin Cook (Microbiology), Bob Wyeth (CSDEP), Lynn Bradley (TNI Program Administrator)

Email Message from Lynn Bradley and Richard Burrow on 3/6/15:

Sounds fine to me.

I wonder if it might be better to replace the word "may" with the word "are" in the following sentence:

This Standard applies to all devices that ~~may not be~~ **are not** the actual test instrument

Richard

From: Lynn Bradley [<mailto:lynn.bradley@nelac-institute.org>]

Sent: Thursday, March 05, 2015 7:11 PM

To: Paul Junio

Cc: Robert Wyeth; Judy Morgan; Ilona Taunton; Alger, Aaren S; Jerry Parr; Robin Cook; Burrows, Richard; Ken Jackson

Subject: Re: Standard Language Conflict

there's even a NIST Publication about single point calibration that Paul Bergeron (LA DEQ) brought to the AC (attached.)

while i can't speak for either LAS or the AC, i don't see any serious objection coming from those folks. the question is more about how and whether the formal standards development process can accommodate a change, at this late date....

lynn

(Addition: Email from Judy Morgan, Chair of LASEC:

Hi Paul,

After reading this again, I have a question regarding the suggested addition.

Current Language

5.5.13.1

- b) **All 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.** The results of such calibration or verification shall be within the specifications required of the application for which this equipment is used or:
- 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.

The underlined sentence above, was eliminated from the new language. The current language is addressing more than just thermometers. It also includes weights, balances, etc. The way the new language is worded appears to eliminate other support equipment and focus only on thermometers. I am proposing the following changes (in red below) to the new language.

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 - 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) 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.

f) 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:

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.

g) 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.

Thanks!

Judy)