

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

September 14, 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: Carl Kircher, Dorothy Love, Tyler Sullivan, Eric Denman and Bill Ray.

Minutes were sent out for review and approval. The committee reviewed the minutes for the meetings dated 6/8/15, 7/13/15, 7/31/15 and 8/10/15.

A motion was made by Janice to approve the 6/18/15 minutes as written. The motion was seconded by Shari. There was no further discussion. Vote: 8 – For, 0 – Against, 1 – Abstain (Silky). The motion passed.

Silky noted that she volunteered to help with the handbook and this is not reflected in the minutes. Silky volunteered for Section 1.5 and 4. This will be added as a correction to the minutes. Attachment D includes an updated list of volunteers that are working on the handbook.

A motion was made by Silky to approve the 7/13/15 minutes with the addition of Silky's sections of the handbook that she will work on. The motion was seconded by Patty and unanimously approved.

A motion was made by Silky to approve the 7/31/15 minutes as written. The motion was seconded by Patty and unanimously approved.

A motion was made by Dale to approve the 8/10/15 minutes. The motion was seconded by Michelle. Vote: 8 – For, 0 – Against, 1 – Abstain (Silky). The motion passed.

The minutes will be finalized and sent for posting on the TNI website.

2. Standard

During the last call, 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 (see 8/10/15 meeting minutes)**. The intention was to vote on the motion by email, but this did not happen. Paul asked for a final vote today. There was no further discussion on the motion. Vote: 9 – For 0 – Against 0 – Abstain. The motion passed.

Final voting results for the addition of “Lot” to the Standard was summarized in the 7/31/15 minutes. This motion also passed.

Paul will forward the language to the SRC for review. Any recommendations will be returned to the committee for a final review and an opportunity to make final changes. The committee will then vote whether to move the language along as a Voting Draft Standard.

3. Standard Interpretation Requests (SIRs)

There are some old SIRs that the LASEC still has listed as on our plate. Paul will look for these and distribute them to the committee if they did not receive a final vote. This will be done by email. SIR #230 was sent back by the NELAP AC with some concerns. Carl sent information to the committee to help with the response to #230.

Silky will look back in her records at some of the older SIRs that were worked on when she was Chair of the committee.

SIR 290

Paul looked attempted to prepare some comments and a possible response that emailed to the committee:

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| 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? |
| Committee Comments | <div style="border: 1px solid black; padding: 5px;"> <p>Technical considerations aren't all provided in this SIR</p> <p>The Correction Factor should be the one for the temperature at which the thermometer is being used</p> <p>Which temperatures were used for bracketing the calibration? At what temperature is the thermometer being used / what is the range of use for the thermometer? What were the correction factors that were found?</p> <p style="text-align: center;">****NOTES PRIOR TO PROVIDING A RESPONSE****</p> <p>The laboratory shall maintain records of established correction factors to correct all measurements. The</p> </div> |

laboratory shall have a procedure to describe how it handles such a situation.

NIST SP819 says that any variability found among correction factors on a thermometer must be within the uncertainty of the thermometer.

TNI EL-V1M2 Section 5.5.13.1 b states "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."

Response:

The TNI Standard does not prescribe control limits which must be met in order for a piece of equipment, whether analytical or support, to be determined to be acceptable. TNI EL-V1M2 Section 5.5.7 states "Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 4.9)."

Unless prescribed by method or regulation, it is up to the laboratory to determine which correction factor shall be used. The TNI Quality Systems Committee cannot be the arbiter of method, instrument, or equipment questions, as that is outside the Charter of this Committee.

After all his review, Paul does not think it is appropriate for the committee to respond to this question. The committee agreed. Silky does not think this requires an interpretation of the standard – it is technical.

Ilona noted that a formal response is not necessary if the committee does not think this is an SIR. Paul will send a response to Lynn and suggest that the lab contact their AB with this question. Paul will also send the comments prepared so that it is clear why the committee does not think it is a SIR. Silky also suggested sending the language about the error of measurement for correction factors.

4. Action Items

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

5. New Business

- None.

6. Next Meeting and Close

The next meeting will be October 12, 2015 at 1pm Eastern. This is Columbus Day, but he would like to go ahead and meet since it is difficult to reschedule meetings. 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: Dale Second: Silky 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) Absent | 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*) 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*) Absent | 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 | |
| 11 | Send Standard language changes to SRC so any recommendations can be discussed at the next meeting. | Paul | 9/21/15 | 10/06/15 |
| 12 | Send update to Lynn regarding SIR #290. | Paul | 9/21/15 | 10/06/15 |
| 13 | Find SIR responses for missing SIRs on the summary table sent by LASEC (Ilona). | Paul | 10/8/15 | |
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