Quality System Expert Committee (QS)
Meeting Summary

March 13, 2017

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference on March 13, 2017. Attendance is recorded in Attachment A – there were 7 members present. Associate Members: Eric Denman, Reed Jeffery, Meera Neb, Tyler Sullens and Patricia Carvajal.

The February minutes were distributed by email. A motion was made by Dale to accept the February 13, 2017 minutes with the deletion of Shari from the associate list and correction of the spelling of Alabama. The motion was seconded by Lizbeth and unanimously approved.

2. Update

Paul pulled up the TNI website on Webex and noted that there are two Standard notices – Volume 2 and Chemistry (V1 – M4.)

The Chemistry section of the Small Lab Handout (SLH) will be based on the current 2016 version, but the sections being updated by the Chemistry Expert Committee will be highlighted in yellow and the text will be updated as appropriate after the new language being worked on is available.

3. Charter

Ilona provided some language from other charters as suggestions to Paul. Paul liked the language and substituted the changes in the DRAFT used last time.

The committee reviewed the DRAFT charter for finalization. There were a few editorial changes made.

A motion was made by Sara to approve the Quality Systems Expert Committee Charter in Attachment E. The motion was seconded by Kristin and unanimously approved.

(Addition: The Chair of the Policy Committee confirmed that each Objective should have a Success Measure listed below it. The Success Measures are not a separate section of the Charter. The Charter will be updated as appropriate at the April meeting.)

4. Checklist

There are four volunteers working on the checklist. Each volunteer will go through the checklist and Paul will compile the changes and send them out to the reviewers for one last review. Volunteers: Marlene Moore, Silky Labie, Lizbeth Garcia, and Gil Dichter. The previous template is being used and changes are being made to that template.

Paul is hoping to finish the checklist by the end of April 2017.

5. SIR #308

This is a variation of SIIR # 108. Paul reviewed the language and conclusion for SIR #108.

Paul provided a DRAFT response by email to SIR #308 as a starting point. The language is taken from SIR #108. Dale thinks a lab needs to get agreement with their AB on what the technologies are. Sara noted that some ABs are accrediting by method and not technologies. Paul noted that this inconsistency is a NELAP AC issue. QS should respond with what is based on the Standard and the committee thinks is correct.

Lizbeth noted that such a response would require them to make some changes in Oregon's policies, but it is doable if this were the final decision. Consistency would be in the best interest of the lab.

Ilona commented that additional information could be added to the comments section of the SIR. It may make sense to add some of the language from the A2LA information sent by email this last week.

Paul reviewed the A2LA language distributed by email. Paul asked if all the language should be included in the comment section. Ilona commented that perhaps it can be included as a comment as an example of how the requirements of the standard could be implemented. Or perhaps the committee could recommend that this type of example be included in the Guidance section on the website in the SIR section.

A motion was made by Lizbeth to approve the response to SIR #308 included in Attachment E. Shari seconded the motion. The vote will be completed by e-mail.

(Addition: Vote:
Chris – For (3/13/17)
Paul – For (3/13/17)
Sara – For (3/13/17)
Dale – For (3/13/17)
Lizbeth – For (3/13/17)
Shari – For (3/13/17)
Bill – For (3/13/17)

Matt – For (3/14/17)
Jessica – For (3/14/17)

The motion passed and Paul will send the response to LASEC.)

6. Small Laboratory Handbook (SLH)

   Paul needs to work on more of the Chemistry module. Jacob did some work on it too.

   Nicole noted that the PT committee is working on the PT related language in the SLH. They should have it done early April.

   Radiochemistry is doing an additional review during their March meeting.

   The Microbiology section was sent to Paul. Robin was not concerned about formatting and focused on the content. Paul asked if someone could read over the information and get a response to Microbiology. Paul will follow-up on this through email.

   Jacob did not have a chance to continue review of the Chemistry section.

   There was not enough time to continue the review of the SLH at this meeting. Paul asked everyone to review everything received to date. He will distribute the SLH and send a request for review by email.

7. Action Items

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

8. New Business

   None.

9. Next Meeting and Close

   The next meeting is planned for April 10, 2017 at 1pm Eastern by teleconference.

   A summary of action items and backburner/reminder items can be found in Attachment B and C.

   Paul adjourned the meeting at 2:19pm 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
Kristin Brown (2016) **Present**	Utah DOH	AB	801-965-2530	kristinbrown@utah.gov
Chris Gunning (2018*) **Absent**	A2LA	Other	301-644-3230	cgunning@a2la.org
Sara Hoffman **Present – Until 1:52pm**	Kansas Health and Environmental Laboratories	AB	785-291-3162	sara.hoffman@ks.gov
Jessica Jensen (2018*) **Absent**	Meridian Analytical Labs	Lab	316-618-8787	jessica.j@meridiantesting.com
Silky S. Labie (2018) **Absent**	Env. Lab Consulting & Technology, LLC	Other	850-656-6298	elcatllc@centurylink.net
Jacob Oaxaca (2019*) **Present**	CA Water Board	AB	916-323-3433	Jacob.oaxaca@waterboards.ca.gov
Shari Pfalmer (2018*) **Present**	ESC Lab Sciences	Lab	615-773-9755	spfalmer@esclabsciences.com
Dale Piechocki (2020) **Present**	Eurofins Eaton Analytical	Lab	574-472-5523	DalePiechocki@eurofinsUS.com
Matt Sowards (2020) **Absent**	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Lizbeth Garcia (2019*) **Present**	Oregon Health Authority	AB	503-693-4115	lizbeth.garcia@state.or.us
Janice Willey (2018) **Absent**	NAVSEA Programs Field Office	Other	843-794-7346	Janice.willey@navy.mil
Bill Ray (2020*) **Absent**	William Ray Consulting, LLC	Other	925-352-5205	Bill_Ray@williamrayllc.com
Ilona Taunton (Program Administrator) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B

Action Items – QS Expert Committee

	Action Item	Who	Expected Completion	Actual Completion
9	Look at the Handbook Table of Contents and volunteer for sections.	All	8/10/15	
23	Check with Richard Burrows regarding their committee doing the update on the Handbook.	Paul	3/14/16	Complete – Paul is working on the section and Chemistry Expert Committee will review his work.
24	Summarize format for Handbook and send to committee members and other Expert Committee Chairs.	Paul	6/10/16	Follow-up needed.
25	Follow-up with Bob Wyeth and Jerry Parr about experience vs. course hours for Technical Directors.	Paul	TBD	
26	Provide in writing, thoughts regarding options for Technical Director approval.	Robin	TBD	
30	Send DRAFT Charter committee members for review.	Paul	2/20/17	Complete
31	Solicit volunteers to help with the V1M2 Checklist update for the 2016 Standard.	Paul	2/20/17	Complete
32	Send SIR #308 Response to LASEC.	Paul	3/27/17	
33	Review SLH to date and send comments to Paul.	ALL	4/6/17	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Update charter in October 2016.	n/a	Delayed. Waiting for format from Policy Committee.

Attachment D. Charter

Laboratory Quality Systems Expert Committee

Charter (Revised 03/13/17)

Mission:

To maintain laboratory quality systems standards (TNI Volume 1, Modules 2 & 3) based on public input and to provide technical assistance on issues related to adopted standards; and to develop tools that facilitate the implementation of the standard.

Composition of the Committee:

The Committee is composed of balanced membership of no more than 15 members from among the following TNI Constituencies: Accrediting Bodies, Laboratories, and Other;
Associate members are not limited in number, and are not required to demonstrate balance in their numbers;
Members serve three year terms, and are eligible to serve two consecutive three year terms

Objectives:

1. Review and revise standards based on input from all stakeholder groups
2. Ensure that the Standard will produce data of known and documented quality
3. Provide technical assistance such as responding to Standard Interpretation Requests (SIRs)
4. Provide technical assistance in developing tools to facilitate the implementation of the standard
5. Ensure continuity with TNI Volume 1 Modules 3 through 7

Success Measures:

- Improving the Standard, such as by:
  - ✓ Increasing the clarity of the intent of the Standard
  - ✓ Incorporating advances in technology
- Timely development of standards based on a 5 year review per ANSI requirements
- Responses to SIRs within the 45 days as per [SIR SOP] suggest goal is to have response finalized within two committee meetings

Decision Making:

Decisions of the Quality Systems Expert Committee can be made by electronic ballot or by the respective votes of the committee member in teleconference or face-to-face sessions. In any case a quorum, representing more than 50% of the committee members must be represented in the voting process.
Decisions will be made, consistent with the requirements set down in the current revisions of SOP-2-100 and SOP-2-101 as follows:

Type of Decision	Decision Making Rule
Meeting dates, times	Person-in-charge decides after discussion
Meeting adjournment	Person-in-charge decides after all business is conducted or allotted time expires
Meeting minutes approval	Request for approval by email to all committee members – changes approved if needed from email. No Vote
Meeting cancellations	Person-in-charge decides
Addition of TNIQS Committee members	Two-thirds of committee must vote and simple majority vote
Removal of Expert Committee Members	Person-in-charge decides after discussion
Approval of Standards – any stage (including persuasive/non-persuasive votes)	At least two-thirds of committee must vote in the affirmative
Creation of a new subcommittee	Simple majority vote.
Election of Committee Chair	Two-thirds of committee must vote and simple majority vote
Standard Interpretation Requests	Simple majority vote of attendees

Available Resources:

- Volunteer committee members
- Participating stakeholders and their organizations
- Existing national and international consensus-based standards
- TNI Infrastructure
- Environmental technical community
- TNI Website and TNI support services (administrative, technical editing, etc.)
- Teleconference and web-based services
- Limited Travel Funding

Anticipated Meeting Schedule:

- Monthly Committee Teleconferences on the 2nd Monday of each month (open to all Full and Associate Members)
- Additional committee teleconferences as needed
- Committee meetings (face-to-face) during semiannual TNI Forums (Winter and Summer)

Attachment E – Response to SIR #308

SIR #308, sent to Quality Systems

Standard		2009 TNI Standard
Volume and Module	**(eg. V1M2)**	V1M2
Section	**Section (eg. C.4.1.7.4)**	4.14.1
Question	**Describe the problem:** Per Clause 4.14.1, the internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is unclear if all test methods need to be audited annually since 4.14 never uses the word "methods" but rather "areas" or "activities". The question is this: Can the test methods be grouped by technology (i.e. GC/MS, ICP/MS, ICP, Spectrophotometry, Gravimetry, Meters, Titrimetry, SFIA, etc.) or does every method have to be audited annually? If grouped by technology, can different test methods within each technology be scheduled annually? The schedule beyond one year would show that tests are rotated for internal audits over time.	
Comments from Committee	Grouping tests by technology allows for the laboratory to address all elements of the management system. This plan of internal audits should be addressed in the laboratory's quality documentation in some place (a policy, procedure, or Quality Manual, for example). The decision to address internal audits by technology is one that may/must be made by the laboratory. A schedule indicating how the laboratory addresses all methods is helpful. Response from A2LA, which was helpful in the QS discussion, and is a way that the committee feels meets the requirements of this Standard: Section 4.14.1 of ISO/IEC 17025 states: "The laboratory shall…..conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit program shall address all elements of the management system, including the testing and/or calibration activities." It is acceptable for a laboratory to audit a sampling of their management system at each audit interval, as long as their overall audit program specifies how this sampling is to be done such that all elements of the management system and the accredited testing/calibration activities are audited within a given timeframe. It is also important to note that the standard requires auditing all "testing and/or calibration activities", not necessarily all testing and/or calibration methods. For some laboratories, auditing all accredited technologies and/or parameters may constitute a sufficiently thorough and comprehensive audit of their accredited activities, such that auditing all methods (which may be redundant and overlap) may not be necessary - as long as there is no evidence or indication that the depth and expanse of the technical portion of their audit is inadequate. Also, since the standard does not require that a full internal audit be done	

annually, it is acceptable for a laboratory's audit program to cover the entire management system (including testing/calibration activities) over a span of a number of years, as long as there is no evidence or indication that the timeframe of this cycle is inadequate. Although R102 – Conditions for Accreditation requires that each organization retain records at least for the period of time between full A2LA assessments, it also requires that:

"…adequate records…must be available to demonstrate full compliance with the requirements for accreditation."

Therefore, if a laboratory's full audit cycle spans a period of time that is greater than the period of time between full A2LA assessments, they must maintain adequate records for their full audit cycle to demonstrate compliance with the requirements for conducting internal audits. For example, a laboratory may specify a record retention period of two years, but their complete audit cycle may span 5 years. In this case, they must retain full records of each 5-year audit cycle even though it exceeds their normal record-retention period.

Response

No, not every method needs to be assessed annually in the laboratory's internal audits.

Yes, different methods within each technology may be assessed on an annual basis.