Quality System Expert Committee (QS)
Meeting Summary

February 13, 2017

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference on February 13, 2017. Attendance is recorded in Attachment A – there were 7 members present. Associate Members: Robin Cook, Eric Denman, Reed Jeffery, Nirmela Arsem, Carl Kircher, Gil Dichter, Ann Ryals (Alabama Power),

The January 9th and 25th minutes were distributed by email and presented on Webex today. A motion was made by Bill to accept the January 9, 2017 minutes as written. The motion was seconded by Matt and unanimously approved.

A motion was made by Dale to accept the January 25, 2017 minutes with the addition of Bullet 2 being passed on to Nicole Cairnes and correction of the section numbering. The motion was seconded by Sara and unanimously approved.

2. SIR #304

Ilona gave an update on the question of adding more information to SIRs. Ilona noted that it was brought up during the CSDP call and general consensus was that additional information should be added to the comments section at this time and not the response. It will be further discussed at the March CSDP call.

3. Charter

Silky provided comments to Paul on the Charter and Decision Making. She provided comments about timely updates of the Standard and timing for SIRs.

The committee reviewed the Decision Making rules chart Silky forwarded and concluded the following:

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

A motion was made by Dale to accept the Decision Making Rules chart above. The motion was seconded by Shari and unanimously approved.

Available resources and anticipated meeting schedule will not change.

Paul will finalize the document and send it to the committee for final review. It will be voted on during the March meeting.

4. Checklist

Paul introduced the topic of the 2016 Standard Volume 1 Module 2 Checklist. The sections of the Standard are into questions and some sections may need to be broken up. Ilona pulled up a copy of the 2009 Standard Checklist in Dropbox and distributed it to the committee. It appears to be sections of the Standard with a general question about whether the lab complies with the section of the Standard. The sections are not changed to questions. Section 4.1.5 a) is an example where it was broken down into multiple lines.

Sara thinks changing the Standard to questions is more cumbersome and she'd prefer to use something like the example in Dropbox. Kristin agreed.

The committee agreed that they would like to use the 2009 Standard Checklist as a template and starting point. Only the sections changed in the 2016 Standard need to be updated. Paul asked for volunteers to work on the checklist, but there were no volunteers. Paul will send an email looking for volunteers and update the committee on progress at the March meeting.

5. Small Laboratory Handbook

Dale shared that the Radiochemistry section is being reviewed, but is not ready to come to Quality Systems. After the meeting in Houston, the subcommittee working on this decided to complete the review by the end of February and then determine how to make the needed changes.

The committee finished up through Section 4.9 in Houston and started with Section 4.10 today. Corrections were made as the committee reviewed the information on Webex – See Attachment D. The committee completed through Section 4.16 of Volume 1, Module 2. Module 3 (Asbestos) will not be included in the Handbook.

6. Action Items

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

7. New Business

None.

8. Next Meeting and Close

The next meeting is planned for March 14, 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 2:28 pm Eastern. (Motion: Dale Second: Bill 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
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**	Kansas Health and Environmental Laboratories	AB	785-291-3162	shoffman@kdheks.gov
Jessica Jensen (2018*) **Absent**	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
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) **Present**	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Lizbeth Garcia (2019*) **Absent**	Oregon Health Authority	AB		lizbeth.garcia@state.or.us
Janice Willey (2018) **Absent**	NAVSEA Programs Field Office	Other	843-794-7346	Janice.willey@navy.mil
Bill Ray (2020*) **Present**	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	Follow-up needed.
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	
28	Follow-up with Expert Committees to prepare a section of the Small Lab Handbook. Radiochemistry is complete and Microbiology has started.	Paul	9/30/16	Complete
29	Send Sections with PT information to Nicole (PT Expert Chair) for her review – especially information on Experimental PTs.	Paul	12/15/16	Complete
30	Send DRAFT Charter committee members for review.	Paul	2/20/17	
31	Solicit volunteers to help with the V1M2 Checklist update for the 2016 Standard.	Paul	2/20/17	

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

- **TNI 4.8 Complaints**
  - Key Points
    - The laboratory must have a policy and prcedure for how it will handle complaints.
  - Discussion
    - Records of complain resolution must be kept. Complaints may be as simple as a client not getting data as fast as they want it. Evaluating complaints is also a way to assess the laboratory's effectiveness in terms of service to the client.
- **TNI 4.9 Control of Nonconforming Environmental Testing Work**
  - Define non-conforming work
  - Key Points
    - The laboratory must have a policy and procedure that it follows if it discovers that it hasn't followed this Standard or other regulatory requirements. The procedure must specify who has the authority to stop and re-start work if questions arise.
  - Discussion
    - Specific job positions and their roles in this process must be included in the laboratory's procedure. State who has the authority to stop any analysis due to the potential of the laboratory not following its procedures as required.

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4.10 Improvement

- Definitions
  - 'Procedure' as defined in Section 3.0 of the TNI Standard
  - 'Policy' as defined by ASQ: "An overarching plan (direction) for achieving an organization's goals."
- Requirements
  - Quality Policy Statement
  - Quality objectives
  - Audit results
  - Analysis of data
  - Corrective and preventive actions
  - Management review
- What do I do?
  - Utilize the requirements identified above to continually make improvements to your laboratory's operations (create a measure of success where possible). Essentially, if an issue is identified make sure that something is done to address it.
  - For example, the review of data showing a decrease in mistakes over time shows improvement in the laboratory

4.11 Corrective Action

- TNI 4.11.1 General
  - Definitions
    - Policy
    - Procedure
    - Corrective action
    - Root cause – DEFINED? [edit to add]ASQ – factor that causes non-conformance; identifying the underlying cause of a failure; the basic problem that, if corrected, will prevent an issue from recurring; explains the causes of the non-conformity, while the root cause is the final cause of the non-

conformity, which should relate to complying with the requirement that was identified as a failure
        - Nonconformance – non-fulfillment of a requirement
        - Management System
    - Requirements
        - Policy that describes how corrective actions will be handled
        - Procedure – describe the process of how corrective action will be handled from reporting to investigation, determining root cause, selection of corrective action(s), and monitoring the implemented corrective actions
        - Designate roles of those that will be responsible for implementing corrective actions when a nonconformance occurs
- TNI Citation 4.11.2 Cause Analysis
    - Definitions
        - Investigation
        - 5 whys; fishbone; brainstorming…
    - Requirements
        - The procedure begins with an investigation to determine the root cause(s) of the problem.
    - What do I do?
        - Outline who will be/is able to perform the investigation and possible ways of identifying the root causes(s) of the problem.
        - There are several ways to go about determining the 'root cause'. You may use any means you wish. [examples would be great] fishbone, 5 whys, brainstorming…. [Nilda Cox has examples]
            •
- TNI Citation 4.11.3 Selection and Implementation of Corrective Actions
    - Requirements
        - Identify potential corrective actions
        - Select and implement the action(s) most likely to eliminate the problem
        - Document which action(s) are selected
        - The corrective actions taken are to be appropriate for the magnitude and the risk of the problem.
    - What do I do?
        - Update any policies, procedures or other documentation necessary to implement the corrective action(s)
            •
- TNI Citation 4.11.4 Monitoring Corrective Actions
    - Requirements
        - Have a process/procedure to monitor the effectiveness of the selected corrective actions
    - What do I do?
        - Document that a follow-up has been performed to assess the effectiveness of the corrective actions that were implemented.
- TNI Citation 4.11.5 Additional Audits
    - If the identification of a nonconformity or departure casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with the Standard, the laboratory shall take appropriate action and audit those areas where a potential problem has been identified as soon as possible.
- TNI Citation 4.11.6 laboratory is to have documented procedures to address sections 4.11.1 and 4.11.3 through 4.11.5

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- Requirements
  - Have a procedure to address the identified sections
  - Identify the individuals or positions that are responsible for assessing each QC data type
  - Identify individuals or positions that are responsible for initiating and/or recommending corrective actions.
- What do I do?
  - Document how you will accomplish those tasks
  - Identify who will do what

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4.12 Preventive Action

- TNI Citation 4.12.1 and 4.12.2
  - Requirements
    - Identify areas that need improvement and potential sources of nonconformance; both technical and management system related.
    - Develop an action plan when opportunities or preventive action is required
    - Implement the action plan and monitoring the implementation to reduce the likelihood of the occurrence of the identified issues.
    -

4.13 Control of Records

- TNI Citation 4.13.1 General
  - Requirements
    - Establish and maintain a procedure for the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.
    - All records are to be legible and are to be stored and retained in a manner that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.
    - Establish a retention time for documents
    - Establish procedures to protect and back-up records that are stored electronically and to prevent unauthorized access to or amendment of these records.
- TNI Citation 4.13.2 Technical Records
  - Requirements
    - Retain all records of original observations
    - Retain all derived data and sufficient information to establish an audit trail
      - Calibration records
      - Staff records
      - Copy of each test or calibration shall have sufficient information to facilitate the identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions similar to the original.
      - Include the identity of personnel responsible for the sampling, performance of each test and/or calibration.
    - Observations, data and calculations shall be recorded at the time that they are made. And are to be identifiable to the specific task.
    - When mistakes occur in records, each mistake shall be lined out, not erased, made illegible or deleted and the correct value entered alongside. Each correction shall be dated and initialed or signed by the individual making the correction.
      - Electronic records are to have equivalent measures to avoid loss or change of original data.
- TNI Citation 4.13.3 Additional Requirements
  - Requirements
    - Establish a record keeping system that allows the history of the sample and associated data to be readily understood through the documentation.
    - Document all laboratory activities such as laboratory facilities, equipment, analytical methods, and related laboratory activities such as sample receipt,

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sample preparation, data verification and inter-laboratory transfers of samples and/or extracts.

- Retain records for a minimum of 5 years of the last entry
- Records are to be made available to the accreditation body
- Data on electronic media are to be supported by the hardware and/or software necessary for their retrieval for a minimum of 5 years.
- Access to archived information is to be documented with an access log.
- All information is necessary for the historical reconstruction of data shall be maintained. Refer to list in 4.13.3.f.i – xix.
- All data is to be recorded in permanent ink; except for automated data collection systems
  - All corrections are to include date and initials of the individual making the correction
  - Corrections made for reasons other than transcription errors must include a reason for the correction.
- In the event that the laboratory were to cease operations a plan is required to ensure that the records are maintained or transferred according to the customer's instructions. All appropriate regulatory and state legal requirements concerning laboratory records must also be followed.

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4.14 Internal Audits

- TNI Citation 4.14.1
  - Requirements
    - A schedule when internal audits will be performed
    - A procedure on how to conduct internal audits that verifies that the operations comply with the requirements of the management system and the TNI standard.
    - All elements of the management system must be audited.
      - Testing and/or calibration activities
    - The Quality Manager is responsible for planning and organizing audits as required by the schedule and/or requested by management.
    - Audits are to be carried out by trained/qualified personnel
    - It is preferable that the auditor be independent of the area being audited whenever possible.

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- TNI Citation 4.14.2 – 4.14.4
  - Requirements
    - When an issue is identified during an internal audit that is not in compliance with the laboratory's policies and procedures timely corrective action is to be taken and must also notify customers if it is found that analytical results are affected.
    - Document all steps of the audit process
      - Audit findings
      - Corrective actions
    - Internal audits must also include a follow-up to verify and record the implementation and effectiveness of the corrective actions taken.

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- TNI citation 4.14.5 Additional Items
  - Requirements
    - A policy detailing the timeframe for notifying a customer of events that impact their analytical data.

- Management must accomplish the notification within the timeframe that has been established.
- The internal audit schedule is to be completed annually

4.15 Management Reviews

- TNI Citation 4.15.1
  - Requirements
    - Develop a procedure and schedule for the completion of a review of the laboratory's management system including testing and/or calibration activities to ensure their continued suitability. Address all items listed in 4.15.1.
    - [this isn't an internal audit]
- TNI Citation 4.15.2
  - Requirements
    - Record the findings from the management review and the actions that will be taken to address the issues that were identified.
    - Management must verify that the actions are carried out within the appropriate time frame
    - The management review must be completed on an annual basis.

4.16 Data Integrity Investigations

- TNI Citation 4.16 Data Integrity Investigations
  - Requirements
    - All investigations resulting from data integrity issues are to be conducted in a confidential manner until they are completed.
    - All investigations are to be documented including any necessary notifications to customers if it has been determined that their analytical results are affected

NOTE – THERE IS NOT CURRENTLY A SECTION ON VOLUME 1 MODULE 3 ASBESTOS

[start here March Meeting]

Volume 1 Module 4

1.1 – 1.3 Introduction, Scope, Terms and Definitions

- Definitions
  - There are no definitions that are unique to the Chemical Testing Module. All terms are as defined in the Quality Systems Module (Environmental Sector Volume 1, Module 2).
- TNI 1.2 Scope
  - Key Points
    - Any requirements that are specified by method, regulation or project is a requirement for the lab, in addition to the requirements found in this Standard.
  - Discussion
    - If a requirement is found in another location, and it is more stringent than what is required in this Standard, the laboratory is obligated to follow it. Included in this is if the laboratory writes a requirement into its own documents (Quality Manual, SOPs, Policies) that is more stringent than the requirements of this Standard, the methods it follows, or applicable regulations, those requirements must be followed. So, don't make things

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