Quality System Expert Committee (QS)
Meeting Summary

January 9, 2017

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference on December 12, 2016. Attendance is recorded in Attachment A – there were 10 members present. Associate Members: Bill Ray, Tyler Sullens, Nirmela Arsem, Reed Jeffrey, Meera Neb, Jennifer Blossom, Carl Kircher (until 1:30pm) and Anne Ryles.

The December meeting minutes were reviewed. A motion was made by Jessica to approve the December 12, 2016 minutes with the addition of Jacob to the committee roster (absent). The motion was seconded by Silky and unanimously approved.

2. Committee Business

Silky nominated Paul Junio to continue as committee chair. The motion was seconded by Jessica and was unanimously approved.

Silky nominated Jessica to continue as committee vice-chair. The motion was seconded by Matt and unanimously approved.

Paul pulled up the DRAFT summary that Ilona sent out to the committee chairs for the changes to the Charter. This has not been formally approved yet, but is expected to be approved at the TNI Board meeting on Wednesday. The differences are the addition of Committee Composition and Decision Making. Ilona sent a copy of SOP 102 to Paul.

Paul pulled up the Houston Presentation and reviewed Plans and Accomplishments. Ilona recommended adding number of SIRs closed and Standard trainings.

3. Committee Membership

Paul forwarded an "Other" application to the committee for review. Balance is currently:
AB – 4
Lab 6
Other 3

Chris may change to an AB. Patty may step off the committee, but Dale, Lizbeth (2019), and Matt would like to serve a second term. Lizbeth is not rotating off at Shannon's term – she started a new term. Paul will continue this discussion by email.

4. Small Laboratory Handbook

Chapter 4 and 5 were reviewed today. Paul pulled the sections up on Webex. Changes were made on screen and are included in Attachment E.

Chapter 5 - Section 4.11 – It would be helpful to add a definition for Root Cause and Non-Conformance. Tyler noted that 4.11.2 also had Root Cause noted. Root Cause was removed in 4.11.2.

Jacob noted that CA is looking closely at the Standard. They have some issues with the current Standard.

Paul asked that everyone continue to review the Small Laboratory Handbook – add comments and examples by email.

Jacob asked where to get to documents. Ilona noted that he can find them in Attachment D of the minutes and Paul is sending the information out by email.

5. Action Items

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

6. New Business

- Paul received comments on SIR 304 when the December meeting minutes were distributed for review and comment.

  Minimal SIR responses have been the preference, but after reviewing the comments by email, it appears that some people would like SIRs to include additional helpful material. The email sent by Matt could be helpful - Document: Determining the Volume of Microliter Syringes. Should this document be added as a reference to the SIR response?

  Paul noted that there is a Mentor Session on Monday afternoon in Houston (Jerry Parr, Robin Cook, Marlene Moore, Paul Junio, Jack Farrell) and he will bring this up. The session will also be looking at some of the issues California raised that they plan to change in the Standard during implementation in their state.

7. Next Meeting and Close

The next meeting is planned for January 25, 2017 at 1pm Central in Houston, TX.

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

Paul adjourned the meeting at 2:31 pm Eastern. (Motion: Jacob Second: Dale 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 (until 1:30pm)**	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
Sara Hoffman **Present (until 1:30pm)**	Kansas Health and Environmental Laboratories	AB	785-291-3162	shoffman@kdheks.gov
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
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 (2017*) **Present (added 1:48pm)**	Eurofins Eaton Analytical	Lab	574-472-5523	DalePiechocki@eurofinsUS.com
Matt Sowards (2017*) **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
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	
29	Send Sections with PT information to Nicole (PT Expert Chair) for her review – especially information on Experimental PTs.	Paul	12/15/16	
30				

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. Small Laboratory Handbook

Chapter 4. WHAT IS A QUALITY MANAGEMENT SYSTEM?

A Quality Management System (QMS) is the same as a Quality System. A QMS describes that manner in which you, as a laboratory intend to direct and oversee the program that will provide the user with "data of known and documented quality".

This system is organized, defined and documented through various policies and procedures. The QMS must describe your objectives and principles relative to quality, and must address:

- how your objective and principles will be achieved through written policies and procedures;
- how your organization is organized including work processes;
- how each individual is accountable for their assigned activities and responsibilities as it relates to generating quality data;
- how you expect policies and procedures to be implemented, and
- how you will evaluate the effectiveness of your system.

The QMS is the framework under which you will plan, implement and assess work performed by your laboratory and the Quality Assurance (QA) and Quality Control (QC) activities that are necessary to meet your stated objectives.

WHY IS IT IMPORTANT?

A QMS is important for two reasons:

1. The System (which is outlined in the Quality Management Plan), serves as a guide to the laboratory in implementing the processes and procedures intended to provide data of known and documented quality.
2. A well thought out QMS provides clients with an understanding of how your laboratory intends to produce and document the data from samples that are submitted for analysis and adds a significant level of confidence in your laboratory's reported results.

TERMINOLOGY AND A LESSON IN HIERARCHY

In order to develop your quality management system, you must understand the difference between a Quality System, Quality Assurance, and Quality Control. These terms are intimately related but represent very different processes. Definitions for each of these terms are found in EL Vol 1, Module2, Section 3, but the relationship is often unclear as many use these terms interchangeably.

> *"Quality System: A structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance (QA) and quality control (QC) activities.*

Quality Assurance: An integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

Quality Control: The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality; also the system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality."

As a summary, these three terms form a hierarchical system in which the QUALITY SYSTEM is the umbrella under which all activities are performed. It is a management system that is designed to ensure data of known and documented quality and describes all activities related to providing a quality work product:

- Policies, Procedures
- Organizational Responsibilities & Accountability
- Assessment

The description of these activities and policies is found in the Quality Manual (QA Manual, Quality Assurance Plan, however named).

QUALITY ASSURANCE are those management activities that implement the policies and oversee the implementation of the plan:

- Planning including developing policies and procedures
- Implementing policies by writing procedures to be used to accomplish the goals outlined in the policies
- Insuring that all procedures are being followed as written
- Assessing how well the procedures and policies are followed
- Assessing how well the implemented processes work
- Establishing a mechanism for addressing failures in processes, procedures or technical work
- Looking for and implementing procedures that will enhance the laboratory's ability to produce data of known and documented quality

QUALITY CONTROL are usually technical activities that monitor how well the processes are working but is not limited to the testing. Quality controls:

- Measure performance of a process
- Verify that performance measures meet specified limits

In this sense, a quality control measure could be related to accuracy of data transcription, ordering and/or receiving supplies, etc.

Note: As a cautionary note, you may use other sources (laboratories, consultants, workshop, etc.) to develop your quality system, but make sure that it becomes your management system. Since the QMS is described in detail in your quality management plan, you must be sure that you are performing what is written, regardless of whether it is "extra" or "not required" for accreditation. When you write it into your Manual, it becomes your requirement.

Chapter 5

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. Essentially, if an issue is identified make sure that something is done to address it.

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….

- TNI Citation 4.11.3 Selection and Implementation of Corrective Actions
    - Definitions
    - 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
    - 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 that tasks
        - Identify who will do what

4.12 Preventive Action

- TNI Citation 4.12.1 and 4.12.1
    - 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
    - Definitions - none
    - 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 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
    - Definitions - none
    - 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 a mistakes occur in records, each mistake shall be lined out, not eased, 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, 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 is to be in place. All appropriate regulatory and state legal requirements concerning laboratory records must also be followed.

4.14 Internal Audits

- TNI Citation 4.14.1
  - Definitions - none
  - 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.
- TNI Citation 4.14.2 – 4.14.4
  - Definitions
  - 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 customer's 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.
- 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.
- 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