Quality System Expert Committee (QS)
Meeting Summary

October 10, 2016

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference on October 10, 2016. Attendance is recorded in Attachment A – there were 9 members present. Associate Members: Bill Ray, Nirmela Arsem, Reed Jeffery and Eric Davis.

The September meeting minutes were reviewed. A motion was made by Sara to approve the September 12, 2016 minutes as written. The motion was seconded by Shari. Vote: For – 7 - Chris, Patty, Lizbeth, Sara, Dale, Shari, and Paul. Against – 0 Abstain – 2 – Silky and Matt (did not attend meeting). The motion passed.

Paul noted that some associate members did not receive information because he has a new computer and needs to rebuild his email list. This will be taken care of by the next meeting.

2. Small Laboratory Handbook

Paul forwarded a number of documents that Committee Members have been working on - Sections 4.1 through 4.9, How to Apply for Accreditation, and Preparing for your Assessment. Paul started with the document he is working on that starts with Section 4.1 – Organization. He reviewed the document and made updates as the committee reviewed it. The new Draft is included in Attachment D and reflects the work done during the meeting.

Dale and Lizbeth commented that the right topics are being looked at and it is a great start.

The committee moved on to the accreditation application section. Shari asked whether it was appropriate to point to specific items on the TNI website or if this would cause problems when the website is updated. Paul likes the detail, but he was concerned when there are changes made. Shari thought she could add a note that the website could change and suggest they search for it if the website has changed.

Paul asked if the summary format is OK compared to the format of the other sections with specific headings. There was agreement that it does not need to be in the same format.

The committee opened the Draft for Preparing for Assessment. They also followed a different format than the other sections – did not follow the key points format. Again, a

different format worked better for the material being covered. The information provided for committee review today is more an outline so everyone can see what is being covered.

Paul reviewed the Handbook Outline (Attachment E). Paul is not sure Asbestos and WET will be included in the Handbook. Sara and Jessica plan to have a Draft of their chapter before the next meeting. Sara and Kristin will be working on the Common Findings section.

Paul will forward useful information that should be considered when preparing each section – older version of the Handbook, presentations Jerry gave, NEFAP accreditation summary, etc... These were originally sent out last year and were provided by Jerry and Ilona.

Paul needs volunteers to help with the Chemistry module. He will pass along the most current copy of this module. Please contact him by email with your interest. He also asked that everyone continue to work on their sections and send them to him a few days before the next meeting.

3. Action Items

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

4. New Business

   None.

5. Next Meeting and Close

   The next meeting is planned for November 21, 2016 at 11am Eastern. This is not the standard date and time. Ilona will send out conference call and Webex invitations.

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

   Paul adjourned the meeting at 2:12 pm Eastern. (Motion: Silky 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) **Absent**	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*) **Present**	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) **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*) **Present**	ACZ Laboratories, Inc.	Lab	970-879-6590	matts@acz.com
Lizbeth Garcia (2017*)? **Present**	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	
27	Send new Handbook format to Robin.	Paul	9/30/16	Complete
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	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Update charter in October 2016.	n/a	

Attachment D.

4.1 Organization

- Definitions
  - 'Laboratory' isn't explicitly defined in the TNI Standard, but for the purposes of this document, it means the body described in Section 1.0 of Module 2 that is applying or is accredited
  - 'ISO/IEC 17025' specifies the general requirements for a laboratory to be determined as acceptable to carry out tests and/or calibrations. These requirements are as determined by ISO, which is an independent, non-governmental international organization with a membership of 161 national standards bodies
  - 'Top management' is a term used in the ISO language, but that term is not defined, so it's a good idea for the laboratory to specify who they have determined as 'Top management'
- TNI 4.1.1-4.1.6 Organization
  - Key Points
    - These sections discuss the ISO requirements regarding organizational structure of the laboratory and where it fits in any larger organization of which it might be a part. The management system requirements are outlined, indicating that these requirements apply to the entire laboratory, not just the people who analyze samples.
  - Discussion
    - Make sure the laboratory's location in a company organization structure is clearly shown. There are many requirements regarding policies and procedures that are required of the laboratory in these sections. Among them are: satisfying the needs of the customer and any regulatory authorities; understanding that the entire organization is affected by these requirements; that authority is granted to appropriate employees to identify and correct departures from the laboratory's approved procedures, and that those appropriate employees are identified in the laboratory's documents (such as SOPs or Quality Manual); define the responsibilities of those employees who manage, perform, or verify analyses; assure adequate supervision of laboratory employees, and; appoint a person as Quality Manager who shall assure that these requirements are implemented and followed.
  - Examples
    - Keep in mind that in a small lab, the customer might be another person within the same facility or organization. Specific names don't need to be mentioned in the laboratory's documentation; it is a good idea to use position titles so that changes need not be made if a person leaves the laboratory. If requirements are listed in one place, such as the Quality Manual, don't re-state them in an SOP, or you'll have to change two documents if you want to make changes in a procedure.
- TNI 4.1.7.1 Quality Manager Requirements
  - Key Points

- The Quality Manager and the Technical Manager may be the same person. The Quality Manager is the person who is the focal point of these requirements. The Quality Manager has to be independent of laboratory analyses. The Quality Manager must conduct or arrange for internal audits of laboratory activities. The findings of any deficiencies must be reported to laboratory management.

- Discussion
  - There are very little actual requirements for the person who is named the Quality Manager, as opposed to the detailed requirements for the Technical Manager (see section 5.2.6.1). The Quality Manager need not perform all duties of the position, but is responsible for assuring compliance with all aspects of these requirements. Monitoring of corrective actions is an important part of improving the laboratory, as when that is done well, the laboratory will learn from and minimize its future mistakes.
- Examples
  - An example of a corrective action tracking system is listed below. Using a system such as this would allow for tracking completion, historical searches, and categorizing for targeted efforts at improvement.

#	Initiated by	Deficiency	Analyst	Dept.	Corrective Action	Due	Follow up by	Closed	Audit

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- On the other hand, tracking non-conformances such as QC failures might look like this:

#	Initiated by	Deficiency	Analyst	Dept.	Method	Matrix	Corrective action	Comment

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❖ TNI 4.1.7.2 Technical Manager Requirements

- Key Points
  - The Technical Manager is the person supervising daily activities in a particular part of the laboratory. The Technical Manager has to monitor quality control and quality assurance standards, as well as the technical validity of the analyses performed by the laboratory. If the Technical Manager will be absent for more than 15 consecutive days, another qualified person must be named. The qualification requirements for the Technical Manager are extensive, and are covered in Section 5.2.6.1.
- Discussion
  - There is an allowance for a person to be named the Technical Director at multiple laboratories, with the approval of the appropriate Accrediting Body. There are three items that would need to be considered in order for this to occur (the hours of the assorted labs, ability to supervise multiple laboratories, and the availability of laboratory services in the area). Monitoring of Quality Assurance and Quality Control standards is done by assuring technical compliance with the methods performed in the laboratory. Given the difficulty

in having a qualified Technical Manager on staff, the need to have an acceptable replacement likely limits the time that a Technical Manager could be out of the office at 15 days. [reminder that the deputy must also meet the requirements of a Technical Manager]

- Examples
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4.2 Management

- Definitions
  - 'Management system' isn't explicitly defined in the TNI Standard, but for the purposes of this document, it means the entire system of laboratory operations, quality, finance, personnel, and other sections of the business of the laboratory
  - [ISO website – describes a set of procedures an organization must follow ….]
  - 'Top management' is a term used in the ISO language, but that term is not defined, so it's a good idea for the laboratory to specify who they have determined as 'Top management'
- TNI 4.2.1-4.2.7 Management
  - Key Points
    - These sections discuss the ISO requirements regarding management system requirements. Those requirements must be distributed to and understood by all employees of the laboratory. The laboratory must have a quality policy that is included in its Quality Manual. That policy must be reviewed annually by laboratory management, and must contain at least five specific elements that are listed in Section 4.2.2. Top management is required to: show a commitment to these requirements; continually improve the effectiveness of the management system, and; ensure that the management system doesn't fail if and when it is changed.
  - Discussion
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  - Examples
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