Quality System Expert Committee (QS)
Meeting Summary

February 4, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1:03pm EST in Crystal City, VA. Attendance is recorded in Attachment A – there were 9 members present.

Paul reviewed the ground rules for the meeting.

2. Small Lab Handbook

This document was originally prepared a number of years ago, but had not really undergone a QS review. The committee has been asked to review and update the handbook to the 2012 (QS) and 2015 Standards. During the review the committee decided that the handbook needed to be completely redone.

An introduction was developed during the last face-to-face meeting in DC (August 2014):

INTRODUCTION

This handbook is NOT a substitute for reading and understanding the Standard. Keep in mind that the TNI Standard is NOT designed to tell you HOW you must do something. It is designed to tell you WHAT you must do. This document should provide you with examples of HOW you might comply with the TNI Standard. The examples provided aren't requirements, they are recommendations that could help with compliance. Often, you have many options on what you can do to comply with the requirements of the Standard. Each individual laboratory must decide what processes are the best for designing and implementing its quality system.

The goal of the TNI Standard and the TNI Accreditation process is to provide the essential requirements for a laboratory to produce data of a known and documented quality.

The TNI Standard is a quality standard for environmental laboratories based on the ISO 17025 Standard with additional requirements specific to the TNI accreditation process. ISO 17025 language is presented in the Standard, and is formatted in *italics* to draw attention to its origin. There is a module on proficiency testing samples with general participation requirements for submittal of PT data to the accrediting bodies. The General Requirements Module (Module 2) of the TNI Standard contains a section on Management Requirements and another on Technical Requirements. The management requirements are related to the operation and effectiveness of the quality management system within the

laboratory and have similar requirements to ISO 9001. The technical requirements address the competence of staff, testing methodology, equipment and quality and reporting of test and calibration results. There are five Modules covering the different types of analytical processes. Not all five of these sections are applicable to all laboratories. When correctly implemented, the quality system can help to continually improve the quality of data and effectiveness of the laboratory.

Analytical testing laboratories seeking accreditation to the TNI Standard will be impacted in a couple of areas. The main difference between formal accreditation and 'just' good analytical practices is the amount of documentation to be developed. There is no doubt that any good analytical laboratory uses qualified analysts for performing tests, checks the performance of equipment used for testing and validates analytical methods. However, many times the outcome of the tests is not fully documented. TNI accreditation requires formal documentation for about everything that supports an analytical result. It's similar to operating in a regulated environment; 'what is not documented is a rumor', assessors consider it as 'not being done'.

Depending on the scope of the laboratory, the initial implementation of the TNI Standard may require a significant dedication of manpower and resources. However, this is primarily a one-time, upfront expenditure of resources. Once a TNI-compliant set of policies and procedures has been put in place, maintenance and periodic updates should require minimal effort.

The TNI Standard is an attempt to add specificity for the environmental analytical technology to the general ISO 17025 language.

Prior to beginning your reading of this Handbook, please take a moment to read the definitions found in Module 2, Section 3. You might want to make specific note of the following:

Batch
Data Integrity
Laboratory Control Standard
Matrix Spike
Quality System
Reference Method
Traceability

Open Discussion/Comments:

- Kim Watson noted that EPA has a terminology document that this committee should be aware of to build consistency in terms. Ilona has these links.

- Natalie – Asked how a small lab is defined. Paul noted that there is not a strict definition – but more than likely, if you think you might be a small lab … you are.

- Dorothy Love – If it is applicable to all labs, why is it titled for small labs? Silky noted that the previous version came from the small lab advocacy group (SLAG) and

was intended to make implementation easier for small labs. The information is relevant to all labs.

- Marsha (large municipality) – She was frustrated with the current version of the handbook and used the Quality Manual Template to implement her program instead.

- Ilona – Commented that the format being proposed today is very different than the format this document has been in since early 2000. Has the committee reviewed this new format with small labs and other stakeholders to make sure this change is appropriate? Paul stated this has not been done. She also noted that Jerry wanted text included to help a lab apply and begin the process towards accreditation. The new NEFAP Accreditation Summary and Oregon's application summary would be helpful in developing this.

- Robin Cook (Microbiology Expert Committee Chair) – There are a number of things that Microbiology would like to add to this handbook that are too proscriptive for the standard. She is concerned the new format won't work to provide this additional type of guidance in implementing the standard.

Paul stated that the comments would be taken into consideration and that he wants to begin reviewing a few of the new sections.

The first section reviewed was Section 4.1 of the handbook:

4.1 Organization

TNI Citation: 4.1 Organization

DEFINITIONS

a. "Laboratory" includes all employees and subcontracted employees, including analysts, management, and support services.
b. "Procedure" means a specified way to carry out an activity or process. Procedures can be documented or not.
c. "Policy" as defined in http://freedictionary.com means a course of action, guiding principle, or procedure considered expedient, prudent, or advantageous
d. "Top management" are those people that the lab defines as directing the overall operations of the laboratory.
e. "Technical Manager" is the person in charge of a laboratory-defined portion of the laboratory, who meets the appropriate qualification requirements as defined in 5.2.6, and shall have the duties described in 4.1.7.2
f. "Management System" is equivalent to Quality System, which is defined as '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.'

OVERVIEW

This section outlines the laboratory's place in an organizational structure, and sets the groundwork for the direction of the laboratory.

DISCUSSION

a. An organizational chart can help show how the lab fits in the organizational structure (for example, by reporting to a City Council or Town Clerk), and may also show reporting roles indicating who is in charge of a given part of the laboratory
b. The laboratory will have a named Quality manager (however named) who shall have the responsibility and authority to assure that all of these procedures and policies are written and followed by everyone in the organization. The QA Manager shall have the duties described in 4.1.7.1
c. One person may fill more than one role, so that the QA Manager and the Technical Manager might be the same person

POLICY

a. There must be a policy that indicates how data are not made available to anyone other than the customer who submitted the samples.

Open Discussion/Comments:

- A concern was raised about whether laboratories designate their Quality Manager's (however named) as top management. There are no requirements in the Standard. There have been situations where labs have not notified their AB that the Quality Manager has been replaced or the position is vacant and temporarily filled.

  Michelle reminded everyone the Standard requires states to define who key personnel are (VxM1: Section 8.1.2.b). ABs do this with their labs.

  Dale noted that the Quality Manager (however named) is asked for on the application.

  It was suggested to add: including the Quality Management system. This suggestion lead to questions about the differences between Quality Management System vs. Quality System vs Management System. Ilona suggested that the term used in the Quality Manual template should be consistent with this documents, so this needs to be looked at. It was stated that Management system is equivalent to Quality Management System.

  Pull "Top Management" definition and put this in the Discussion section since it is not in the Standard.

  Paul noted that when ISO refers to management system this is equivalent to TNI's quality system. Chris disagreed – management system encompasses all – quality and management practices.

  Trinity: would prefer to see the term key personnel used and also agrees that management system is quality system.

Management system is sometimes used interchangeably with quality system in the Standard.

The committee added (d) and (e): Top Management and Management System

Discussion (c): Shannon would like to add: Ensure sure that how these roles are filled is clearly spelled out somewhere.

- Shannon asked if the text is going to make it clear what is a requirement and what is guidance. Michelle also suggested looking at the language from the standpoint of whether it is a requirement or clarification/suggestion.

- Matt was concerned that having to flip back and forth would make the handbook less useable. There are times when it will be important to reiterate the Standard. The handbook should not just reference the Standard.

- Chris commented that he doesn't want this to be the cliff notes version of the standard. Doesn't want sections directly out of the standard. Everything under Discussion needs to be a discussion.

- Ilona suggested changing the Discussion section to "Highlights" (key items from the standard) and Implementation (this is the place for suggestions, examples, etc.).

- Matt asked about the policy statement. At anytime regulation can override what is in the Standard.

- Richard Burrows: He understands not wanting to repeat stuff out of the Standard – but sometimes you have to repeat. What about a grey box approach to the standard? Similar to what DoD did with the Standard.

- Ilona commented that the committee really needs to go back to the client to make sure this format will work for it's intended purpose. At a minimum the client would be small labs and Jerry Parr. Having been a part of the original group working on this document, she is concerned about the direction. Who is the intended audience? If the new format is continued, the committee should look at all the section headings and define what goes into each section – rules for the section. This will help determine what the correct section headings should be. The committee also needs to look at the Quality Manual template to make sure there are no conflicts. Will this committee also update the Quality Manual template?

- Paula (new lab applying for accreditation): Asked if there are any FAQs or a forum for questions? There is a small lab forum for questions on the website, but it is not used very much anymore.

  Chris asked what a new lab would want to see in the handbook. Teresa Embrey is also from the same small lab as Paula. She would like to see the standard referenced

in the handbook. Michelle wants to emphasize that the whole standard applies to a lab regardless of size. Kim Watson made this point too.

- Robin Cook - Asked if the handbook is a document for implementation purposes – if so … it needs to be retitled. She thinks people want to know how someone did it in their lab and does it work. This is where this committee should go.

  Shannon noted that if examples are used there needs to be several examples – not just one. Ilona agreed and suggested that the examples also need to be from different sized labs.

  James Davis – Cincinnati Ohio Metropolitan Sewer District – Chose his AB to be PA. He went through the Standard and then through PA's regulations. PA gave examples. He feels examples are the key. They are the most helpful thing to a new lab.

- Zonetta: The committee needs to go back to what the intended purpose of the handbook is. The committee needs to know what the work product is. The committee also needs to understand how often this is going to be updated. Know what you are getting into. Ilona suggested seeing if Jerry Parr would be available to give some insight into the project and the client. The committee agreed.

- Shannon is concerned that we are going to far – we need to go back to Ilona's comments about who is the customer, what are the real goals, etc. Ilona suggested seeing if Jerry Parr would be available to give some insight into the project and the client. The committee agreed.

- Jerry joined the meeting and provided the following insight:

  - The handbooks generally go to a laboratory that is not accredited. They are trying to understand how to become accredited.

  - The last handbook was missing a process section. How do you do it? When do you run PTs, how do you pick an AB, etc.?

  - Paul asked about taking the Standard and using grey boxes. Jerry is not opposed to it. Jerry noted that the ISO language is so hard to read, he'd probably prefer just doing the grey boxes.

  - Jerry thinks a lot of labs read the handbook first and then the Standard. Silky noted that the new approach was to make this something that had to be read with the standard.

  - This is meant to be something that a new laboratory can use to get started. They know how to do the laboratory work, but don't know how to get started.

  - Jerry forwarded a copy of the original handbook during the break.

- April (lab in Oklahoma): She needs help knowing how to implement.

BREAK

Jerry shared the original document written by Tom McAninch. It was the first version of the Handbook. It is broken into sections such as Organization, etc. He partly quotes from the standard and offers examples.

Silky noted that Tom points out the problem areas and does not go through every detail or get specific with the manual.

Michelle – Tom points out the problems small labs may have. She thinks this format would be more helpful because it is something that stands alone and is easily readable.

Paul pulled up the current handbook to compare to Tom's version.

The committee decided that they need to read through both documents and find what they like and do not like. Then the committee needs to prepare an outline of what this next revision should look like. Ilona noted that SIRs, the FAQ document LASEC is developing and past presentations on common assessment findings should be taken into consideration too.

Concern was expressed about preparing the next handbook with multiple authors. Ilona suggested that sections could be distributed to multiple people, but it will need to be finally edited by one person to make it sound like one voice.

Jerry suggested everyone read through the standard as though they are new and implementing the standard for the first time.

<u>When reviewing the information, the following questions should be considered (A straw poll of the membership in the audience was taken and the results are in parentheses.):</u>

What are the desired sections?

What format should it be? (Conversational (12), Bullet (2), Grey Box (2))

Call out requirements vs. suggestions? (11 – yes, 5 – No)

Call out the standard reference? (All – yes)

Are you going to use examples? (All – yes)

Is it a companion document to the Quality Manual Template?

How many tables and forms might be included?

List of SOPs a lab might want?

Is the document organized like the standard? Or flow of the lab? Organized in the order of applying to be an accredited lab? Process document of applying – to implementation? (Have a process document of when you need to do the things to become accredited.)

Go through the most common findings and the SIRs. (All – yes.) Jerry will give Ilona some presentations on the most common findings. Ilona will also send a message to Jack Farrell.

Is it a full synopsis review of the standard or just problem pieces? (Vote – Problems)

The committee decided to talk about what should be considered in the process discussion in the document:

- Emphasize it's OK to have findings – this is normal?
- Andy Valkenburg – Expectations after the audit.
- How to approach corrective actions to an assessment?
- Michelle – Need a process intro, meat in the middle and a final what to do after the assessment.
- Jerry – He and Chuck Wibby did a presentation a number of years ago on implementation of the Standard in a lab. He will send this the committee as an idea of how to organize this.
- Mike Miller – Thinks you need to reference the standard throughout the handbook.
- Paul would prefer a more conversational approach.
- Andy V. would like to see some checklists in the handbook – an appendix? A list of items the lab needs to address and a column where the lab can track if they have the information.
- Silky: Have a process document of when you need to do the things to become accredited using citations to the handbook and Standard.

Robin Cook asked if Advocacy should be doing this instead of Quality Systems? Jerry noted they can't add it to their plate and they don't have the technical expertise needed.

Jerry commented that the sections on PTs, Microbiology, Radiochemistry and Chemistry should be saved for the end as these Standards are completed.

Additional Comments on the Handbook:

- Dale asked if there should be a limit on the size. No - It needs to be easy to use – size is not the issue.
- It should not take weeks to go through – one sitting. 2-3 hours at the most.
- Include information on the costs of accreditation if available and useful.
- Needs to be complete for publication in Summer 2016 at the latest.
- Need to do a Webinar/Survey to get input from the user community on what they want to see in the document. Jerry will give the committee a list of emails of the people who have bought the handbook.

Action Items:

- Everyone will read through the handbooks and come up with how they think it should be organized. This should be sent to Ilona a week before the next meeting.
- Ilona will send copies of the SIRs and the FAQs the LASEC is working on.
- Jerry will forward copies of past presentations where common assessment finding were presented. These will be forwarded to the committee members too. He will also forward copies of the Chuck and Jerry presentation.

3. Things to Consider for Future Standard Updates

Paul keeps a master list of things that arise that should be considered during future Standard updates. He asked if anyone had a comment on something they'd like to see changed in the QS Standard.

- Robin read the new section on thermometer checks in the Microbiology section. She would like to see something similar in Module 2.
- Trinity: is there a difference between plasticware and glassware in terms of verification? Does the Standard address single use plasticware in terms of verification
- Jerry:
  1. Jerry has been arguing this since1995. Education qualifications for technical managers need to be updated.
  2. Qualifications for Quality Manager – needs more definition.

Robin had someone approach her about a problem they were having. The analyte enterococcus was not listed in the tests for Micro TD and the individual was denied the TD title for that analyte by the AB. In her professional opinion is she can do the ones listes she can do enterococcus. Also, this lnagauge is a bit of a carry-over from circa 1999 and no one was enterococcus testing for discharges. Enterococcus is much more common now.

Jason – Can you have experience requirements instead of only educational?

Dorothy Love – They have a situation where they have a technical director who cannot be replaced because their AB requires that the TD have two years experience in the testing arena.

Shannon – Needs to be an accredited school that education.

- Paul: An oven is support equipment – how do you calibrate it?

  Shannon – Calibration vs. Verification is a needed discussion.

  Jerry commented that the committee should make sure you are getting Matt Sica and Joe Konschnik's input on reference standards when the standard gets open again.

- Bob Wyeth – You will be adding items to work on as you work on the handbook.

4. Action Items

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

5. New Business

   - None.

5. Next Meeting and Close

   The next meeting will be the second Monday in March.

   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 4:57 pm EST (motion – Silky, Second – Patty. 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
Michelle Wade (2016) (Vice-chair) **Present**	Wade Consulting and Solutions	Other	913-449-5223	michelle@michellefromks.com
Katie Adams (2016) **Absent**	USEPA Region 10	Other	360-871-8745	Adams.Katie@epamail.epa.gov
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
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 – after 3:30**	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
Shannon Swantek (2017*) **Present**	Oregon Public Health Division	AB	(503) 693-4130	Shannon.swantek@sate.org.us shannon.swantek@dhsoha.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 Executive Committee

	Action Item	Who	Expected Completion	Actual Completion
1	Review the two handbooks – Tom's and the version currently being sold. Also review information sent by Ilona (SIRs, FAQs, Assessment Findings). Prepare an outline of how you think the handbook should be organized and comment on any key elements of design or content that should be considered. Send to Ilona by Mon, Mar 2nd.	All	3/2/15	
2	Compile comments and distribute in summary to all committee members for discussion at 3/9 meeting.	Ilona	3/4/15	
3	Compile SIRs, Findings and FAQs. Send to committee members.	Ilona	2/18/15	
4	Send copies of presentations with lists of most common assessment findings.	Jerry	2/18/15	
5	Send list of emails for people who have purchased the handbook.	Jerry	3/1/15	
6	Send copy of Chuck and Jerry presentation to Ilona.	Jerry	2/18/15	

Attachment C

Backburner / Reminders – QS Executive Committee

	Item	Meeting Reference	Comments
1	Update charter in October 2015.	n/a	