Quality System Expert Committee (QS)
Meeting Summary

July 13, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 9am Central in Chicago, IL. Attendance is recorded in Attachment A – all 13 members were present, as well as a numerous members who have rotated off of the committee.

Minutes will be reviewed during the next regularly scheduled conference call.

2. Working Draft Standard

Paul provided an over view of the issues – See Attachment D.

Paul presented the language changes made during the June 8th meeting that the committee plans to send to SRC as the final draft language for the Voting Draft Standard. There were concerns raised about Section 5.5.13.1 e).

Chris noted that plastic is not eligible for Class A. The sales literature implies that plastic ware can be Class A. There are plastic graduated cylinders that have an A on it. ASTM #694 states glassware only. Version 2010.

Trinity O'Neal: The microbiology standard has something different between Micro and QS as far as frequency of verification. Robin (chair) stated that they were following e) iv) and that is where quarterly comes from.

The Hach website states that plastic ware is not Class A. Chris noted that the plastic all states that the plastic is made in compliance with Class A requirements, but does not state that it is Class A.

Jan Wilson, Labmart is selling plastic graduated cylinders as Class A.

Corning also sells ISO 1042 and DIN 12681 certified plastic ware, but they note that these requirements are not as stringent as the Class A requirements.

James Broderick: Asked a question about a thermometer used for microbiology work. Robin noted that the Microbiology standard is defaulted to. It has to be in range of use for each thermometer.

Katie thinks e) iii) is a problem because only checking at first use does not cover the need. Paul asked what iii) would be – distillation tube. It should be changed back to

"Volumetric containers" instead of the change to "measuring" devices. Paul made this change.

Trinity: The importance is the point of interest when using a thermometer. She is concerned about how labs apply correction factors. Paul noted the standard is not specifying how a lab is handling correction factors, it is up to the lab. He asked for suggested language if Trinity thinks this should be included in the standard.

Tyler Sullens: Verify labware that has been set-up to Class A standards. Jessica noted that verified and certified are two different things.

Tyler suggested the following changes to the language in ii):
"… volumetric dispensing devices that are mechanical or that are used at more than one volume shall be checked for accuracy on a quarterly basis."

Another option for ii): Volumetric dispensing devices that are used at more than one volume shall be checked for accuracy on a quarterly basis.

Robin: Summarized what she thinks is agreed to: Class A, single use – once per lot checks and everything else is quarterly. The committee needs to work on language that states this.

Chris would like to see the term calibrated deleted and verification used instead.

Glass microliter syringes are not serialized. Silky thought there was still some sort of paperwork that comes with the syringe. Shannon noted this has been a problem in the past and it would be more appropriate to just state they are exempt.

Paul still thinks there is an issue with defining what Class A glassware is. Chris offered the following definition from ASTM:
Class A volumetric glassware provides the highest accuracy. Class A volumetric glassware complies with the Class A tolerances defined in ASTM E694, must be permanently labeled as Class A, and is supplied with a serialized certificate of precision. All Class A volumetric glassware is actually glass; volumetric plasticware is not eligible for Class A status.

He thinks this should be included in the standard. Paul made the changes. Shannon and others want to be sure the language does not allow a company to call something Class A that does not meet ASTM E694. A certificate can always be obtained for a serialized piece of Class A glassware.

After further tweaking of the language, the final version agreed to was:

e) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, the laboratory shall verify volumetric measuring devices as follows:

i) Class A glassware certified to the requirements of ASTM E694 must be permanently labeled as Class A and supplied with a serialized certificate of precision Such glassware is exempt from any verification requirements;
ii) Glass microliter syringes are exempt from any verification requirements;
iii) Disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use;
iv) All other volumetric support equipment shall be checked for accuracy on a quarterly basis.

3. Small Lab Handbook

Paul reviewed the Outline/Table of Contents of the Small Lab Handbook (Attachment E). The committee would like to include all the modules – not just Microbiology and Chemistry.

Comments:

George Detsis: Suggested including an appendix on the Corrective Action process. The committee noted that this is already a part of the standard.

Robin confirmed that the "2015" standard is the standard being used in this handbook.

Paul then pulled up the first DRAFT of the handbook disclaimer and introduction (Attachment F).

Silky asked if the glossary will take into account the European English used in the ISO language. Paul would like to see this happen.

Chris pointed out that ISO will be updated in 2017.

Chad Stoike: Asked if the handbook needs to specifically state that TNI accreditation is not the same as ISO 17025. Ilona noted that a lot of labs do use the TNI disclaimer and that making a statement that the labs are not ISO 17025 compliant may cause some issues. Shannon noted that there is a different emphasis on ISO 17025 and it might be worth making the statement.

Michael D. likes the current language because clients use language in their bid packages that the current language encompasses.

Paul reminded everyone that more volunteers are needed to help with sections of the Handbook. Please contact Paul or Ilona if there is a section you can help with.

4. Action Items

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

5. New Business

    - None.

6. Next Meeting and Close

    The next meeting will be August 10, 2015 at 1pm Eastern. Ilona will send out a conference and Webex invitation. *(Addition: A special meeting to work on the WDS was held on 7/31/15.)*

    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 12 pm Central.

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	michellefromks@gmail.com
Katie Adams (2016) **Present**	USEPA Region 10	Other	360-871-8748	Adams.Katie@epa.gov
Kristin Brown (2016) **Present**	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*) **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
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
Shannon Swantek (2017*) **Present**	Oregon Public Health Division	AB	(503) 693-4130	shannon.swantek@state.or.us
Janice Willey (2018) **Present**	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
8	Send new wording for Section 5.5.13.1 to Cathy Westerman and get input.	Paul	7/13/15	
9	Look at the Handbook Table of Contents and volunteer for sections.	All	8/10/15	
10				

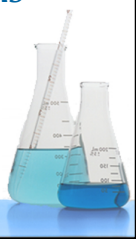
Attachment C

Backburner / Reminders – QS Executive Committee

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

TNI QUALITY SYSTEMS

Voting Draft Standard
07/13/15



Quality Systems

Module 2 states: All support equipment shall be calibrated or verified at least annually, using a recognized National Metrology Institute, such as NIST, traceable references when available, bracketing the range of use.

Quality Systems

Module 5 Verification (of thermometers) shall be performed at least annually (see TNI Volume 1, Module 2, Section 5.5.13.1). This verification may be accomplished by a single point provided that it represents the method mandated temperature and use conditions.

Quality Systems

Standard Interpretation Request

This section requires support equipment to be calibrated or verified annually with references "bracketing the range of use". The 2003 NELAC standard had comparable language requiring calibration or verification "over the entire range of use". Under the 2003 standard, an exception was permitted allowing the use of a single point calibration for narrow range use thermometers, such as those used for sample storage (>0-6°C), BOD (20±1°C) and micro incubators (35±0.5°C and 44.5±0.2°C), drying ovens (103°C-105°C), etc.

Quality Systems

Standard Interpretation Request

However, the same exception has not been extended to the 2009 TNI standard requirement. As a result, labs are being cited for not performing bracketing checks for these thermometers. Although the AB for the state where this issue developed allows the use of a temperature at or below and at or above the boundary of the range of use, the requirement still requires the lab to take the equipment out of normal use and re-adjust the settings multiple times.

Quality Systems

Standard Interpretation Request

The process provides data that is probably less reliable than a single point check and requires significantly more time to perform. For example, a single point check in the range of 44.3-44.5°C for a fecal incubator would seem to be better data than a check around 40°C and a second around 50°C.

Quality Systems

Standard Interpretation Request

Quality Systems response:
An exemption for narrow range use thermometers is not described in the 2003 NELAC Standard and historical data does not provide that an exemption was made on an organizational level. The use of a single point calibration/ verification check for the narrow use range thermometers exemption is not described in the 2009 TNI Standard.

Quality Systems

Back to the issue at hand

Conflict identified

What options do we have?

Quality Systems

Option 1

Nothing

Quality Systems

Option 2

Remove the reference to Module 2, Section 5.5.13.1

Quality Systems

Option 3

Modify the Microbiology language so that thermometer verifications still require bracketing

Quality Systems

Option 4

Modify the Quality Systems language so that a single point thermometer verification was allowed

Quality Systems

Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available.

Quality Systems

i) If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable;

Quality Systems

ii)If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.

Quality Systems

Keep in mind that the presentation of Section 5.5.13.1 was also changed to create a better flowing 'thought process', but there were no other changes made to requirements

Quality Systems

Time out while we bring up the Standard.

Questions?

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Chair – Quality Systems Committee
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Attachment E – Outline/Table of Contents - Small Laboratory Handbook

Small Lab Guidance Table of Contents

1 – Introduction / Disclaimer Paul Junio

1.5 – The Standard Explained Silky Labie

2 – Overview of Accreditation Process Shari Pfalmer
- Which AB?

3 – Why are you doing this? Why get accredited?
- Client requirements

4 – What is a Quality Management System Silky Labie
- Why is it important?
- These are the things you have to have to develop your system

5 – The Standard Walk-through – section by section
- V1M1 4 through 8
- V1M2 4 and 5
- V1M3
- V1M4 (Richard Burrows?)
- V1M5 Elizabeth Turner; Robin Cook
- V1M6 Dale Piechocki; Bob Shannon
- V1M7 (Rami Naddy?)

6 – Preparing for your first assessment Jessica Jensen; Michelle Wade

Appendices
- Common Findings
- SIRs
- Secondary Accreditation

<u>Format to use for Walk Through –</u>
HEADER (including TNI Standard Module/Section)
KEY POINTS
DISCUSSION
EXAMPLES

Attachment F: Draft Introduction

INSERT TNI DISCLAIMER

DISCLAIMER – FRIENDLY VERSION

This manual is guidance only and is based on the technical knowledge and experience of the authors. It is intended to help explain the requirements of the TNI Standard and to provide laboratories some guidance on how to develop policies and procedures that will be in compliance with the TNI Standard. The subjectivity of parts of the TNI Standard precludes consistent interpretation by all accrediting bodies.

There are no guarantees with this manual. Because some elements of the TNI Standard contain vague language, even highly competent technical experts frequently disagree on the interpretation of the Standard.

This manual is not a substitute for the TNI Standard, Standard Methods, other the test methods, and/or state and federal requirements and regulations. These other documents contain straight-forward requirements that have not been discussed in this manual. The lab must consult the other documents for complete coverage.

This material represents the opinion of its authors. It is intended solely as guidance and does not include any mandatory requirements except where such requirements are referenced. This guidance does not establish expectations of being implemented universally, exclusively, in whole, or in part.

This guidance does not establish or affect legal rights or obligations and is not finally determinative of the issues it addresses. It does not create any rights enforceable by any party in litigation with TNI, its accreditation bodies, or affiliated institutions. Any decisions made by TNI regarding requirements addressed in this guidance will be made by applying the applicable standards, policies or procedures to the relevant facts.

Having said that, we really are trying to make this easier on a beginning laboratory. If you aren't sure about something, PLEASE ask questions. Your Accrediting Body won't bite. They may growl a little, but biting is frowned upon.

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

THE STANDARD EXPLAINED (NOT REALLY, BUT IT’S A START)

The goal of the TNI Standard and the TNI Accreditation process is to provide a set of minimal requirements for a laboratory to become accredited.

The TNI Standard is a quality standard for environmental laboratories based on the ISO/IEC 17025 Standard with additional requirements specific to the TNI accreditation process. There is a section on proficiency testing samples with general participation requirements for submittal of PT data to the Accrediting Bodies. There are two quality sections in the TNI Standard: Management Requirements and 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 (5) modules covering different analytical disciplines (Asbestos, Chemistry, Microbiology, Radiochemistry, and Whole Effluent Toxicity). Not all five of these modules 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.

The TNI Standard is the MINIMUM that must be done to maintain accreditation. States can prescribe additional requirements for their own needs. Laboratories can do MORE than what the Standard requires. In fact, if your Quality Manual makes mention of things that you as a lab say you WILL do, then you MUST do them to stay in compliance with your own quality system.

ACRONYMS AND DEFINITIONS

The laboratory community loves TLAs. What's a TLA, you ask? Simple – it's a Three Letter Acronym. We use them all of the time, and have already thrown some at you in this Handbook. We've tried to define each acronym upon its first use. But just to be safe, we have created a list of Acronyms. It can be found in Appendix XX.

[NOTE – the Consensus Standards Development Program is developing a Glossary. That Glossary will be included or referenced in this Handbook]

ISO (International Organization for Standardization)

Module 2 of the TNI Standards is based on the ISO/IEC 17025:2005 requirements that are relevant to the scope of environmental testing services. The ISO/IEC 17025:2005 language is included in its entirety in the TNI standard, and appears as italicized text. Keep in mind when reading the Standard that the ISO language is European English, and words have different meanings than how they are commonly used. For example, ISO refers to a standard method. We use the term reference method, instead, so as to avoid the confusion involving the methods compendium known as Standard Methods for the Examination of Water and Wastewater.