

**Quality System Expert Committee (QS)  
Meeting Summary**

**May 9, 2016**

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference on May 9, 2016. Attendance is recorded in Attachment A – there were x members present. Associate Members: Carl Kircher, Tyler Sullens, Robin Cook, Reed Jeffrey, Bill Ray, Eric Denman, and Eric Davis.

*(The February and March 2016 minutes were not reviewed during today's meeting and were reviewed by email instead.*

*A motion was made by Dale on 5/18/16 to approve the February 15, 2016 minutes as written. The motion was seconded by Jessica on 5/18/16.*

*A motion was made by Jessica on 5/18/16 to approve the March 14, 2016 minutes as written. The motion was seconded by Shari on 5/23/16.*

*Vote for both motions:*

*Dale – For (by email – 5/23/16)*

*Patty – For (by email – 5/23/16)*

*Chris – For (by email – 5/23/16)*

*Jessica – For (by email 5/23/16)*

*Matt – For (by email on 5/23/16)*

*Kristin – For (by email on 5/23/16)*

*Paul – For (by email on 5/23/16)*

*Shari – For (by email on 5/23/16)*

*Silky – For (by email on 5/23/16)*

*Janice – For (by email on 5/24/16)*

*The motion passed and the minutes will be posted.)*

2. Committee Membership

Paul sent out an email with Lizbeth Garcia's application to join the committee and asked that everyone review the information. Shannon is dropping off the committee. Paul thanked her for her service.

*(Addition:*

*A motion was made on 5/13/16 by email by Matt to add Lizbeth Garcia to the committee. The motion was seconded by email by Kristin on 5/13/16. There was no further discussion by email. Vote:*

*Shannon – Abstain (email 5/13/16)*

*Silky – For (email 5/13/16)*

*Sara – For (email 5/13/16)*

*Matt – For (email 5/13/16)*

*Patty – For (email 5/13/16)*

*Shari – For (email 5/13/16)*

*Chris – For (email 5/13/16)*

*Dale – For (email 5/16/16)*

*The motion passed and Lizbeth Garcia will be added to the committee.)*

### 3. Small Laboratory Handbook

Paul sent an email this morning with some work done on Section 4 of the Handbook by Patty. He highlighted Section 4.11 and the individual bullet points. He would like to like at these sections and decide on a format.

In Section 4.11, there is a title based on the Standard – Example:

- ❖ 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)

Paul took this same format and tried to apply it in Section 4.1 but didn't break it out as much as seen in the example above. He forwarded this by email too. Example:

#### **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
- ❖ TNI 4.1.1 Organization
  - Requirements
    - Organizational structure
  - What do I do?
    - Make sure the laboratory's location in a company organization structure is clearly shown
- ❖ TNI 4.1.2 Organization
  - Requirements
    - Comply with the requirements of the Standard and Customers
  - What do I do?
    - Keep in mind that a customer might be the end user of the data, someone within the organization, or someone asking to have testing done

Matt prefers the second example. Others commented that separating everything out will make it overwhelming.

There may be instances where it is helpful to break things up more and other instances where sections can be lumped together. It depends on the information being reviewed. The committee continued to review and discuss options. Section headings in the Handbook should be dependent on the section headings in the Standard. Paul will write something up to summarize the approach to help people work on their sections.

Paul looked at the Table of Contents. He added Bill Ray to work on Section 3. An updated Table of Contents can be found in Attachment D. Bill asked about size of laboratories and structure. California has a lot of very small laboratories within packaging plants that need to be certified. Most of the methods done are the short hold time methods that cannot usually be sent to a larger lab. Robin noted that Florida does not require some of these analyses to be performed by an accredited lab – they just need to follow the procedures. Kansas has a two tiered system and the second tier does the short hold time analysis. Virginia has a two tiered accreditation system also.

Silky noted that methods with hold times less than 15 minutes were exempted from certification in Florida. She agreed with Robin's statement.

Bill Ray described some of the issues small labs are dealing with in California. Bill Ray provided the following reference from CA regulations:

*13176. (a) The analysis of any material required by this division shall be performed by a laboratory accredited by the State Department of Health Services under Article 3 (commencing with Section 100825) of Chapter 4 of Part 1 of Division 101 of the Health and Safety Code.*

*(b) No person or public entity of the state shall contract with a laboratory for environmental analyses for which the department requires registration or accreditation pursuant to this chapter, unless the laboratory holds a valid certificate of registration or accreditation.*

Chris gave a seminar in April regarding the TNI standard in Orange County with Jerry Parr. There was a lot of local lab attendance at this meeting. CA is looking at different types of accreditation options. He expects a lot of local labs at the summer meeting in August.

Tyler asked why the guy in the lab boat is not going for FSMO accreditation instead of lab accreditation. Bill noted that there is no requirement for samplers to be accredited at this time – see reference he sent above. Tyler is curious if the requirement is broad enough that the FSMO accreditation is an option. Bill commented that it is not currently an accepted accreditation in CA. He also noted a number of union issues that surface that complicate the accreditation process too. CA is currently updating their accreditation standards.

Paul emphasized that this discussion shows the need for the Handbook. Sometimes people over think what they need to do to become compliant with the Standard.

Silky is working on the Quality Management System and Module 2, Section 4. Paul and Patty have done part of Section 4 and Silky will finish up on it.

Module 1, Section 4-8: Paul is looking for a volunteer or he will ask for help from the PT Expert Committee. Patty will work on this section.

Module 3: Paul will likely call someone in NY for help.

Module 5: Robin is working on this section. Robin asked for format guidelines. Paul suggested using:

- Header – from the actual Standard – TNI Standard Referenced
- Definitions
- Requirements
- What do I do?

Robin showed the committee what Micro is working on. They are commenting directly into the Standard in order to compile the information. Paul noted that they don't want to include the whole Standard in the Handbook. They want labs to look at the Standard and use the Handbook to highlight sections of the Standard to help the lab implement the Standard. Robin will reformat the information before it is submitted.

Paul decided to take the document Robin sent and review it with the committee. The committee only looked at the comments knowing the format needs to change.

Paul asked if Source Water is clear. Carl does not think this is clear. Robin thinks it could be included in the Handbook.

Method Selection: “Must be approved by a regulatory body.” Keep it simple. In some cases it needs to be approved by the client. The end user of the data specifies the requirements. If the client requests an odd method ... it is appropriate to suggest another method.

Method Validation: Silky noted that reference methods do need to participate in a PT program. Robin noted she could add something along the lines of: ... this does not relieve the requirement to participate in PT programs.

Example Log Sheets would be helpful. Including calculation formulas would also be helpful.

Sterility: Great comments. Paul asked if the term Work Instruction is used in the TNI module. It is not. Paul thinks this might be a term that will be used in other parts of the Handbook. Robin’s goal is to make things less complicated for labs.

Materials and Media: It was asked whether the Standard is specific about when a certificate can be accepted by the manufacturer. Robin stated it is not and this is an AB question.

Paul suggested that some states could add an “Appendix” to the Handbook, but it may be detrimental because it emphasizes differences between ABs. This could make things more complicated.

Robin will take these initial comments back to the Microbiology Expert Committee and they will continue to work on the document. She will continue to have her committee put comments in the Standard and she will later put it in the proper format before it is resubmitted.

Volume 2 – Section 5. Silky will help with this section.

An updated copy of the TOC with responsible authors can be found in Attachment D.

#### 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 is planned for June 13, 2016. Ilona will send out a conference call and Webex invitation.

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

Paul adjourned the meeting at 2:34 pm Eastern.

**Attachment A  
Participants  
Quality Systems Expert Committee (QS)**

| <b>Members (Exp)</b>                                       | <b>Affiliation</b>                           | <b>Balance</b> | <b>Contact Information</b> |  |
|--|--|----------------|----------------------------|--|
| Paul Junio (2018)<br>(Chair)<br><b>Present</b>             | Northern Lake Service                        | Lab            | 262-547-3406               | <a href="mailto:paulj@nslab.com">paulj@nslab.com</a>                                     |
| Kristin Brown (2016)<br><b>Present</b>                     | Utah DOH                                     | AB             | 801-965-2530               | kristinbrown@utah.gov  |
| Patty Carvajal (2017*)<br><b>Present</b>                   | San Antonio River Authority                  | Lab            | 210-227-1373               | pmcarvajal@sara-tx.org   |
| Chris Gunning (2018*)<br><b>Present</b>                    | A2LA   | Other          | 301-644-3230               | cgunning@a2la.org  |
| Sara Hoffman<br><b>Present</b>                             | Kansas Health and Environmental Laboratories | AB             | 785-291-3162               | shoffman@kdheks.gov  |
| Jessica Jensen (2018*)<br><b>Present</b>                   | A&E Analytical Laboratory                    | Lab            | 316-618-8787               | jessica@aelabonline.com  |
| Silky S. Labie (2018)<br><b>Present</b>                    | Env. Lab Consulting & Technology, LLC        | Other          | 850-656-6298               | elcatllc@centurylink.net   |
| Shari Pfalmer (2018*)<br><b>Present</b>                    | ESC Lab Sciences                             | Lab            | 615-773-9755               | spfalmer@esclabsciences.com  |
| <a href="#">Dale Piechocki (2017*)</a><br><b>Absent</b>    | Eurofins Eaton Analytical                    | Lab            | 574-472-5523               | DalePiechocki@eurofinsUS.com   |
| Matt Sowards (2017*)<br><b>Present</b>                     | ACZ Laboratories, Inc.                       | Lab            | 970-879-6590               | matts@acz.com  |
| Shannon Swantek (2017*)<br><b>Absent</b>                   | Oregon Public Health Division                | AB             | (503) 693-4130             | <a href="mailto:shannon.swantek@state.or.us">shannon.swantek@state.or.us</a>             |
| <a href="#">Janice Willey (2018)</a><br><b>Absent</b>      | NAVSEA Programs Field Office                 | Other          | 843-794-7346               | <a href="mailto:Janice.willey@navy.mil">Janice.willey@navy.mil</a>                       |
| Ilona Taunton<br>(Program Administrator)<br><b>Present</b> | The NELAC Institute                          | n/a            | (828)712-9242              | <a href="mailto:Ilona.taunton@nelac-institute.org">Ilona.taunton@nelac-institute.org</a> |







## **Attachment D. Handbook Table of Contents**

### 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? Bill Ray

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 Patty

V1M2 4 and 5 Paul 4.1-4.9; Patty 4.10-4.16 Section 5.3-4 Silky

V1M3 NY?

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 (Advocacy?)

SIRs

Secondary Accreditation

Chapter 5 outline:

HEADER (including TNI Standard Module/Section)

KEY POINTS

DISCUSSION

EXAMPLES