Quality System Expert Committee (QS) Meeting Summary

June 8, 2015

1. Roll Call and Minutes:

Paul Junio, Chair, called the meeting to order at 1 pm Eastern by teleconference. Attendance is recorded in Attachment A – there were 9 members present. Associates members on the call included: Eric Denman, Elizabeth Turner, Carl Kircher, Bill Ray and Robin Cook. All members present were able to link into Webex for screen sharing.

2. Small Lab Handbook

Paul shared the outline drafted by Paul, Jessica and Michelle when they were able to meet face-to-face:

Small Lab Guidance Table of Contents

- 1 Introduction / Disclaimer
- 1.5 The Standard Explained
- 2 Overview of Accreditation Process Which AB?
- 3 Why are you doing this? Why get accredited? Client requirements
- 4 What is a Quality Management System

Whys 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

V1M5

V1M6

V1M7

6 – Preparing for your first assessment

Appendices

Common Findings SIRs

Secondary Accreditation

Paul would like to use this Draft to allow people to "sign up" to prepare specific sections.

The following sections were volunteered for:

Section 2 - Overview of Accreditation Process - Shari

Section 5 - V1M5 – Elizabeth Turner, Robin Cook

Section 5 - V1M6 – Dale Piechocki, Bob Shannon

Section 6 - Preparing for Assessment – Jessica Jensen; Michelle Wade

Carl asked if it was necessary to put the more specialized modules into the handbook such as Radiochemistry. Paul noted that if they have someone interested in putting the section together ... he would like to include it.

The committee talked about format. Paul opened the current handbook to look at the format. He noted that Tom's format was more conversational, but it did not necessarily identify specific parts of the standard. Only the headings are from the Standard.

The committee liked Tom's header format, but would like to include the standard reference too. The committee would like to see a handbook with more discussion of the standard and not regurgitation of the standard. Some really liked highlighting key points. Paul thinks it is OK to highlight warnings and tips.

Format:

Header (with Standard reference) Key Points Discussion Examples

It was asked if SIRs should be included in the Standard Walk through. Most felt they should stay in the Appendices so they can be easily updated.

Ilona suggested reading through Tom's conversational style before beginning to write. It may help make it easier to write in a similar style.

The next step is to distribute the outline so more people can volunteer to start working on it.

Elizabeth Turner has been asked to give a talk on this at the Kansas/AWWA West Annual Conference in September. They want a small lab advocate to cover Root/Cause analysis and status of the small lab handbook.

Ilona asked if we need target dates. Section 1 will be worked on at the next meeting in Chicago.

Michelle and Jessica will also work on their section with the intent to have it done for Chicago.

3. Standard

Paul sent the WDS feedback to the committee. Paul took a first attempt to address the comment and also sent this to the committee. This was sent 6-8-15.

He commented that Section 5.5.13.1 e) has the major changes. He reminded everyone that this deals with volumetric measuring devices – not things like beakers.

Dale noted that section e) iii) does not have timing. Carl thinks one time should be sufficient. (Robin - Filter funnels for Micro would be an example of what this section would apply to. These checks are done before first use and marked accordingly.) In Robin's lab she does this when the sharpie mark fades.

Some labs buy Class A plastic volumetric cylinders. It's an issue of labware vs. glassware. Should this language read labware instead? This should be labware.

Paul asked if g) is really necessary. He is concerned that removing it may make people question whether it is still a necessary thing to do. Carl noted that there is something similar elsewhere in the Standard, but he would prefer to leave it in. It was agreed to leave it.

The committee reviewed the Standard language Paul sent with the changes made today. There was agreement with the text.

Paul then pulled up Cathy Westerman's email and the committee checked to make sure her concerns were addressed by the changes. There is still concern expressed on need and frequency of checks. Some felt it forced people to have Class A glassware.

Carl asked if he has a Class B graduated cylinder that is not used at a single point, would that mean he would have to check it quarterly? The response was yes if the results are dependent on its accuracy.

A question was asked about auto-titrators. Paul does not think this falls under this requirement because it is the test instrument. Carl might disagree and they would need to be done quarterly as he sees the Standard. He compares it to a balance.

There was additional discussion surrounding whether all equipment coming into a lab needs to go through these types of checks regularly. It was pointed out that at some point

there has to be a level of trust in the manufacturer. In some cases a lab will state that the manufacturer is ISO accredited and that affords them to accept the instrument.

Paul will reach out to Cathy Westerman with the language developed today and see what her response is.

The final outcome:

- e) The laboratory shall calibrate or verify volumetric measuring devices as follows:
 - Class A labware and Glass microliter syringes are exempt from any calibration or verification requirements;
 - ii) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, volumetric dispensing devices shall be checked for accuracy on a quarterly basis;
 - volumetric containers that are used at a single point shall be calibrated or verified at that point prior to or in conjunction with first use;
 - iv) Disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use.

4. Action Items

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

5. New Business

• Be sure to get registered in the hotel and sign-up for the conference in Chicago. QS will meet Monday morning. It looks like there may be a shortage of rooms.

6. Next Meeting and Close

The next meeting will be in Chicago on July 13, 2015 at 9am Central.

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 2:25 pm Eastern.

Attachment A Participants Quality Systems Expert Committee (QS)

| Members (Exp) | Affiliation | Balance | Contact Information | |
|---|--------------------------------|---------|---------------------|---|
| Paul Junio (2018) | Northern Lake | Lab | 262-547-3406 | paulj@nlslab.com |
| (Chair) | Service | | | |
| Present | Wada Canaultina | Other | 913-449-5223 | mai ala alla fira malca (a mina a il |
| Michelle Wade (2016) (Vice-chair) | Wade Consulting and Solutions | Other | 913-449-5223 | michellefromks@gmail. |
| Present | and Solutions | | | com |
| Katie Adams (2016) | USEPA Region 10 | Other | 360-871-8748 | Adams.Katie@epa.gov |
| Present | | | | |
| Kristin Brown (2016) | Utah DOH | AB | 801-965-2530 | kristinbrown@utah.gov |
| Present | | | | _ |
| Patty Carvajal (2017*) | San Antonio River Authority | Lab | 210-227-1373 | pmcarvajal@sara- tx.org |
| Absent | | | | |
| Chris Gunning (2018*) | A2LA | Other | 301-644-3230 | cgunning@a2la.org |
| Present | | | | |
| Jessica Jensen (2018*) | A&E Analytical Laboratory | Lab | 316-618-8787 | jessica@aelabonline.co m |
| Absent | | | | |
| Silky S. Labie (2018) | Env. Lab Consulting & | Other | 850-656-6298 | elcatllc@centurylink.net |
| Absent | Technology, LLC | | | |
| Shari Pfalmer (2018*) | ESC Lab Sciences | Lab | 615-773-9755 | spfalmer@esclabscienc es.com |
| Present | | | | |
| Dale Piechocki (2017*) | Eurofins Eaton Analytical | Lab | 574-472-5523 | DalePiechocki@eurofins US.com |
| Present | 107 | | | |
| Matt Sowards (2017*) | ACZ Laboratories, Inc. | Lab | 970-879-6590 | matts@acz.com |
| Present | 0 5 1 " | 100 | (500) 000 1100 | |
| Shannon Swantek (2017*) | Oregon Public Health Division | AB | (503) 693-4130 | <pre>shannon.swantek@stat e.or.us</pre> |
| Absent | | | | |
| Janice Willey (2018) | NAVSEA Programs Field | Other | 843-794-7346 | Janice.willey@navy.mil |
| Present | Office | | | |
| 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 |
|---|---|------|------------------------|----------------------|
| 7 | Update Handbook Outline and Summary and send to committee for review. | Paul | 4-23-15 | Complete |
| 8 | Send new wording for Section 5.5.13.1 to Cathy Westerman and get input. | Paul | 7-13-15 | |
| 9 | | | | |
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Attachment C

Backburner / Reminders – QS Executive Committee

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