

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

February 8, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on December 14, 2020. Attendance is recorded in Attachment A – there were 14 members present. Associate Members present: Carl Kircher, Halley Hastings, Chris Fuller, Paul Junio, Jack Denby, Ashley Larssen, Rachel Van Excel, Kasey Raley, Karna Holquist, Renee Jernigan, Linda O'Donnell, Patricia Carvajal, Eric Denman, Tom Widera, Jessica Jensen, Joe Manzella, Cindy Redmond, Carol Barrick, Tiffany Shaw, Debra Zeller, and Kristin Brown.

The January 11th minutes were sent by email and shared on Webex. Earl made a motion to approve the December 11, 2021 minutes as written. The motion was seconded by Jenna. There was no further discussion, and they were unanimously approved.

The January 26, 2021 minutes from the virtual conference were sent by email and shared on Webex. A motion was made by Earl to accept the meeting minutes as written. The motion was seconded by Tony and unanimously approved.

New Committee Members: Amy Schreader, Stephanie Atkins and Nicole Cairns. Nicole is not here today, but Amy and Stephanie introduced themselves. *(Addition: David Caldwell decided not to join the Committee, so Stephanie Atkins had the next greatest number of votes and agreed to join the Committee.)*

. 2. Virtual Conference Re-Cap

Debbie shared the slides used during the Virtual meeting. Ilona noted that there were 157 participants in the meeting.

Jessica and Ilona reviewed the Q&A from the Virtual Conference and it looks like everything got covered between responses to Q&A during the webinar and the summary in the minutes.

Debbie pulled up the 1/26/21 minutes and reviewed what happened at the conference.

3. New SIR – SIR 401

SIR 401 to QS 02-05-21

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.5.13.1 e.i
Describe the problem: The term "Microliter" is a trademark for Hamilton Company syringes. Are other brands and types of syringes acceptable, such as SGE MicroVolume, Hamilton GasTight, or Agilent syringes? If so, what is the definition of a glass microliter syringe (i.e. maximum volume, plunger construction, etc.). Thank you.	
Committee Comment:	
Response:	

One is capitalized (Microliter) and one is not (microliter) . The capital M is trademarked my Hamilton. Kristin Brown (Chair, NELAP AC) mentioned that she hoped that the Committee could point out the Capital “M”. The Standard does not capitalize the “M”.

Kathi mentioned that this is not equally assessed. Some allow other syringes to fall into this exception.

Paul recommended the following response:

The term “Microliter” refers to a Hamilton syringe due to its capitalizing of the letter M. The Standard refers to microliter in the lower case of M. The Standard does NOT require a specific brand of syringe. As for what constitutes a microliter syringe, a syringe that is sold in terms of measuring in microliters is a microliter syringe.

The trademark information needs to be included in the first sentence.

Michelle asked if it has something to do with a certificate received from the manufacturer. Kathi said no.

Jessica looked up the other syringes. SGE and Agilent do not use the word microliter.

Paul noted that in the 2003 Standard it talked about the need of a certificate. Kathi pointed out that the certificates were not actual tests of that syringe. They tested a certain number and gave all of them a certificate.

Possible response: The term “Microliter” is trademarked to a Hamilton syringe due to its capitalizing of the letter M. The Standard refers to microliter (uL) in the lower case of M. The Standard does NOT require a specific brand of syringe. As for what constitutes a microliter (uL) syringe, a syringe that is sold in terms of measuring in microliters (uL) is a microliter (uL) syringe.

Carl Kircher will be interested in impact on Section 5.5.13.1. If it is not class A, are they impacted by the requirement for checking volume dispensing devices.

Final language of response for Debbie to send back to Lynn Bradley and the LASEC: The term “Microliter” is trademarked to a Hamilton syringe due to its capitalizing of the letter M. The Standard refers to microliter (uL) in the lower case of M. The Standard does NOT require a specific brand of syringe. As for what constitutes a microliter (uL) syringe, a syringe that is sold in terms of measuring in microliters (uL) is a microliter (uL) syringe.

A motion was made by Earl to accept the final language above. The motion was seconded by Lizbeth and unanimously approved.

4. Summary of Changes Table

Support Equipment

There was general agreement that a list should be left in. Kathi noted that more language needs to be added to make it clear when a pH meter or balance is support equipment and when it is analytical equipment.

Records

Kathi is surprised that people are struggling with electronic records. Ilona noted that Training has had a request for a class.

Kathi will take a look at QSM for some info they included on electronic records. Kathi will send this to Ilona and Debbie.

SOP Requirements

There was a suggestion to put the list in paragraph form.

Have the laboratory define how each SOP will address the needed items.

Ilona noted that there were a lot of ideas thrown out, but there was a not a definitive favorite.

Jessica commented that some of the assessors would like to see the list stay because they cite to that level of detail.

Kathi thinks another issue is that it is frustrating to have to refer to her safety manual in every SOP. Could these sections be left out? Is the list the right list?

Maybe the requirement is that all the items need to be part of the lab’s Quality Management System, but don’t need to have all of them in the method SOP.

John Gumpfer – there are sometimes when a specific SOP may need extra safety procedures, but generally it would be better to be in the management system. Only need safety if it is unique. Some ABs have already done something like this.

Jenna thinks the list should be condensed and come up with a list of required topics, but something like safety and waste management could be elsewhere.

Debbie asked people to click on Yes or No (in Webex) to moving in this direction. Linda says no because a new analyst doesn't understand what they are supposed to do. The SOP has everything they need to know. She would rather not leave things out. It is a better training tool. Debbie noted that SOPs could continue to include important Safety and waste disposal information specific to the method.

Carl would support it if EPA is good with it. He said the list originally came from the Environmental Monitoring Measurements Council. Does it still need to be there? Carl would like to see the list stay the same but clarify what is needed.

More discussion next meeting.

5. Action Items

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

6. New Business

New business will be looked at next month if any is needed.

7. Next Meeting and Close

The next regular meeting will be on March 8, 2021 at 1pm Eastern by teleconference.

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

Debbie adjourned the meeting at 2:34pm Eastern (Motion – Earl, Second – Kathi Unanimous Approval).

Attachment A

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

Member	Organization	Expiration	Representation	Email
Debbie Bond (Chair) Present	Alabama Power	2023*	Lab	dbond@southernco.com
Kathi Gumpfer (Vice-Chair) Present	ChemVal Consulting	2024	Other	kgumpfer@chemval.com
Nicole Cairns Absent	NYSDOH	2024*	Lab	nicole.cairns@health.ny.gov
Michael Demarais Present	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis Present	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Lizbeth Garcia Present	Oregon Dept. of Environmental Quality	2022	Accrediting Body	LIZBETH.GARCIA@dhsosha.state.or.us
Stephanie Atkins Present	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson Present	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen Present	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak Present	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
William Ray Present	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross Present	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Amy Schreader Present	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Michelle Wade Present	A2LA Workplace Training	2024	Other	mwade@a2lawpt.org
Alyssa Wingard Present	NAVSEA LQAO	2024	Other	alyssa.wingard@navy.mil
Ilona Taunton (Program Admin) 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
63	Consider starting a list of items to add to the small laboratory handbook.	All	TBD	
65	Add ISO/IEC 17025:2017 language from the 2016 TNI Standard into the DRAFT Combined Standard.	TBD	TBD	
73	Change black text in combined Standard to italics in preparation of starting to work on updating language in the Standard.	Jessica	2/2/20	<i>4/15: Needs to be started.</i>
77	Prepare summary document of comments received during the 9/25/20 Public Webinar.	Jessica, Kathi, Paul Junio	11/9/20	
78	Send SIR 393 back to LASEC.	Jessica	11/16/20	1/11/21 – will be resent.
79	Send Public Webinar responses to attendees of the webinar.	Ilona	2/15/21	
80	Send SIR 401 Response to Lynn and LASEC.	Debbie	2/15/21	
	Send QSM info they included on electronic records. Send to Debbie and Ilona.	Kathi	3/5/21	

