Quality Management System Expert Committee (QMS)
Meeting Summary

July 10, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on June 10, 2023. Attendance is recorded in Attachment A – there were 9 voting members present.

Associate members present: Kelvin Yuen, Linda ODonnell, Kathleen Lloyd, Jeanette Hernandez, Alma McCammond, Kim Fielder, Eric Davis, Ty Atkins, Debra Zeller, Carol Barrick, Paul Junio, Amanda Grande, Sarah Brown, Tammy Kreutzer, Ron Houck, Patty Carvajal, Fida Kased, Sushmitha Reddy, Lisa Parks, Jessica Jensen, Cindy Redmond, Kristin Brown, and Nicole Van Aken.

Debbie reviewed the minutes from the June meeting. A motion was made Earl approve the June 12, 2023 minutes as written with a correction: Guide 31 is not something you get accredited to. People are accredited ISO/IEC 17034. The motion was seconded by Jenna and unanimously approved.

2. Continue SIR Review

Debbie started with SIR 270 (Section 5.5.13.1) to determine if any changes need to be made to the DRAFT Standard. She stopped after SIR 415 (5.5.13.1.3.ii). See Attachment B.

3. Recommended Language from NEFAP EC

Debbie shared what is currently in the Standard (Section 7.3) for sampling. They are requesting the following language be added:

-Where available, NEFAP Accredited Sampling Organizations shall be used for sampling activities unless the laboratory justifies the use of internal samplers or another sampling organization.
-Where NEFAP Sampling Organization is not used the laboratory shall consider the risk and document any risks in addition to the justification.
-Where NEFAP accredited Sampling Organization is not used the laboratory shall consider the risk and document any risks associated with the sampling activities the laboratory uses.

There have been comments that this could make things more difficult for laboratories since there are not a lot of accredited FSMOs. Some labs think this is out their control.

This language is too strong. It is a no win situation for small labs. Instead list what is needed and then note that NEFAP meets those requirements. Kathi will work on some language.

Suggested language from Kathi:
7.3.4 Laboratories which engage in field sampling activities shall use appropriate sampling procedures that meet the needs of its customer. Sampling shall be performed by personnel trained specifically for this activity. Use of NEFAP Accredited Sampling Organizations meets these requirements.

4. New Business

Alyssa will be stepping off the Committee as a Voting Member, but will continue as an Associate. Ilona will contact Jordan Adelson to see if DoD can provide a new candidate. Kathi thought Judy Solomon might be the right person.

5. Next Meeting and Close

The next meeting will be face-to-face in Minneapolis on July 31, 2023.

Debbie adjourned the meeting at 2:30pm Eastern.

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 Gumpper (Vice-Chair) **Present**	ChemVal Consulting	2024	Other	kgumpper@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
Carla McCord **Absent**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins **Absent**	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
Zaneta Popovska **Absent**	ANAB	2025*	AB	zpopovska@anab.org
Sean Hayes **Present**	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov
Amy Schreader **Absent**	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard **Absent**	NAVSEA LQAO	2024	Other	alyssa.wingard@navy.mil
Ashley Larssen **Present**	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) **Present**	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org

Attachment B - SIRs Reviewed

#	2016	Actual Request	Final Response	Comment	Paul Comments	Revise or No Revision
270	5.5.13.1	This section requires verification of volumes of volumetric dispensing devices (except Class A Glassware) if quantitative results are dependant on their accuracy. Historically, this section has been interpreted to include disposable pipettes and plastic tubes used for measuring sample volumes or final volumes after digestion. Section 5.5.13.1.d appears to require quarterly checks of these devices. Quarterly checks seem excessive when the items are one use items. Once per lot number seems more reasonable and would be similar to receiving a certificate from the manufacturer about the accuracy of a particular lot number.	A verification of one pipette or tube per lot would meet the requirements stated in Sections 4.6.2 and 5.5.2.	This language is unchanged in the 2016 standard. The SIR is still valid.	We should add language addressing single use items as needing to be checked once per lot. EDIT SINCE NEW ORLEANS - we already did this	NO REVISION
274	5.5.13.1	The standard states "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Would class A plasticware be considered the same as Class A glassware ie - you do not need to check it on a quarterly basis? Or would Class A pastic ware be considered the same as non-class A labware? The same question for V1M5 section 1.7.3.7 iii.2 "2. equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels) shall be verified once per lot prior to first use. This verification may be volumetric or gravimetric." Would you need to check Class A plasticware once per lot?	Plasticware is not glassware. Any volumetric dispensing devices that are not Class A glassware or glass microliter syringes must be checked for accuracy on a quarterly basis.	This language is unchanged in the 2016 standard. The SIR is still valid.	done	NO REVISION - standard requires checking prior to or in conjunction with first use.

335	5.5.13.1	We check all our thermometers used in the laboratory that are used for monitoring ovens, refrigerators, freezers, incubators, water baths and any meter where we actually report a temperature reading. Our question is with the use of ATC probes (automated temperature compensation) that are used in conjunction with a probe – like pH, Ammonia and Dissolved Oxygen. If we don't report any temperature reading, and the measured value (in hit case pH, NH3, DO) is determined to be accurate, do we have to annually verify the ATC reading? We have never done this, and we don't think this applies, but it did come up in conversation so I thought I'd ask.	Determined not to be an SIR.	As ATC can be a test instrument, it could be interpreted as the section on support equipment and verification/calibration does not apply. Is there a way to clarify this?		This section is for support equipment, not instruments. Kathi will look at QSM, table 6.1 to see language there.
367	5.5.13.1	We have one set of weights (primary) that we use to check balances on a daily basis and we send it to a third party for calibration and certification on a year basis. We also have another set of weights (secondary) that we use only during the time when we send the primary set for calibration. My question is how often does the secondary set of weight need to be calibrated and certified?	Determined not to be an SIR.			NO further REVISION - added "weights" to list of support equipment in 5.5.13.1
378	5.5.13.1	d) 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. Question: do reference thermometers need to be calibrated annually? These are traceable to NIST.	As long as the reference thermometer is not being used as a piece of support equipment such as described in 5.5.13.1 c, a reference thermometer is a reference standard as described in 5.6.3.1 and would need to be calibrated before and after any adjustment, and in accordance with the lab's documented procedure.			Drinking Water Cert manual requires calibration every 5 years. POSSIBLE REVISION

393	5.5.13.1	We have one set of weights (primary) that we use to check balances on a daily basis and we send it to a third party for calibration and certification on a year basis. We also have another set of weights (secondary) that we use only during the time when we send the primary set for calibration. My question is how often does the secondary set of weight need to be calibrated and certified?	Determined not to be an SIR.		See SIR 367
455	5.5.13.1	I have a question with respect to Class A volumetric labware made of HDPE and other plastics. I have read the TNI interpretation that only Class A glassware is exempt from verification, and that plastic volumetric labware requires verification. Would the certificate of analysis provided by the manufacturer be sufficient to document the confirmation to Class A or would each laboratory be required to perform the check inhouse on each lot prior to use? My thoughts are that the certification protocols performed by the manufacturer would be more accurate than the standard practices that laboratories currently use to verify Class A tolerance, and that the volume would not be subjected to changes during shipment as sterility potentially may be, which I believe was one of the driving factors in requiring labs to confirm product sterility for microbiology supplies that are certified as sterile by the manufacturer. Any information you can provide (or point me to) would be greatly appreciated.	Not an SIR		NO REVISION - 5.5.13.1.e.iv already states labs need to check before use

304	5.5.13.1.3	Volume 1, Module 2, Section 5.5.13.1.e states, "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Our laboratory analyzes VOCs in air, and uses gas tight syringes up to 100 mL to prepare gas standards. We are unsure of whether or not we must complete quarterly checks on these syringes. We're hesitant about using DI water to perform the quarterly checks on these syringes because they're used for preparing gas standards and we're unsure if moisture in the syringe would affect standard preparation. We're also unaware of how we could complete the quarterly checks using air. Our syringe vendor only offers a verification certificate for newly purchased syringes. For these reasons, it may be impractical to complete quarterly checks. As I understand it, glass microliter syringes do not require quarterly checks because they deliver such a small volume that a quarterly check would be impractical. Knowing this, if our 100 mL gastight syringes are similar in form (and from the same vendor) as our glass microliter syringes, would they require quarterly checks or not? At a minimum is there any documentation we'd have to have on file for the syringes?	If the syringe in question is neither Class A nor a glass microliter syringe, then it must be checked for accuracy on a quarterly basis. The laboratory must have documentation on file of this quarterly check.	This language is unchanged in the 2016 standard. The SIR is still valid.	there seems an obvious difference between a microliter and non-microliter syringe	REVISION - consider allowing gas syringes to forego quarterly verification.

415	5.5.13.1.3.ii	The standard clearly requires volumetric devices to be verified at least once per lot prior to use. A common example of the disposable single use device is the plastic digestion tubes. Would the manufacturer's LOT SPECIFIC certificate of accuracy suffice to meet this requirement, or is the laboratory obligated to repeat the work already done and verify the tubes again prior to use? (File uploaded: Lot 1904119 2019.09.pdf)	Determined not to be an SIR.		REVISE - consider adding a statement that manufacturer or lab can verify volume. *Find manufacturer volume verification to see if any specific items included need to be required if a lab is going to use manufacturer cert.