Quality Management System Expert Committee (QMS)
Meeting Summary

August 14, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1:15 pm Eastern (due to some technical difficulties) by teleconference on August 14, 2023. Attendance is recorded in Attachment A – there were 9 voting members present (1 additional member was shown in attendance but was unable to respond).

Associate members present: Nicole Bennington, Sarah Brown, Patty Carvajal, Alexander Chieh, Eric Davis, Brian Eichelberger, Kim Fielder, Paul Junio, Douglas Kablik, Fida Kased, Carl Kircher, Tammy Kreutzer, Kathleen Lloyd, Ryan McMullin, and Kelvin Yuen.

Brian, as a new associate, introduced himself.

Minutes will be approved by email.

2. Workgroup Updates – Technical Specialist

Debbie didn't specifically request feedback on TS, but got some regardless. It was recommended to get feedback from the EPA DW program, and to adjust one year to annually. ABs will work at all of the ways that a person can become a TS for consistency between Modules.

Definitions – 14 or so terms were requested/created/edited. All have been reviewed and were presented by Paul. Duplicate and replicate received feedback. They are used so differently in different applications that we can't define them.
Suggestion to check procedure against 17025 to assure that we don't have an issue by requiring it to be written. Paul has already done a quick review and didn't see any issues on this topic. ISO frequently uses procedure as 'analytical method'. Paul thought there were 2 instances that ought to be discussed to make sure.
(Addition – the definitions work group met after this meeting and found no instances of concern. The commenter was notified and this issue is closed.)

Language Workgroup – Nick reported that internal audit language didn't get feedback other than changing 12 months to annually. Main thing was record retention, which had been changed from last entry to last use, but the direction seems to be to change it back to last entry. We will search out additional feedback and see what is best.

A brief discussion on transfer of ownership entailed. Do we need the language since it would be a requirement of labs that are out of business (not enforceable). Debbie pointed out that buying and selling shares in a laboratory isn't what this is about.

Also requested feedback on critical supplies and services. The term legally defensible has specific meaning and we may need to use legally admissible. We also want to use traceable as metrological traceability, not just what we talk about in the laboratory. Traceability needs to be 'an unbroken chain'. Consumables task force is working on guidance for the records required for chemical and services. The proposed list is a small portion of what labs accredited to 17034 must have. ISO Guide 31 has this information which helps if you use an accredited provider. We don't want to make that a requirement (using accredited providers). We may go with a set of bare minimum requirements (Service provider, credentials of provider, title, description of service, unique ID of equipment serviced, certified values, uncertainty limits and traceability for calibration services, date of service and certification, signature).

Subcontract lab WG and Measurement Traceability WG to start – they should look at those requirements and lead the direction of how this would be addressed.

Consumer TF is working on guidance. Any comments from the committee? Nick thought we touched on this in Minneapolis. We want this in the Standard, but can we hold the labs to this? They have to ask the provider for this, but if they don't get it, is it a finding for the lab? Debbie thinks that is the approach. The Certificate needs to provide that information. Do we require already a certain quality of the laboratories or not? Nick says that it is sort of touched on, as traceability references 17034. The other part of this is have we considered 'where available' accredited CRMs are required? Tony asked if that is too onerous? It's hard to have a finding for the lab when the provider can't provide what is requested. Tammy has been working with CTF and this is pared down from the ISO requirements. COA comparison shows that they are very different. Larger companies are spot on, but smaller ones aren't. This is why CTF is looking to produce Guidance. There isn't consistency, so it's tough to fit all sizes. How do we minimize the risk when ordering supplies? Nick likes it as Guidance. It's tough to write a finding if a lab doesn't find someone who meets all of these requirements. If the COA has nothing useful it doesn't help the laboratory, which is why this is great as guidance and not a requirement. Empower the labs to know what is good and what isn't good. Earl agreed that labs should want this, so it helps to have as much of this as possible. The finding approach maybe isn't as good as the risk approach. Debbie heard a few dissenting requirements, but there are likely clarity items we can address in this section. We could have a list of items on the side, but maybe not try to fit all of this into the Standard, since traceability is already covered. Debbie is ok with leaving the list completely out of the Standard, but have it available for Guidance. Any other thoughts? Patty agreed with the Guidance direction.

Proposed NEFAP language – Section 7.3.4 language was inserted with a small edit by Kathi. "Labs performing field sampling activities shall define the competence requirements of personnel and authorized personnel to and authorized personnel to perform sampling. Where the laboratory arranges for an external sampling organization to be used, the laboratory shall have procedures to ensure that the experience and technical competence of the samplers are sufficient for sampling activities and that they comply with the relevant clauses of this document and other sampling documents (i.e., sampling plans, sampling methods, regulatory documents, etc.). Use of NEFAP Accredited Sampling Organizations meets these requirements)."

Patty asked when a laboratory is performing field sampling, for example when the lab is a section of an organization that also performs field sampling. Some assessors have the interpretation that if it is under the umbrella, it's a requirement. Eric agreed that this would be a hard sell with those doing the sampling. Debbie said just removing the first sentence wouldn't make t his any easier. The lab is a separate entity and doesn't really arrange for the sampling, they are just receiving samples done by part of the same, but larger, organization. Functionally that isn't how municipalities in particular work. Kim had the same question regarding internal and external, because they may be independent even in the same organization. Debbie has the same issue. Her accreditation excludes the sampling, even thought they are in the same organization. Do we need to address this, similar to how we bring in a calibration service? Patty asked if this would be the lab coordinating this? Debbie responded that if the lab is having any decision making voice, then it might apply and must use a competent sampler. Patty still thinks that puts more requirement on the lab when it may not be their role. Debbie asked if that would be clear in the QS documents and that this wouldn't apply. Patty and Eric say it all too often is up to the assessor. We have to be careful with how it is written. Debbie says we need to bring in NEFAP and have a bigger picture discussion. TNI has accreditation for sampling because it is demonstrated to matter. Patty thinks the first sentence is good, and the rest complicates it. Earl asked if the sampling part of the organization reports to the lab? Patty is responsible for that group as QA, but they are two distinct groups that don't report to each other. This has come from some assessors, but not all. Wants to make sure it doesn't gain traction. Debbie asked since they are in your organization, isn't it likely that the competence is assured? Patty pointed out that it is under an entirely different supervisor, so it doesn't apply. Eric said if you are a contract lab, you have no say in what is brought to you. That is functionally how municipal drinking water labs operate. You can't force the entire municipality to operate under the same purview and utilities won't appreciate that. Think of it more like a lab thing. Debbie added that TNI and its sampling modules aren't mentioned in any other location and ought to be. We could say 'consider using' but that carries no weight. Patty said that's a dangerous path. It should come up in initial project review. Eric thought states need to be the driver on this, not labs. Debbie pointed out that this brings it up as an option. Patty asked if NEFAP mentions the lab portion? Debbie hears the obstacles and will table it for now. Before it's removed, she will talk with other groups, as we can't decide it here and now.

3. SIR 465 Response

Related to 5.5.13.1 e, a discussion regarding syringes seems to offer a conflict. Class A syringes don't need to have anything done, but then 4.6.2 says you do something else (verify).Following discussion, it is determined that a response of 'Volumetric verification is not required for glass microliter syringes or Class A glassware. Glass microliter syringes and Class A glassware are required to be inspected as complying with any specifications or requirements prior to first use. The laboratory decides how to perform the inspection or verification mentioned in 4.6.2. and must retain records of actions to check compliance'. This will be forwarded to Lynn. Are there any comments to go along with this? Hearing nothing, the SIR was considered done.

4. SIR Review

    1. Due to a lack of time, none was performed

5. Next Meeting and Close

    Debbie briefly shows the draft schedule for Columbus. QMS meets both morning and afternoon of Wednesday, January 24. The next meeting will be by teleconference on September 11, 2023, at 1pm Eastern.

    Debbie adjourned the meeting at 14:23 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) **Absent**	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 **Present**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
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
Zaneta Popovska **Absent**	ANAB	2025*	AB	zpopovska@anab.org
Sean Hayes **Present (didn't respond)**	ORELAP	2026*	AB	sean.hayes@oha.oregon.gov
Amy Schreader **Present**	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Ashley Larssen **Absent**	KC Water	2024*	Lab	ashley.larssen@kcmo.org
Ilona Taunton (Program Admin) **Absent** (Minutes by Paul Junio)	The NELAC Institute	n/a	(828)712-9242	Ilona.taunton@nelac-institute.org