

Quality Management System Expert Committee (QMS) Meeting Summary

June 12, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on June 12, 2023. Attendance is recorded in Attachment A – there were 10 voting members present.

Associate members present: Alexander Chieh, Lisa Parks, Sean Hayes, Jeanette Hernandez, Debra Zeller, Ty Atkins, Cindy Redmond, Alma McCammond, Douglas Kablik, Nick Slawson, Kelvin Yuen, Nicole Van Aken, Amy Schraeder, Annmarie Beach, Kristin Brown, Fida Kased, Dan Jackosn, Brian Lamarsh, Carol Barrick, Kim Fielder, Kathleen Lloyd, Ron Houck, Debra Zeller and Linda O'Donnel

2. Meeting

The Committee will be meeting in Minneapolis the week of July 31st. The following voting members think they will be there: Debbie, Kathi, Michael, and Amy.
Maybe: Nicole

Proposed summer agenda:

- Update from QMS Committee and QMS Workgroups
- “Critical Supplies and Services” and Section 5.6.4
Break
- Valid / non-Valid SIR Review (for updates to V1M2)
- Draft Volume 1 Module 2 Review

3. Consumables Task Force

The Consumables Task Force reached out to Debbie to ask if a definition could be developed for Critical Supplies and Services and information could be added to Section 5.6.4.

Requested items from Consumables Taskforce – 6/7/2023

DEFINITION:

Critical Supplies and Services - A supply, product, or service that directly affects the result, therefore requiring traceability and verification to ensure data that is method compliant, legally defensible, and of known documented quality.

Discussion:

Delete “directly”.

This definition will be included in the DRAFT Standard with the deletion.

FOR 5.6.4.2

Chemical Certificate Contents:

- Supplier name and contact information
- Manufacturer name & contact information, if different
- Title (certificate, information sheet, etc.)
- Name of material
- Unique identification for material
- Description of material
- Intended purpose
- Instructions (for use, storage, etc.)
- Certified values and uncertainty limits
- Period of validity
- Traceability
- Date of Certification
- Signature of certifier

Service Certificate Contents:

- Supplier name and contact information
- Credentials of supplier
- Customer receiving the service
- Title (certificate, information sheet, etc.)
- Description of service provided
- Unique ID of equipment serviced
- Certified values with uncertainty limits
- Traceability
- Date of service and certification
- Period of validity
- Signature of certifier/technician

Discussion:

These are taken from ISO Guide 31. This is not everything in Guide 31, but includes what is considered the minimum. Is a separate list needed for reagents vs solids?

What is on a certificate is out of the laboratory's hands? Maybe the Standard could require that supplies be purchased from a manufacturer following ISO Guide 31 or accredited to ISO/IEC 17034 instead of the lists above?

Chemical Certificate Contents

Separate the bullet with Certified Values and Uncertainty limits. Add Uncertainty limits for CRMs. Add "for CRMs" to traceability.

Remove "intended purpose", "description of material" and "period of validity".

Separate “certified values” and “uncertainty limits”.

Some have seen certificates without signature. They are electronically developed.

Remove “Signature of certifier/technician.”

Section 6.5.2 may have some duplicated information to that being proposed above. The section being looked at above looks at what records are required.

Debbie asked if these lists are helpful to have in the Standard? One challenge is that not all manufacturer’s currently provide all these items.

Service Certificate Content

Remove “traceability” and “validity”.

First and second sentence should be “Service Provider” instead of “Supplier”.

Change “value” to “specification”.

Remove “Title, ...”).

Debbie would like to consider adding this to the agenda in Minneapolis.

4. Workgroups

Debbie would like to develop some new Work Groups to work on language issues that were found when reviewing SIRs:

- Section 4.2.8.1 and 5.2.7 – Data Integrity
 - Kelvin Yuen
 - Kim Felder
- Section 4.5.5 – Subcontracted Work
 - Kelvin Yuen

- Section 5.6.4.2 – Purchased/prepared supply records
- Section Section 5.5/5.5.8 – This section has lots of SIRs.
- Sectopm 5.6
- Sectopm 5.8

Earl, Alma and Nicole are willing to work on any workgroup where needed.

The Definition and Language Workgroups each need one more member.

Debbie asked that people can contact her if they are interested in working on one of these Work Groups. She is asking the first two Work Groups and the Definition and Language Work Groups to complete their work within 3 months.

Debbie will send the information by email to the rest of the Committee to see there are more volunteers.

5. SIR Review Continued

Debbie restarted the review at Section 5.4.7.1 – No revision is needed.

Section 5.4.7.2.b - No revision to the Standard is needed.

Section 4.13.1.2 /5.4.12 (2003) – No revisioin needed.

Section 4.13.3.h – Revise – See SIR #329. Language sent to Work Group.

Section 4.6.2 – No revision is needed.

6. New Business

No new business.

7. Next Meeting and Close

The next meeting will be by teleconference on July 10, 2023, at 1pm Eastern.

Debbie adjourned the meeting at 2:20pm 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 – until 1:27pm Eastern	ChemVal Consulting	2024	Other	kgumpper@chemval.com
Nicole Cairns Present	NYSDOH	2024	Lab	nicole.cairns@health.ny.gov
Michael Demarais Present	SVL Analytical	2023*	Lab	michael@svl.net
Tony Francis Absent	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Carla McCord Present	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 Present	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard Absent	NAVSEA LQAO	2024	Other	alysa.wingard@navy.mil
Ashley Larssen Absent	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