Quality Management System Expert Committee (QMS)
Meeting Summary

December 13, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by webinar on December 13, 2021. Attendance is recorded in Attachment A – there were 9 members present. Associate Members present: Carl Kircher, Kristin Brown, Jessica Jensen, Linda O'Donnell, Neanette Hernandez, Patty Carvajal, Brian Lamarsh, Debra Zeller, Lisa Parks, Michelle Wade, Nicole Van Aken, Joe Manzella, Kelvin Yuen, Ty Atkins, Karna Holquist, Paul Junio, Tiffany Shaw, Karina Blanton, Carla McCord, and Douglas Kablik.

The October and November minutes were reviewed on Webex.

A motion was made by Nicole to approve the October 11, 2021 minutes with a couple of changes (date in text is October 11, 2021 and not September 13, 2021. Members present was 9 – Lizbeth was present). The motion was seconded by Lizbeth and unanimously approved.

A motion was made by Jenna to approve the November 8, 2021 minutes as written. The motion was seconded by Lizbeth and unanimously approved.

2. QS Definitions Workgroup

Paul Junio noted that the Workgroup hasn't met recently, but the group is working on definitions. Some members wanted to define monthly, but Paul would prefer not to do this since there haven't been any issues with this term. Annualy will be defined.

The Workgroup could use 15 minutes during the meeting in San Antonio.

3. 17025 Crosswalk Workgroup

They just finished the Crosswalk for QMS Committee review.

4. Language Workgroup

Nicole provided an update (see Attachment B). There are 5 sections that the group is working on.

The list of topics included in SOPs:
They have replaced some of the language to align it better with ISO/IEC 17025:2017.
They removed some of the redundant language.

Nicole commented that the group will meet one more time before San Antonio, so they may have additional language to share. She will let Debbie know how much time is needed in San Antonio after the Workgroup meets.

Debbie asked if the Workgroup wants public feedback during the meeting. Yes.

5. Competency Workgroup

Debbie shared the Competency Workgroup's Draft presentation and asked people to review it.

6. San Antonio Meeting

The agenda needs to get to Suzanne by Thursday. Debbie and Ilona will finish it.

Debbie wants to review SIRs to make sure the new ones are addressed in Standard.

<u>Attendees in San Antonio:</u>
Voting Members:
Kathi – Can be there is needed. Otherwise maybe.
Amy – Planning to be there
Debbie – Will plan to be there, but travel option may change.
Ashley – There.
Nick – There
Jenna – No – No travel allowed.
Nicole – Hoping to be there, but travel approvals are days before the travel.

Associate Members:
Paul – Will be there to present workgroup.
Jessica – Will be there.
Bryan LaMarsh – Present
Carl Kircher – Present
Michelle Wade – will be there

7. 17025 Crosswalk - Section 5.5

Debbie continued review of the language updates made by the Workgroup. See Attachment C for the work done on Section 5.5.

8. New Business

No new business.

9. Next Meeting and Close

The next meeting will be in San Antonio, TX at 8am Central. There will be no virtual options for this conference.

Debbie adjourned the meeting at 2:24pm 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 by phone**	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
Lizbeth Garcia **Present**	Oregon Dept. of Environmental Quality	2022	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Stephanie Atkins **Absent**	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Present**	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen **Absent**	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak **Present**	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
William Ray **Absent**	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross **Absent**	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Amy Schreader **Present**	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

QMS Language Update Workgroup

Tasks Assigned:

TASK #1: V1M2, 4.2.8.5 – specifically paragraph f. Only analytical (or technical?) procedures need to address the items in the list in section f and not all items in f are required.

Suggested Change	Justification
Clarify that paragraph f is not a required outline, all topics must be covered when applicable but exact wording of headers and specific order is not required. Modify the language from F to clarify that it applies to method procedures and add G for "administrative" SOPs Work on language for the final sentence of f) Clarify the difference between types of procedures for instance: administrative SOP and Method/Analytical SOP may not require all of the same components listed. Some would like to see the list in bullet points, this makes the list harder to assess to as you can reference individual bullet points. Also commented to put the list with comma, so that the headers do not look like they must be used in that exact wording. Suggested wording for final sentence of f) Each test method SOP must address the following if applicable: Do we need to have separate list for something that MUST be in the SOP then we can have a list for areas that are not always applicable.? 2/8/2021: Suggestion - Have procedures within QMS that address the following topics, and where unique, include applicable sections in method SOPs. Very specific sections may be required in method SOPs. Suggestion – streamline topics.	SOPs can be written in any format that includes all of the information necessary to accomplish what is defined in the standard. The formatting and language needs to be modified so laboratory understand there are many ways to accomplish this requirement. Again, this is a list. Not all of these items are required, and since this list is written for methods, these bullets don't apply to non-method SOPs

Under *Management (ISO/IEC 17025:2005, Clause 4.2)* – See *ISO/IEC 17025:2017, Clauses 7.2 Selection, verification and validation of methods and 8.3 Control of management system documents*

Part of 4.2.8 Additional Management System Requirements

4.2.8.5 The laboratory shall maintain documents that accurately reflect all current laboratory activities.

a) These documents shall provide instruction for implementing management system requirements and test method requirements.

b) These documents may be from external sources or internally prepared. For example, they may be equipment manuals provided by the manufacturer, published reference methods, or internally written procedures. External documents that contain sufficient information to perform the activity do not need to be supplemented or rewritten as internal procedures.

4.2.8.6 The laboratory's test method documents shall include instructions for all fields of accreditation.

a) In cases where modifications to published reference methods have been made by the laboratory, these modifications shall be clearly identified and described in the test method instructions.

b) In cases where the published reference method provides options, is ambiguous, or provides insufficient detail, the choices and/or clarifications made by the laboratory shall be clearly identified and described in the test method instructions.

c) These instructions shall include or reference the following topics where applicable:

i. These topics must be included in the instructions:

- identification of the method,
- applicable matrix or matrices,
- scope and application, including analytes to be analyzed,
- summary of the method,
- Interferences,
- safety measures for hazards specific to the test method, beyond general safety measures covered below,
- equipment and supplies,
- reagents and standards,
- sample collection, preservation, shipment and storage,

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Deleted: b) The relevant SOPs shall be readily accessib … [3]

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- complete list of quality controls to be analyzed and preparation instructions for those quality controls,
- type of calibration to be analyzed and calibration instructions,
- procedure,
- data analysis and calculations, and
- references.

ii. These topics must be addressed but may be included by reference to other documents or records:

- definitions,
- limits of detection and quantitation,
- calibration evaluation and acceptance criteria,
- data assessment and acceptance criteria for quality controls,
- actions for handling out-of-control or unacceptable data,
- general laboratory safety
- pollution prevention and waste management.

iii. These topics are optional:

- Additional information on method performance and
- any tables, diagrams, flowcharts and validation data.

Note: The bulleted lists here are topics to be covered and are not intended to provide any document formatting requirements.

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Reference: 17025:2005	**Mark E if Exact Match**	**Indicate whether the language 'Changed - Equiv ' 'Changed - Not Equiv 'or was 'Deleted'.**	**17025:2017 reference (add the language if different from 2005)** *Give an opinion of whether the rewording is equivalent to the previous language* *Review performed by K. Gumpper*	**Keep or Drop comments**
5.5 Calibration Requirements *(ISO/IEC 17025:2005, Clause 5.5)*				
ISO/IEC Clauses 5.5.1 to 5.5.12 apply with respect to equipment in environmental testing laboratories.		**Deleted**	**This is a TNI note that is no longer needed. The difference between calibration labs and environmental labs is of less concern and need not be distinguished.**	DROP
5.5.1 ISO/IEC language		*Changed Equiv*	**6.4.1** The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability. NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80	

			provides guidance to produce in-house quality control materials. **6.4.2** When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	
5.5.2 ISO/IEC language		*Changed Equiv*	**6.4.5** The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. **6.4.7** The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration. **6.4.4** The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service. **6.4.6** Measuring equipment shall be calibrated when: — the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or — calibration of the equipment is required to establish the metrological traceability of the reported results. NOTE Types of equipment having an effect on the validity of the reported results can include: — those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement; — those used to make corrections to the measured value, e.g. temperature measurements;	

			— those used to obtain a measurement result calculated from multiple quantities.	
5.5.3 ISO/IEC language		*Changed Equiv*	**6.2.3** The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations. **6.4.12** The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results. **6.2.5** The laboratory shall have procedure(s) and retain records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authorization of personnel; f) monitoring competence of personnel. **6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following: **7.2.1.2** All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3). *If we include 7.2.1.2, these may be equivalent.*	

5.5.4 ISO/IEC language		*Changed Equiv*	**6.4.13** Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable: a) the identity of equipment, including software and firmware version; b) the manufacturer's name, type identification, and serial number or other unique identification;	
5.5.5 ISO/IEC language		*Changed Equiv*	**6.4.13** Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:	
5.5.5 a) ISO/IEC language		*Changed Equiv*	6.4.13 a) the identity of equipment, including software and firmware version;	
5.5.5 b) ISO/IEC language	*E*		6.4.13 b) the manufacturer's name, type identification, and serial number or other unique identification;	
5.5.5 c) ISO/IEC language		*Changed Equiv*	6.4.13 c) evidence of verification that equipment conforms with specified requirements;	
5.5.5 d) ISO/IEC language		*Changed Equiv*	6.4.13 d) the current location;	
5.5.5 e) ISO/IEC language		*Changed – Equiv (manufacturer's instructions are external documents)*	**8.3.1** The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document. NOTE In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.	

5.5.5 f)	*ISO/IEC language*		*Changed Equiv*	6.4.13 e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;	
5.5.5 g)	*ISO/IEC language*		*Changed Equiv*	6.4.13 g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;	
5.5.5 h)	*ISO/IEC language*		*Changed Equiv*	6.4.13 h) details of any damage, malfunction, modification to, or repair of, the equipment.	
5.5.6	*ISO/IEC language*		*Changed Equiv*	**6.4.3** The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.	
5.5.6 NOTE:	*ISO/IEC language*		*Changed Equiv*	**6.4.2** When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	
5.5.7	*ISO/IEC language*		*Changed Equiv*	**6.4.9** Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).	

5.5.8	*ISO/IEC language*		*Changed Equiv*	**6.4.8** All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity. 6.4.13 f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;	
5.5.9	*ISO/IEC language*		*Changed Equiv*	**6.4.2** When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.	
5.5.10	*ISO/IEC language*		*Changed Equiv*	**6.4.10** When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.	
5.5.11	*ISO/IEC language*		*Changed Equiv*	**6.4.11** When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.	
5.5.12	*ISO/IEC language*		*Changed Equiv*	**6.4.12** The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.	