Quality Management System Expert Committee (QMS)
Meeting Summary

April 10, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on April 10, 2023. Attendance is recorded in Attachment A – there were 8 voting members present. Associate members present: John Gumper, Alexander Chieh, Tamy Kreutzer, Hong Yu, Annmarie Beach, Brian Hulme, Fida Kased, Linda O'Donnell, Douglas Kablik, Ron Houck, Brian Lamarsh, Ty Atkins, Sarah Brown, Debra Zeller, Carol Barrick, Eric Davis, Paul Junio, Kristin Brown, and Lisa Parks.

Ron and Ryan added to the Committee as new Associate members. Ron introduced himself.

Debbie shared meeting minutes on screen for review, but they could not be voted on since there were only 7 members present at the start of the call. They will be voted on by email instead.

(Addition: Debbie distributed the December, January and February minutes for voting by email. A motion was made by Earl and seconded by Tony on May 1, 2023 to approve the December 12, 2022, January 11, 2023 and February 13, 2023 minutes as written and sent by Debbie on April 28, 2023. There was no further discussion.

Vote:
Jenna – For (email 5/2/23)
Nicole – For (email 5/2/23)
Michael – For (email 5/2/23)
Zaneta – For (email 5/2/23)
Alyssa – For (email 5/3/23)
Sean – For (email 5/3/23)
Carla – For (email 5/3/23)
Ashley – For (email 5/2/23)
Stephanie – For (email 5/2/23)

The motion was approved.)

2. SIR Review Continued

Debbie continued the review of SIRs to determine if any changes need to be made to the DRAFT Standard.

4. New Business

No new business.

5. Next Meeting and Close

The next meeting will be by teleconference on May 8, 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 – 1:22pm 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 **Present**	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 **Absent**	A2LA	2023*	Accrediting Body	nslawson@a2la.org
Earl Hansen **Absent**	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak **Absent**	NJ DEP	2024	Accrediting Body	Jenna.Majchrzak@dep.nj.gov
Zaneta Popovska **Present**	ANAB	2025*	AB	zpopovska@anab.org
Sean Hayes **Absent**	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
22	4.2.8.5	Are SOPs required for procedures not performed (e.g., “legal coc” 5.5.8.3.1 f) says “if required”; or subcontracting)	SOPs are not required for activities that the laboratory is not required to perform. The converse is obviously true, in that you must have an SOP if you perform, or are required to perform, these activities. The first paragraph of 5.5.4.1.1 states that SOPs must "accurately reflect all phases of current laboratory activities". Where an activity is not performed, such as legal Chain of Custody, the laboratory should not be required to have an SOP for what it doesn't do. Compliance could be demonstrated if the lab's Quality Manual states 'We do not perform legal CoC, and will refuse any samples requiring legal CoC', although this is not mandatory.	This section was edited in 2009 but the SIR is still valid.	This relates to SIR 323 which was rejected as an SIR. There needs to be clarification that the Standard DOES NOT apply where it has not been requested or where it isn't the regulation of the land. As it relates to this SIR, a laboratory can't be expected to have a procedure for a process that it doesn't perform.	NO REVISION question of clarity, not enforcement, so a NOTE isn't exactly an issue
418	4.2.8.5.e	During an assessment, we were given SOP's for multiple methods; ie. SOP Method 8260B, 8260C and 624 was one document. The laboratory felt that by putting these three methods together, it was an SOP for the accredited analytes and methods. Our assessors interpreted this as each individual method should have an SOP; ie. SOP 8260B, SOP 8260C and SOP 624. There was some confusion and extra citations in the SOP to try to reference the variation in the three methods. Do the laboratories need to have individual SOP’s for each individual method?	Determined not to be an SIR.			NO REVISION
101	4.3.1	Is instrument software (or any other software) considered a controlled document? Are equipment manuals considered controlled documents?	Software is among the items listed in Section 5.4.3.1 as a document that must be controlled. Equipment manuals fall under the categories of "procedures, specifications" that are also listed in 5.4.3.1 as documents that form part of a laboratory's quality system 5.4.2.1 and 5.4.2.3.m also support having control over the documents, such as software and equipment manuals, that are part of a laboratory’s quality system.	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	17025-2017 8.3.1 has a note to address this. QS should identify the note as a required list and add these items (instrument manuals and equipment manuals) as among the required items.	NO REVISION Added 8.3.2.1 to clarify that documents that provide instruction to personnel for lab activities must be controlled.

363	4.3.1 and 4.3.2.2	The standard does not explicitly state that a laboratory must have a legitimate copy of the TNI standard. However section 4.3.1 indicates laboratories must "control all documents that form part of its management system" and specifically mentions standards. Section 4.3.2.2(a) states "authorized editions of appropriate documents are available." Do these two sections effectively ensure that laboratories must have a copy of the TNI standard? Note: Chris Gunning of A2LA uses these sections to require laboratories they accredit to have a copy of ISO 17025 or the TNI standard depending on which accreditation the laboratory is seeking.	Because the TNI standard contains specific requirements that laboratories must address, and because these requirements are not universally available from other sources, yes, an authorized edition of the appropriate TNI standard revision under which the lab holds accreditation must be available within the laboratory's controlled document system.			We added possible language 8.3.2.2 to address this.
18	4.3.2.2.b	This section requires documents to be reviewed "periodically". I have interpreted this to mean that NELAC wants the documents reviewed but requires the lab to establish the frequency. NELAC further supports this position by specifically requiring data integrity procedure to be reviewed annually (5.4.2.6). However, some assessors with whom I work take the position that since 5.4.14.1 requires labs to annually review the "suitability of procedures" and 5.4.13.1 requries labs to annually conducts audits on "all elements of the quality system" that these are inferred or indirect requirements to annually review all procedures. Since 5.4.3.2.2.b addresses the issue directly, I take the position that it prevails over any indirect or inferred interpretation of the standard,	The Quality Systems Committee sees no conflict here. The internal audits must show compliance with the laboratories policies and procedures. This is a procedural review for compliance and suitability. The periodic review of SOPs is set by the lab and does require that technical management review current procedures. This can be done with internal method audits. If the AB finds issues that would indicate that periodically has been stretched too long, then the AB could impose a finding that would require the timeframe be shortened. Also, support procedures can be allowed to have longer periods between review, such as when changes are needed due to a change in laboratory practice	No change in language in 2009 and 2016	address - 17025 addresses the outcome of, not the timeframe between, assessments	REVISED Made the following addition: 8.3.2.2 The laboratory shall review documents on a frequency defined by the laboratory.
115	4.5.4	What is the documentation needed as the 'record of evidence of compliance'? Our clients are asking for our NELAP certificate, PT results, insurance certificates and QA manual. But we interpret this statement to mean having the NELAP certificate on file.	The requirements outlined in 5.4.5.1 refer to a subcontracted laboratory and the tests to be performed. They are 1) the laboratory is accredited under NELAP for the tests or 2) the laboratory meets the statutory or regulatory requirements for performing the tests. In the case of the first requirement, the NELAP Certificate that identifies the accredited test would meet the requirement. If other statutory or regulatory requirements exist, the laboratory must be prepared to provide documentation to indicate that these additional requirements have been met. However, under "Service to the Client" (5.4.7), the laboratory shall cooperate with the client "to monitor the laboratory's performance.... provided that the laboratory ensures confidentiality to other clients."	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	address	REVISE It should be clear in 4.5.5 (however numbered under 6.6.2) that TNI accreditation for the analytes/methods is sufficient.
361	4.6.2	Would a verification of sample preservation pH require the same accuracy as a sample pH determination? For example, many of the preservation requirements are a pH<2 (and not pH <2.0). If the requirement were to pH below 2.0 then narrow-range paper or a meter would be used for the verification. Since the tenths place in the measurement is not part of the method requirement, wide-range pH paper should be sufficient to verify the preservation of the sample. Is broad range pH paper acceptable for verification of preservation to pH 2?	Determined not to be an SIR.			NO REVISION

79	5.10.11	LAB's question for TNI concerns the documentation of the laboratory's scope of accreditation in the test report. In this situation, our laboratory is licensed for a small number of tests in the State of Minnesota, which is adopting the NELAC Standard. Our laboratory is licensed for a full scope of parameters in the State of Arizona, a non-NELAC state. In Section 5.5.10 of the 2003 NELAC Standard, is there a requirement for qualifying data that is not included in the laboratory's scope of accreditation? If there is a requirement (either directly or implied), how should the laboratory indicate the lack of NELAC licensure on the Arizona-only parameters in order to comply with the NELAC Standard? Is it sufficient to include a disclaimer on the cover page of the reports for Arizona-only work that indicates the data may only be used for compliance purposes in the State of Arizona and not in NELAC states?	Based on the standards quoted above, if the laboratory is issuing a NELAC-compliant report and the report has results that are not accredited under NELAC, you must identify those methods that do not meet the NELAC requirements (i.e., methods certified by another accrediting body). The committee cannot comment on reports that are issued for Arizona compliance purposes.	The 2009 and 2016 standards retain the requirement. The SIR is still valid	address - try to clarify the requirement / expectation	REVISED Already Paul will work on a possible additional note.
16	5.10.11 (b)	The standard states the report should note whether the sample result was calculated on a wet weight or a dry weight basis. The narrative that accompanies every analytical report out of our laboratory states "all sample results are reported on an "as-received" basis unless otherwise noted". Why does the report have to note whether it is dry or wet weight a second time, when we have already noted "as-received"?	5.5.10.2(i) requires identifying whether data are calculated on a dry weight or wet weight basis Recording sample result as being calculated on the basis of 'as received' does not indicate wet or dry weight basis. As or more importantly, identifying results as having been calculated on an 'as received' basis would not comply with requirements in 5.5.10.1 to report results unambiguously. The laboratory could have a statement: "All results are wet weight unless otherwise noted."	Thi section was revised in the 2009 standard to read "Results that are reported on a basis other than as received (e. g., dry weight)."	maintain the language from 5.10.11 b) in its new location (possibly within 7.8.3.1)	NO REVISION Clarified in 2016 revision.
93	5.10.2	This section deals with information that shall be on the Test Report. e) identification of the test method used; and h) reference to the sampling plan and procedures used by….. Is it a requirement that the revision level of these documents be listed on the Test Report?	The laboratory should verify how the state requires reporting methods.	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	How would a NOTE be received indicating that reporting requirements to this level are not addressed by the Standard, but should be verified with the end user? Talk to the AC for advice. Capture the	REVISE It should be clear in 7.8.2.1 that revision must be included in the report or made available if using a shortened format.