Quality Management System Expert Committee (QMS)
Meeting Summary

October 9, 2023

1. Roll Call:

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

Associate members present: Brian Eichelberger, Jeanette Hernandez, Ryan McMullin, Paul Junio, Anagha Chitre, Ty Atkins, Debra Zeller, Kathleen Lloyd, Alma McCammond, Tiffany, Soccorro, Carl Kircher, and Megan Rothgerber.

Minutes will be approved by email. Initially there were not enough voting members on the call to review minutes.

Debbie welcomed Brian Eichelberger as a new associate member.

2. Workgroup Update – Language

As the workgroups complete updates for the sections they are working on, the language will be put into the DRAFT standard. The full Committee will start reviewing the language of the Standard and will review these updates as part of that task. All updates will have track changes turned on. The language will not be reviewed by the full Committee before it is added to the DRAFT.

The Language Workgroup was working on Technical Records – 4.13.3.h.

Remove "goes out of business". Change to:
The laboratory shall have a plan to ensure that customer records are maintained or transferred according to contractual, regulatory, and state legal requirements in the event that the laboratory is no longer obligated to maintain records (i.e.,transfer of ownership, loss of business, etc.)

This will be pasted into the DRAFT standard into section 7.5.2.

This should complete the task assigned to Language Workgroup.

3. SIR Review

Debbie continued the review of SIRs to determine whether a revision is necessary to the Standard. She started with Line 66, Section 5.6.3.1 See Attachment B for review information.

4. New Business

    1. Membership: Ilona will reach out to Jordan Adelson. *(Addition: Jordan Adelson submitted an application to join the Committee.)*

5. Next Meeting and Close

    The next meeting will be by teleconference on November 13, 2023, at 1pm Eastern.

    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	2026	Lab	dbond@southernco.com
Kathi Gumpper (Vice-Chair) **Present**	ChemVal Consulting	2024	Other	kgumpper@chemval.com
Nicole Cairns **Present – Joined 2:13**	NYSDOH	2024*	Lab	nicole.cairns@health.ny.gov
Michael Demarais **Present**	SVL Analytical	2026	Lab	michael@svl.net
Tony Francis **Present**	SAW Environmental	2026	Other	tfrancis@sawenviro.com
Carla McCord **Absent**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins **Present – Joined 1:30**	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Absent**	A2LA	2026	Accrediting Body	nslawson@a2la.org
Earl Hansen **Present**	Retired	2024	Other	papaearl41@hotmail.com
Jenna Majchrzak **Absent**	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
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

#	2016	Actual Request	Final Response	Comment	Paul Comments	Revise or No Revision
77	5.6.3.1	I'm trying to determine if NELAC requires that the weight sets used to verify balances prior to use MUST be Class 1.	A laboratory may use any class to verify the balance if the weights are traceable to a national standard. A Class 1 (or "S") weight is normally considered a reference standard, but may be used as a working standard. If the laboratory has designated the weight as a reference standard, the weight may only be used for calibration (i.e. calibrating/checking working standards). Standards that are used for daily calibrations (5.5.5.2.1) must be traceable to NIST. The Class1 or “S” weights can be used to verify the working standards, since these are traceable to NIST.	Althought this language was revised in the 2005 version of ISO 17025, the SIR is still valid.	done	NO REVISION
124	5.6.4	For subsection a), I would like an interpretation of the requirement to obtain the manufacturer's Certificate of Analysis for reagents. Does this mean just "ready-made" reagents (e.g. the color reagent for a test) or does this also include pure chemicals (e.g. a bottle of sodium chloride crystals)?	The standard requires that Certificates of Analysis be obtained for all reagents. This does not mean that the C of A is automatically supplied. In some cases, you may need to request such information from a manufacturer. This includes both "ready-made" and pure (neat) chemicals.	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.		REVISION - clarify that unavailable doesn't mean it didn't come with the package
192	5.6.4.2	This section requires the lab to retain records of the standard or reagent manufacturer's Certificates of Analysis. One of our largest standard manufacturers recently stopped automatically sending hard copies of the C of A with the material, stating that it can be accessed electronically from their website. The manufacturer says an advatange of this, among other things, is "immidiate accessibility for audits". My question is if hard copy of the C of A onsite at the lab is stictly required, or if access to the electronic copy "on-demand" is sufficient.	The laboratory must maintain copies of the Certificates of Analysis (CoAs), whether in hard copy or electronic format, in accordance with the lab's records and document control procedures and as required by the TNI Standard. The laboratory must maintain and control all records used to document lab activities, including CoAs, and all records must be made available to the accreditation body. The laboratory must retain all records (hard copy or electronic) for a minimum of five years (V1M2, section 4.13.3), and labs must incorporate procedures to maintain CoA from manufactures that do not have the same retention schedule for electronic CoAs.	This language is unchanged in the 2016 standard. The SIR is still valid.	done	NO REVISION
198	5.6.4.2	My question is about documentation and traceability of consumables. Are environmental labs required to maintain records (ie Certificate of Analysis, storage, date of receipt, etc.) for such consumables as carrier gasses used for MassSpec or Spec type instrumentation?	5.6.4.2 requires documentation for "standards, reagents, reference materials, and media". Carrier gasses are not referenced within this section. However, a carrier gas is a laboratory consumable material that affects the quality of tests, and is subject to the policy and procedure requirements	This language is unchanged in the 2016 standard. The SIR is still valid.	done	NO REVISION

422	5.6.4.2	This section of the Standard specifies, "Documented procedures shall exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory." Question: What does the Standard mean by "technical operations of the laboratory"? Would a 1:1 HCl dropper used to acidify a VOC sample during sample collection require the documentation and labeling of paragraphs b) and/or d)? Do reagents that are used at collection fall under the definition of "technical operations of the laboratory"?	If the laboratory provides or uses the reagents, they would be part of the "technical operations of the laboratory" and would therefore require documented procedures as described in section 5.6.4.2. If the reagents are provided by the client, they would not fall under the "technical operations of the laboratory."			REVISION - technical operations of the laboratory should be updated to match ISO's term "laboratory activities" or we should define "tech operations..."

251	5.6.4.2 d)	Assuming that we have a working definition for reagents, does the word "prepared" in 5.6.4.2(d) refer only to standards or all three (standards, reference materials and reagents)? Assuming the latter, see the discussion below for the actual question). Prepared reagents are readily defined as reagents that are prepared in the lab by modifying (diluting, mixing, etc.) one or more precursor reagents or standards. However there is some ambiguity concerning the term “container”. Suppose I make 200 ml of a reagent stock, say the Ammonium Molybdate reagent used in total phosphorus analysis that is stored in a lab refrigerator. Every time we perform a TP run, a small amount of this reagent is poured into a second container, a removable, plastic reagent well that is part of our discrete analyzer’s autosampler. At the end of the day, this reagent is not completely used up, and to minimize waste, we cap the removable plastic well and store it in the refrigerator overnight. It is refilled the following day for the next day’s analysis. Since the reagent stock was prepared only once, it would be assigned a single, unique serial number. The mere act of pouring some of this reagent into a second container should not (logically) require one to generate a second serial number. To summarize the question, is only one unique	The use of the reagent at analysis requires that all data necessary for the historical reconstruction of the data be available (see 4.13.3 f). Somewhere with the analytical batch, reference must be made to the unique serial number of this reagent. A new serial number need not be created due to the act of pouring the reagent from one container to another. The unique serial number is created at a point in time when the reagent, standard or material is made in the lab. If no changes are made, then a new number need not be created. The act of removing the container from its specific location on the instrument requires that the container be labeled with the reagent's unique identifier in order to comply with the traceability requirement of 5.6.4.2 c.	This language is unchanged in the 2016 standard. The SIR is still valid.	verify that this doesn't conflict with micro autoclave cycle	REVISE - the prepared item needs to be traceable; Consider "be traceable to the preparation records" instead of "unique ID"

416	5.6.4.2.c	The standard as written states, "Records shall be maintained on standard, reference material, and reagent preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials." Does the laboratory need to have a single document that includes each of these items or can the laboratory's record keeping system allow multiple records/documents (including electronic) that contain or reference the required items? Or more simply, can the Standard be interpreted to mean that "reference to" can be applied to the string/list of items, such as the record may include a "reference to" the method of preparation, "reference to" the date of preparation, "reference to" the expiration date and "reference to" preparer's initials?	The standard does not state a requirement for a single record. There are many ways a laboratory could maintain the records listed in section 5.6.4.2.c, including the system described in the interpretation request. The record-keeping system is acceptable if it meets the record requirements in 4.13.1.			REVISE - see if there's a better way of wording, maybe without "reference to".
412	5.6.4.2.d	"All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date." If the reagent is from the same lot but came in multiple bottles, do they need a unique ID? For example, if a case of Methylene Chloride came in a pack of 4 bottles, can all 4 bottles share the same ID or do they need to be distinguished despite having the same manufacturer lot number?	For the example given, each container does not require a distinct unique identifier. Clause 5.6.4.2 d) refers to standards, reference materials, and reagents prepared in the laboratory, not original containers received from the manufacturer or vendor.			REVISE - need to be clear on records and labeling needed for purchased vs. prepared items

419	5.6.4.2.e	I sent the attached email, on behalf of the IETLA, and in response Jerry Parr directed me to submit an SIR. Through the SIR process, I am requesting clarification on the intent of section 5.6.4.2 e) and that an implementation guidance document be developed for section 5.6.4.2 e). This section is open to a number of interpretations depending on the reader's perspective. An SIR is needed to state the intent and purpose of this language and provide guidance to ABs and assessors on how to evaluate or assess a laboratory for compliance with this section. Additionally, the SIR needs to provide clarification and guidance to laboratory's on how to implement this section across their scope of accreditation for all prepared reagents. Here are some examples of the questions facing laboratories and ABs on interpreting this section: Does this section only require a laboratory to have documented procedures on how a reagent is prepared and its preparation is documented per the method (test method or SOP) to show evidence the prepared reagent meets the requirements of the method? Does a laboratory have to evaluate or verify, in some way, that all prepared reagents (e.g., buffers	Determined not to be an SIR.			NO REVISION

452	5.7.1	This section states that "The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration". Question: Is it required to have a sampling plan if we are sampling at a private resident's home? In these situations, it is generally only one or two samples - one from the private well and one from a tap outside. It is our stance that it would not be necessary to create a sampling plan in these circumstances.	Not an SIR			NO REVISION
43	5.8.3	Is the sample acceptance plan required to be communicated to clients at any particulary frequency, i.e. annually?	5.5.8.3.2 states that the "sample acceptance policy shall be made available to sample collection personnel." The introduction included in 5.5.8 states "the following are essential to ensure the validity of the laboratory's data," which would mean that the laboratory can't invoke 5.1.2, which states "When a laboratory does not undertake one or more of the activities covered by this Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply" to avoid having such a policy. However, the Standard makes no mention of any period under which the acceptance policy must be communicated to clients.	This sentence is not in the 2009 or 2016 standards. The SIR is obsolete.	archive	NO REVISION

356	5.8.5	The standard states: a) The laboratory shall have a documented system for uniquely identifying the sample containers that hold samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates. and: c) The laboratory ID code shall be placed as a durable mark on the sample container. Here is my question: Say an analyst is performing TDS/TSS. The sample bottle is labeled. They pour their sample first into a graduated cylinder to get the correct volume for the test. Then they pour from the graduated cylinder into a filter and flask before transferring the sample to a labeled beaker to go into the oven. Both the graduated cylinder and the flask are acting as and meet the definition of a container for the sample. According to the standard, do the graduated cylinder and filter flask require a durable mark to be made on them? If they do that would mean a lot of time removing labels between samples as the equipment is shared between many samples.	Determined not to be an SIR.			NO Further REVISION - already revised by a workgroup

246	5.8.5 a)	Question: Do labs have to uniquely identify sample containers when received at the lab? The 2009 standard states: "The laboratory shall have a documented system for uniquely identifying samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates." The 2003 standard stated the same but also added: "The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample." Since the 2009 standard dropped the wording above in the third paragraph, some are interpreting this to mean the labs do not need to uniquely identify sample containers anymore. However, since the 2009 standard does still include sample containers in the last sentence of the second paragraph, above, some are interpreting that sample containers must be uniquely identified.	The laboratory shall assign a unique identifier to each sample received. The laboratory shall use a system for recording how it uniquely identifies multiple containers of the same sample. The system must be able to identify the sample container from which the analytical result was obtained.			NO Further REVISION - already revised by a workgroup
431	5.8.7.2.ii	When samples do not meet sample acceptance criteria, can you please confirm whether the actual test result(s) are required to be qualified on the test report? Other sections of the standard clearly state that 'results' shall be reported with appropriate data qualifying codes (e.g. V1M4 1.7.2.1.a for Method Blanks). V1M2 5.8.7.2.b.ii states 'analysis data' instead of 'results'. In general, should both 'analysis data' and 'results' be interpreted as qualitative test results in the test report?	Determined not to be an SIR.			REVISE - Consider removing if covered by 7.4.3

429	5.8.7.3	Regarding “TNI 2016 V1M2 Section 5.8.7.3 The laboratory shall utilize a permanent chronological record such as a logbook or electronic database to document receipt of all sample containers.” I interpret this requirement as to the ability to filter or organize samples in a chronological order according to the receipt date regardless of the sample IDs. My interpretation allows creation of sample IDs using a schedule. The samples will be received, and information can be sorted using the receipt date. For example, I can schedule and create sample IDs A123, A124, A125. The receipt date can be A123=02/03/22, A124=02/01/22 & A125=02/02/22. If my system can organize the samples in chronological order according to the receipt date A124=02/01/22, A125=02/03/22 and A123=02/03/22, then the sample ID sequence should be irrelevant. Is this interpretation correct?	Determined not to be an SIR.			REVISE - chronological record may not be necessary; date/time of sampling and receipt are important.
81	5.8.8	I am a project manager for Head Start child care centers in New York City. We needed samples of drinking water to be tested for lead. I was disturbed to to see ATC Associates (NELAC certified) did not have a chain of custody form. I was concerned that there was an unsigned gap in the chain of custody when samples were delivered by FedEx courier to a lab nearby. The question is: isn't a complete continous, signed Chain of Custody form required so the sample could be accounted for specifically by a signed individual - in order to be in accordance with Nelac and the EPA method?	A complete, continuous Chain of Custody form is not required for samples submitted under NELAC, unless otherwise specified by the client. Note that 5.4.12 differentiates between sample handling and tracking and legal chain of custody protocols. 5.4.12.1.5 requires that a record keeping system allow historical reconstruction of all laboratory activities. "The records shall include the identity of personnel involved in sampling, sample receipt, preparation, or testing." A laboratory that does not record the receipt of samples by a specified individual is not compliant with this aspect of the standard. Note that TNI 2009 does not contain identical language to 5.4.12.1.5, so a laboratory that does not record the receipt of samples by a specified individual and that is accredited under TNI 2009 is not outside of compliance with regard to this issue.	The response discusses the differences between 2003 and 2009 (and 2016) and is still valid.	done	REVISE - consider including in 7.1 to clarify with customer when legal chain of custody measure are needed and what those measures entail.

436	V1M2	Throughout the TNI Standard there are terms and requirements that state the following (as examples): • "The laboratory shall have instructions to/that…" • "The laboratory shall have measures to…" • "The laboratory shall have procedures to…" • "The laboratory shall have a policy to…" • "The laboratory shall implement procedures that…" • "Procedures shall be implemented to…" • "Programs shall be established to…" • "Procedures shall exist to…" • "Instructions shall be maintained to…" • "These [checks/activities/calibrations/etc.] shall be performed according to a defined procedure." • "The laboratory shall have a program and procedure" • "The laboratory shall have a policy and procedure" • "Procedures shall be in place to…" • "Procedures shall ensure that…" • "The laboratory shall have a system that…" • "The laboratory shall have an arrangement/arrangements to…" • "The laboratory shall establish and maintain procedures for…" • "The laboratory shall establish a system	Determined not to be an SIR.	Definitions workgroup is already working on this.		DONE - completed by the definitions WG.
105		General question: does the accreditation process include all steps in the process, including sample prep? Specifically, if a lab is not accredited but performs the digestion of a water sample for method 6020 analysis then sends the digested aliquot to an accredited lab for the actual analysis can the results be considered valid from an accredited lab?	Cancelled January 2018 - direct to lab's AB			NO REVISION