Quality Management System Expert Committee (QMS)
Meeting Summary

September 11, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on September 11, 2023. Attendance is recorded in Attachment A – there were 9 voting members present.

Associate members present: Sushmitha Reddy, Tina Buttermore, Alma McCammond, Kelvin Yuen, Debra Zeller, Kim, Megan Rothgerber, Thomas Fritz, Jeanette Hernandez, Ryan McMullin, Paul Junio, Amanda Grande, Cindy Redmond, Tammy Kreutzer, Carl Kircher, Eric Denman, Douglas Kablik, Cody Danielson, Joann Slavin, John /Gumpper, Matt Sica, Kathleen Lloyd, Sarah, Fida, Linda O'Donnell, Brian Lamarsh, Brian Eichelberger, Ty Atkins, Sarah Brown, and Carol Barrick.

Debbie welcomed Brian Eichelberger, Megan Rothgerber, Matt Sica and Joann Slavin as a new associate members.

Judy Solomon needs to be contacted regarding interest in joining the Committee representing DoD. *(Addition: Judy got back to us on 10/6/23 and is not able to join at this time. Ilona will follow-up with Jordan Adelson.)*

2. Definitions Workgroup

The Definitions Workgroup is done unless something else comes up. They reported an overview in Minneapolis. They decided not to pursue a definition for duplicate or replicate. They have been working on how ISO/IEC 17025:2017 uses the word "procedure" and make sure we are OK defining "procedure" as "written". Paul sent the following message to Mitzi to follow-up on a question she asked in Minneapolis:

At NEMC, you expressed concern that by TNI requiring procedures to be written, there could be conflict with the use of the word 'procedure' in the ISO language. The TNI Definitions workgroup has completed its review of the term 'procedure' in ISO language. We didn't find any instances where the ISO use of 'procedure' would be in conflict with TNI requiring that procedures be written. If you think we have missed something, please let me know.

3. SIR Review

Debbie continued the review of SIRs to determine whether a revision is necessary to the Standard. She started with SOP 461 (Section 4.3.2.2.c) and finished with SIR 392 (Section 5.5.8). See Attachment B for review information.

4. New Business

   No new business.

5. Next Meeting and Close

   The next meeting will be by teleconference on October 9, 2023, at 1pm Eastern.

   Debbie adjourned the meeting at 2:26pm 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**	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 **Present**	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 **Absent**	ANAB	2025*	AB	zpopovska@anab.org
Sean Hayes **Absent**	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 - SIR Review

#	2016	Actual Request	Final Response	Comment	Paul Comments	Revise or No Revision
461	4.3.2.2.c	The lab believes that placing inactive documents in an electronic folder entitled "Inactive" is sufficient to remove the documents from issuance and avoids UNINTENTIONAL use as the standard specifies. If personnel open and use information from the electronic Inactive folder, then it would clearly be INTENTIONAL use. Others have said that access to inactive electronic documents must be restricted in order to avoid unintentional use, but the standard does not have this specific requirement. Please clarify if the use of an electronic Inactive folder is sufficient or must access to this folder be restricted per the Standard.	Not a valid SIR			REVISE Consider adding language from current V1M2 4.3.2.2.d to clarify document must be marked.
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
458	4.6.2	If the lab purchases containers, reference materials, pre-preserved containers, and reagents that are accompanied by a Certificate of Analysis, does the lab need to test a sample from a batch lot to verify compliance i.e. Is the Certificate of Analysis sufficient to document acceptability for use if all meets the labs needs? Thank you, two questions but I think they can be answered yes/no.	With this letter, I am advising you that your question is not a valid SIR. The language in V1M2 4.6.2 is clear, in that it requires the laboratory to ensure that supplies, reagents, and other consumables that they purchase must not be used before they are verified to comply with requirements defined in the Standard and/or methods. Although section 4.6.2 does not address how that verification is performed, other language in the Standard (particularly the Microbiology module) and methods do specify how and when that verification must be performed. Certificates of Analysis only show the parameter values when the product was tested at the vendors lab, but cannot show whether anything occurred during the shipping and transporting of the products to alter them. If you are still unclear about what is acceptable, please ask your Accreditation Body.			NO REVISION - ISO 17025:2017, 6.6.2 covers this better

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. DONE 5/8/23
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)." The SIR is obsolete.	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 scope of accreditation	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.
354	5.4.7.1	5.4.7.1 States "calculations and data transfers shall be subject to appropriate checks in a systematic manner". Is there a specified time period between checks? We check these quarterly since that seems to be the generally accepted convention for a lot of routine checks, but I am unable to find a reference to a specific time requirement for calculations.	Determined not to be an SIR.	No need to revise anything for section ISO 17025:2017 7.11.6.		NO REVISION

375	5.4.7.2.b	1. The SM 5210 b BOD states that the incubation period is 5 days +/- 6 hours. We track the date/time of our readings in and out, but also the time in and time out of the incubator. Being the time in and out of the incubator our mechanism to make sure incubation is within the 5 days +/- 6 hours. What date/time of the analysis should be reported with the result? 2. If is the analysis (read in /read out) – doesn't this should fall within the range of 5 days +/- 6 hours. It is my understanding that this range is not just for incubation but the readings must also be within this range. Is this the right approach? And if not how much outside of the this range of incubation should the reading be performed then?	Determined not to be an SIR.			NO REVISION
270	5.5.13.1	This section requires verification of volumes of volumetric dispensing devices (except Class A Glassware) if quantitative results are dependant on their accuracy. Historically, this section has been interpreted to include disposable pipettes and plastic tubes used for measuring sample volumes or final volumes after digestion. Section 5.5.13.1.d appears to require quarterly checks of these devices. Quarterly checks seem excessive when the items are one use items. Once per lot number seems more reasonable and would be similar to receiving a certificate from the manufacturer about the accuracy of a particular lot number.	A verification of one pipette or tube per lot would meet the requirements stated in Sections 4.6.2 and 5.5.2.	This language is unchanged in the 2016 standard. The SIR is still valid.	We should add language addressing single use items as needing to be checked once per lot. EDIT SINCE NEW ORLEANS - we already did this	NO REVISION

274	5.5.13.1	The standard states "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Would class A plasticware be considered the same as Class A glassware ie - you do not need to check it on a quarterly basis? Or would Class A pastic ware be considered the same as non-class A labware? The same question for V1M5 section 1.7.3.7 iii.2 "2. equipment such as filter funnels, bottles, non-Class A glassware, and other containers with volumetric markings (including sample analysis vessels) shall be verified once per lot prior to first use. This verification may be volumetric or gravimetric." Would you need to check Class A plasticware once per lot?	Plasticware is not glassware. Any volumetric dispensing devices that are not Class A glassware or glass microliter syringes must be checked for accuracy on a quarterly basis.	This language is unchanged in the 2016 standard. The SIR is still valid.	done	NO REVISION - standard requires checking prior to or in conjunction with first use.
335	5.5.13.1	We check all our thermometers used in the laboratory that are used for monitoring ovens, refrigerators, freezers, incubators, water baths and any meter where we actually report a temperature reading. Our question is with the use of ATC probes (automated temperature compensation) that are used in conjunction with a probe – like pH, Ammonia and Dissolved Oxygen. If we don't report any temperature reading, and the measured value (in hit case pH, NH3, DO) is determined to be accurate, do we have to annually verify the ATC reading? We have never done this, and we don't think this applies, but it did come up in conversation so I thought I'd ask.	Determined not to be an SIR.	As ATC can be a test instrument, it could be interpreted as the section on support equipment and verification/calibration does not apply. Is there a way to clarify this?		This section is for support equipment, not instruments. Kathi will look at QSM, table 6.1 to see language there.

367	5.5.13.1	We have one set of weights (primary) that we use to check balances on a daily basis and we send it to a third party for calibration and certification on a year basis. We also have another set of weights (secondary) that we use only during the time when we send the primary set for calibration. My question is how often does the secondary set of weight need to be calibrated and certified?	Determined not to be an SIR.			NO further REVISION - added "weights" to list of support equipment in 5.5.13.1
378	5.5.13.1	d) Temperature measuring devices shall be calibrated or verified at least annually. Calibration or verification shall be performed using a recognized National Metrology Institute traceable reference, such as NIST, when available. Question: do reference thermometers need to be calibrated annually? These are traceable to NIST.	As long as the reference thermometer is not being used as a piece of support equipment such as described in 5.5.13.1 c, a reference thermometer is a reference standard as described in 5.6.3.1 and would need to be calibrated before and after any adjustment, and in accordance with the lab's documented procedure.			Drinking Water Cert manual requires calibration every 5 years. POSSIBLE REVISION
393	5.5.13.1	We have one set of weights (primary) that we use to check balances on a daily basis and we send it to a third party for calibration and certification on a year basis. We also have another set of weights (secondary) that we use only during the time when we send the primary set for calibration. My question is how often does the secondary set of weight need to be calibrated and certified?	Determined not to be an SIR.			See SIR 367

455	5.5.13.1	I have a question with respect to Class A volumetric labware made of HDPE and other plastics. I have read the TNI interpretation that only Class A glassware is exempt from verification, and that plastic volumetric labware requires verification. Would the certificate of analysis provided by the manufacturer be sufficient to document the confirmation to Class A or would each laboratory be required to perform the check inhouse on each lot prior to use? My thoughts are that the certification protocols performed by the manufacturer would be more accurate than the standard practices that laboratories currently use to verify Class A tolerance, and that the volume would not be subjected to changes during shipment as sterility potentially may be, which I believe was one of the driving factors in requiring labs to confirm product sterility for microbiology supplies that are certified as sterile by the manufacturer. Any information you can provide (or point me to) would be greatly appreciated.	Not an SIR			NO REVISION - 5.5.13.1.e.iv already states labs need to check before use

304	5.5.13.1.3	Volume 1, Module 2, Section 5.5.13.1.e states, "Volumetric dispensing devices (except Class A glassware and Glass microliter syringes) shall be checked for accuracy on a quarterly basis." Our laboratory analyzes VOCs in air, and uses gas tight syringes up to 100 mL to prepare gas standards. We are unsure of whether or not we must complete quarterly checks on these syringes. We're hesitant about using DI water to perform the quarterly checks on these syringes because they're used for preparing gas standards and we're unsure if moisture in the syringe would affect standard preparation. We're also unaware of how we could complete the quarterly checks using air. Our syringe vendor only offers a verification certificate for newly purchased syringes. For these reasons, it may be impractical to complete quarterly checks. As I understand it, glass microliter syringes do not require quarterly checks because they deliver such a small volume that a quarterly check would be impractical. Knowing this, if our 100 mL gastight syringes are similar in form (and from the same vendor) as our glass microliter syringes, would they require quarterly checks or not? At a minimum is there any documentation we'd have to have on file for the syringes?	If the syringe in question is neither Class A nor a glass microliter syringe, then it must be checked for accuracy on a quarterly basis. The laboratory must have documentation on file of this quarterly check.	This language is unchanged in the 2016 standard. The SIR is still valid.	there seems an obvious difference between a microliter and non-microliter syringe	REVISION - consider allowing gas syringes to forego quarterly verification.

415	5.5.13.1.3.ii	The standard clearly requires volumetric devices to be verified at least once per lot prior to use. A common example of the disposable single use device is the plastic digestion tubes. Would the manufacturer's LOT SPECIFIC certificate of accuracy suffice to meet this requirement, or is the laboratory obligated to repeat the work already done and verify the tubes again prior to use? (File uploaded: Lot 1904119 2019.09.pdf)	Determined not to be an SIR.			REVISE - consider adding a statement that manufacturer or lab can verify volume. *Find manufacturer volume verification to see if any specific items included need to be required if a lab is going to use manufacturer cert.