Quality Management System Expert Committee (QMS)
Meeting Summary

March 13, 2023

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by teleconference on March 13, 2023. Attendance is recorded in Attachment A – there were 12 voting members present. Associate members present: Lisa Parks, Rachel Van Exel, Sushmitha Reddy, Nicole Van Aken, Shannon Swantek, Kristin Brown, Brian Hulme, Linda O'Donnell, Kathleen Lloyd, Douglas Kablik, Tammy Kreutzer, Michelle Wade, Jessica Jensen, Alma McCammond, Cindy Redmond, Carol Barrick, Hong Yu, Ty Atkins, Carl Kircher, Debra Zeller, and Annmarie Beach.

2. SIR 453 – February 16, 2023

Debbie received SIR 453 from Lynn Bradley with an additional note from Maria Friedman:

"...the Standard is clear about calibrating a device, however the core issue seems to be what do we consider the "device" to be calibrated. The SIR submitter gives an example of a pipette that uses interchangeable tips. The pipette "device" itself cannot function without an attached tip, so I would consider the pipette + tip combination to be the "device" to be calibrated, in the same way that a digital thermometer with a detachable remote probe can only be calibrated when both the thermometer unit and probe are used together. My main take-away is that the device (pipette) should be calibrated the same way it is used, meaning, with tips, and bracketing volumes they dispense (whatever combination of settings and tips that requires). I don't think the Standard language is clear about that, so in this case I think this is a valid SIR.

The Committee discussed the information. Debbie asked if it would be appropriate to add Committee comments so it will be clear what the Committee is thinking on this. There was agreement and language was developed. Don't need to verify tips.

Response:

SIR 453

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.5.13.1 e) iii.
Describe the problem: The question relates to quarterly calibration verification of manual repeating pipettes where the settings on the mechanical device are (for example) 1-5 step-wise by 0.5, but these settings don't directly correlate to a volume dispensed. It is the choice of tip size used on the device that	

confers the volume dispensed based on a combination of the tip size and the selected setting on the device. (Here is an example device for reference - https://brandtech.com/product/handystep-repeating-pipettes/).

Is it sufficient to verify the calibration of the device using the range of SETTINGS on the device and one tip size, or does the range of VOLUMES measured with the device and it's multiple tip sizes need to be used instead (which would necessitate using multiple tip sizes and possible difficulty hitting the midpoint range of BOTH settings and volumes)? It is our thought process that using the range of volumes instead of the range of device settings would be verifying both the tips and the device calibration at the same time instead of just the device calibration, while using the device settings would be verifying the calibration of just the mechanical device itself, about which this section is referencing.

Committee Comments: The pipet device cannot function without a tip, so the range of use must be tested using whatever tip is necessary to accomplish the verification. A repeater pipet tip houses a plunger that is used to seal the tip. The actual air displacement to push the plunger is controlled by the pipet mechanism.
The standard is clear that the range of use of volume must be verified.

Response: The standard requires the range of volumes be verified, including the mid-point of volume of the range of use. An appropriate tip for the volume dispensed must be used to verify the device at the lowest volume, the largest volume, and mid-point volume in the range of use.

A motion was made by Kathi to approve the language above. The motion was seconded by Earl and there were no further comments:

Roll Call Vote:
Debbie - For
Kathi - For
Michael - For
Carla - For
Stephanie -For
Nick - For
Earl - For
Jenna - For
Amy - For
Ashley - For
Nicole – For

The motion was approved and Debbie will send this back to Lynn Bradley.

3. 4.13.3 – Language Workgroup

Debbie would like to talk more about “last use”. It was originally changed to “last use” because it might mean a DOC would not be kept. She talked to Robin Cook to get some feedback on small laboratory views. Kathi gave an example of a lab that was still using an old bottle of HCl for a titration, but they no longer had its certificate. This is why “last entry” could be a problem. Another example is method validation documentation.

This was discussed in the CSDP EC meeting last week. Maybe some records should just be kept longer than 5 years. Language could be added about maintaining method validation documentation for a longer period of time.

Nicole still thinks an iDOC is important because the criteria could be different than a continuing DOC. Jessica noted that if the person continues to pass the continuing criteria, why is the iDOC still important? Kathi thinks an expert witness would question the lack of iDOC documentation. Not everyone agreed with this.

A number of people remember being taught that iDOCs need to be maintained for all employees that were still employed. This was beyond the 5 years. This is not in the Standard. Perhaps it is an SIR? Ilona searched through the SIRs. She is mainly seeing questions about how to do DOCs. SIR 339 is a little related – if a lab has an iDOC for the method on file – can people do a continuing DOC and have it count as an iDOC. This doesn't answer the questions we are asking. Kathi suggested it might be in the DW Manual.

Ashley note that in Section1.6 in Asbestos testing it says that all demonstration data must be readily available at the laboratory. Needs to be on hand indefinitely. Is this in Module 2.

A decision on this will affect other TNI committees. Debbie still hesitates using "last use." She is thinking to get feedback from other committees. Ilona suggested talking to Chemistry first because there were some comments in the background of SIR 339 that noted that Chemistry is working on DOC language. Though keeping initial demonstration data is a given in other programs likes FIFRA and TSCA, it is not in our Standard.

No decision has been made. This will be further discussed.

4. Continued review of SIRs

She is skipping the SIRs related to Technical Manager at this time. The Committee will be looking at about 70 SIRs. As issues arise, the language will be sent to a Work Group to work on. Ilona will add SIRs sent in the last year for Debbie to add to the table.

Debbie started with SIR 13 (Section 4.13.2) to determine if any changes need to be made to the DRAFT Standard. She stopped after SIR 154 (Section 4.2.8.4.r). See Attachment B.

5. New Business

Debbie shared the possible schedule for the Summer meeting on screen.

6. Next Meeting and Close

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

Debbie adjourned the meeting at 2:14pm 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 **Absent**	SAW Environmental	2023*	Other	tfrancis@sawenviro.com
Carla McCord **Present**	Virginia	2025*	AB	carla.mccord@dgs.virginia.gov
Stephanie Atkins **Present**	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Present until 1:35pm**	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 Present **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
13	4.13.2	This section of the standard talks about observation, data and calculations recorded at the time they are made. Currently our lab has a policy in place to mark the preservation checks for each sample separately. Example a specific sample has a pH of less 2 and chlorine result of zero. Would it be sufficient to document the pH and chlorine checks by a general statement for example "all samples extracted in the batch had a pH less than 2 and chlorine result of zero"?	No. 5.4.12.2.1 requires observations to be recorded at the time they are made. 5.4.12.2.5.1 requires date/time of sampling to be recorded, so as to demonstrate compliance with holding times. 5.5.8.3.1(2) states the laboratory shall implement procedures for checking chemical preservation prior to or during sample preparation or analysis. 3(b) requires the results of these checks to be recorded. 5.5.8.3.1(d) (2) (iv) requires comments resulting from inspection for sample rejection to be linked to the laboratory ID code. So, the lab could, for example, use a check box on a sample receipt form to indicate a sample's preservation was checked and the result was less than 2 and chlorine was zero as long as the observation was unequivocally linked to each sample checked. The lab could not simply preprint this statement on an analytical report or document preservation after-the-fact in an extraction log because doing so would not comply with requirements to record observations at the time they are made and link the results of preservation checks unequivocally with sample identification numbers.	The 2009 and 2016 standards are virtually identical to 2003 Notes from ISO 17025 are now included but does not change the intent of the language.The SIR is still valid.	4.13.2.1 of ISO refers to retaining original records. One can't retain an original record if only a generic statement is made. 17025-2017 covers this in 7.5.1 (Original observations, data and calculations shall be recorded at the time they are made and shall be identifable with the specific task). I don't feel that this requires addressing in our revision.	committee agreement that this need not be addressed in revised Module 2
374	4.13.2.1	Under 4.13.2.1 the Standard states “The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail”. Should that be interpreted to mean that if you have a thermometer with a temperature correction factor that you would need to record both the originally observed temperature and the corrected temperature on a daily temperature check (ex. refrigerator).	Determined not to be an SIR.			No Revision needed

328	4.13.2.1 & 4.13.3.a	See Email for entire request - 1.5 pages. In conclusion, the generality of sections 4.13.2.1 and 4.13.3.a allows for unrestricted interpretation of what should be documented and traceable. We would therefore appreciate your assistance in clarifying traceability requirements for support equipment. Does TNI contend that all support equipment is required to be traced to individual results, or is there a distinction between analytical equipment, that is required to be traced to individual results, and support equipment, that is required to be calibrated and correctly maintained, but not necessarily traceable to individual results? If the former, then where exactly is the limitation on what is required to be traceable? It is our hope that TNI will consider a cost to benefit comparison in their deliberation on this SIR.	Original Final Response by QS on 10/20/18: Additional information - Support equipment verification requirements vary in their timeframes. Where something must be verified prior to each day of use, that verification would apply to any data from that day. Where the verification is prior to first use, then it would apply to any data associated with that use. The laboratory must retain all records necessary to establish an audit trail and allow the history of the samples to be followed through its documentation and records. To accomplish this, the laboratory must establish links to various activities such as equipment calibrations or verifications, standards source and preparation, sterilization checks etc. These links may or may not be in a single record – it is up to the laboratory to ensure that the record system design meets the audit trail and history requirements of 4.13.2.1 and 4.13.3.a. We have already exempted glass microliter syringes and Class A glassware from any ongoing verification. They must be verified prior to use. It stands to reason that they shouldn't need ongoing tracking in their usage, as we have said they don't need tracking.	4.13.3.a) The first sentence needs to be revised because it is used as a catch-all reference for non-conformances. A piece of support equipment may not have one audit-trail record. This should be clarified. If it could affect the result, it needs to be in the record. "links may or may not be in a single record".		No Revision needed beyond the Language Worgroup proposed revision of 4.13.3

433	4.13.3	Throughout the 2016 TNI Standard, and specifically within section V1M2: 4.13.3, the laboratory is required to produce, ensure, implement, etc. a system that produces records that document all laboratory activities, have documentation that allows historical reconstruction, etc. Labs are also required to have and maintain SOPs that meet all of the method and regulatory requirements as well as accurately reflect the laboratory's operations, and the analysts are required to read, understand, and follow their SOPs. Question: Is the laboratory required to have a record, that they fill out like a benchsheet or logbook (or whatever terminology the lab might use), electronic or hardcopy, where they document every step of the test or every action that is taken in the laboratory? Such as: - exact times of each step of a organics sample extraction - reaction times/wait times of a sample digestion or extraction - pH checks within a sample digestion/extraction (note, not a pH check for preservation acceptance purposes, but a pH adjustment that is required within a digestion/extraction step) Or, is having these times, steps, requirements, etc. listed in the SOP acceptable as part of the laboratory's proof of 'historical reconstruction' of all laboratory activities?	No, the laboratory is not required to have a record, that they fill out like a bench sheet or logbook (or whatever terminology the lab might use), electronic or hardcopy, where they document every step of the test or every action that is taken in the laboratory. Per TNI V1M2 4.13.3 f) ii, "...reference to the specific method used..." is part of the "information necessary for the historical reconstruction of data". A separate record is, however, required to record deviations from the SOP, per TNI V1M2 5.4.1 "...Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer." and TNI V1M2 5.10.3.1 "...test reports shall, where necessary for the interpretation of the test results, include the following: a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions".			Revise - Language Workgroup to review section f) before we propose to remove it. f) may help clarify this type of question or it maybe it needs additional items to help with interpretation?
366	4.13.3.f	On a recent internal audit, the QA Officer gave us a deficiency for not recording the cleaned dish drying times in and out of the oven or furnace for SM 2540 C, SM 2540 D and SM 2540 G analysis. The drying times and temperature of the oven and furnace are documented in the SOP. As this is part of the preparation of materials to be used for the analysis and not the actual analysis of the sample, is this considered a time critical step that	Determined not to be an SIR.			No Revision - ISO 17025:2017, 7.5.1 covers this adequately.

329	4.13.3.h	"...in the advent that the laboratory transfers ownership" Our laboratory is owned in shares (akin to stocks in publicly traded companies) where 2000 shares = 1% of the laboratory. If the company is owned in shares, during normal trading/sales of shares, is each sale of a share considered a transfer of	Determined not to be an SIR.	Consider re-wording h) so that labs are clear that the data may not just be disappeare		Revise - send this comment to Language Workgroup
70	4.14.1	This section deals with the annual Quality Audit. One sentence reads: "Such audits shall be carried out by trained and qualified personnel who are, whenever resources permit, independent of the activity to be audited." What is the meaning of "trained and qualified" as used in the sentence? Trained and qualified in environmental matters, auditing techniques etc?	Since "trained and qualified" is not defined, it would be up to the laboratory to state what their requirements are. It would be expected that the person performing the audit has a knowledge of the portion of laboratory operations that are being audited. NELAC 5.5.2.6 states that the lab management defines the minimal level of qualifications for all positions.	This language is unchanged in the 2009 and 2016 standards. The SIR is still valid.	17025-2017 covers this in 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.) I don't feel that this requires addressing in our revision.	No Revision - ISO 17025:2017, 6.2.3
108	4.14.1	In the description of internal audits, it states "The internal audit program shall address all elements of the quality system, including the environmental testing activities." Does this mean that every method has to be audited yearly? For Labs that are running 300 or more methods this doesn't seem reasonable.	see 308			see 308
230	4.14.1	The standard states that "The internal audit program shall address all elements of the quality system, including the environmental testing activities." We are unclear as to what is expected in reference to "Environmental Testing Activities." For example, if we have 10 methods used for environmental testing are we required to audit each of those specific test methods yearly, or is acceptable to audit the laboratory as a whole is operating under the quality system.	see 308			see 308

308	4.14.1	Per Clause 4.14.1, the internal audit program shall address all elements of the management system, including the testing and/or calibration activities. It is unclear if all test methods need to be audited annually since 4.14 never uses the word "methods" but rather "areas" or "activities". Can the test methods be grouped by technology (i.e. GC/MS, ICP/MS, ICP, Spectrophotometry, Gravimetry, Meters, Titrimetry, SFIA, etc.) or does every method have to be audited annually? If grouped by technology, can different test methods within each technology be scheduled annually? The schedule beyond one year	No, not every method needs to be assessed annually in the laboratory's internal audits. Yes, different methods within each technology may be assessed on an annual basis.			Revise - Language workgroup is working on this section
64	4.2.8.1	This standard calls for "3) in-depth, periodic monitoring of data integrity". What is TNI's interpretation of "periodic"? ELAP suggested "Each calendar quarter the QAO audits 5 % or 5 data packages, which ever is more" in the DI plan template we provide to labs. However, the monitoring should be dependent upon the lab's scope (chemistry, microbiology, asbestos) and workload (number of samples analyzed). Does TNI leave it up to the lab to decide at what frequency they perform the monitoring?	There is no definition of periodic. The laboratory must clarify its intentions for complying with this requirement in the QAM or elsewhere. If the laboratory hasn't defined its requirements sufficiently, it could be cited for failure to comply with this section.	The 2009 and 2016 standards contain the identical language. The SIR is still valid.	address	Revise - The committee agrees that this needs to be addressed for clarity in Module 2
154	4.2.8.4.r	If a lab's QAM defined "signature" on technical records, reports and chain of custodies as the hand written signature or electronic equivalent, would this meet the signature requirement for each of these documents? As we upgrade our LIMS and QC software, we have the ability to electronically sign off on chains and lab documents but want to know if this would be acceptable.	Electronic signatures are acceptable (see references above) provided that the signature is unique to the individual. Some states may have regulatory requirements pertaining to the use of electronic signatures. The laboratory should ensure that state requirements are met.			No Revision - ISO 17025:2017, 7.5 and 7.8 cover identify who did what