

**Quality System Expert Committee (QS)
Meeting Summary**

November 8, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by webinar on November 8, 2021. Attendance is recorded in Attachment A – there were 11 members present. Associate Members present: Carl Kircher, Michelle Wade, Jeanette Hernandez, Kelvin Yuen, Tina Buttermore, Renee Jernigan, Tom Widera, Karina Blanton, Kristin Brown, Carol Barrick, Halley Hastings, Karna Holquist, Patty Carvajal, Chris Gunning, Joe Manzela, Carla McCord, Kathleen Lloyd, and Ty Atkins.

There were not enough voting members available to do any business in October, so the September and October minutes need to be reviewed and voted on. Lizbeth was present in October and Nicole was not. Ilona will recheck the October attendance and update if needed.

A motion was made by Nicole to approve the September 13, 2021 minutes as written. The motion was seconded by Lizbeth and unanimously approved.

2. SIR 412

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M2
Section (eg. C.4.1.7.4)	5.6.4.2.c
Describe the problem: 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?	

Comments: A laboratory may choose to assign an additional identifier to purchased standards, reference materials, and reagents. However, this additional identifier would be required to link to the unique ID or lot number assigned at the time of preparation. The use of the solvent at analysis requires that all information necessary for the historical reconstruction of the data be available (see 4.13.3.f).

Response: For the example given, no. 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. Additionally, the unique identifier requirement refers to the content(s) of the container rather than the container itself. Section 5.6.4.2 does not limit storage of a preparation to a single container, therefore multiple containers may be used to store the same content produced from the same creation event under a single unique identifier.

The response above was developed at the October meeting and Debbie sent the response for email comment. Debbie reviewed the comments verbally that came in through email.

There was a comment about just responding to the question asked. Change the first sentence and delete everything after “Additionally ...”.

After further discussion, the language was changed to:

Comments: A laboratory may choose to assign an additional identifier to purchased standards, reference materials, and reagents. However, this additional identifier would be required to link to the unique ID or lot number assigned at the time of preparation. The use of the solvent at analysis requires that all information necessary for the historical reconstruction of the data be available (see 4.13.3.f).

Response: 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.

A motion was made by Ashley to approve the language above. The motion was seconded by Nicole and there was no further discussion.

Since Amber’s sound was having an issue, she could not vote. Kathy added in after the vote. The vote will be re-done by email to obtain a 2/3 vote.

(Addition:

Nicole motioned by email on 11/12/21 to approve the language for SIR 412 as discussed during the 11/8/21 meeting. The motion was seconded by Amy (11/12/21) and there was no further discussion.

Votes:

Tony – For (11/12/21)

Michael – Against (11/12/21)

Debbie – For (11/12/21)

Lizabeth – For (11/12/21)

Bill – Against (11/12/21)

Stephanie – For (11/12/21)

Ashley – For (11/15/21)

Earl – For (email 11/12)

Nick – For (email 11/16)

Alyssa – For (email 11/16)

Kathi – For (email 11/17)

Amber – For (email 11/18)

Jenna – Against (email 11/18)

The motion passed and Debbie sent the response to Lynn Bradley and the LASEC.)

Ilona found a comment from Patty in Chat:

Some ABs will interpret the standard as written. Which means some will require each container be uniquely identified.

3. 17025 Crosswalk

It has been awhile since the ISO/IEC 17025 Crosswalk has been looked at by the full committee. The updates are being done by a Workgroup that meets each month.

Debbie started with Section 4. She shared the document on Webex and reviewed the changes.

Carl asked about Section 4.13.2.3. The Workgroup thinks this language can be dropped because the new language covers electronic records better. Carl was curious about the final language and will be watching this one.

Jenna noted that the old language requires that changes need to be initialed and dated, but new language states the person making the change needs to be identified. She was curious if that means someone can state that another person made the change. Suggested that this be looked at closely. Debbie added a note to the table.

The Committee ended after completing Section 4.15.2. Section 5 will be reviewed at the December meeting.

4. SIR 416

Debbie wanted to note that SIR 416 was sent back for some rewording after it was approved in September. Debbie worked on this through email and did an email vote to approve the revised language.

Committee Comments: The intent is to ensure that there is an unbroken chain of records allowing the metrological traceability to be readily understood. The chain of references can be as extensive as necessary, and the laboratory needs to be able to access the records at least for the minimum required retention time and explain how to trace the information from one record to another, if asked.

Response: 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.

Voting Results:

A motion was made by email on 9/16/21 by Nicole Cairns to approve the revised language (above) in response to SIR 416. The motion was seconded by email on 9/16/21 by Amy Schreader. There was no further discussion.

Vote:

Earl – For (Email 9/16/21)

Debbie – For (Email 9/16/21)

Lizbeth – For (Email 9/16/21)

Amy – For (Email 9/16/21)

Kathi - For (Email 9/16/21)

Tony - For (Email 9/16/21)

Alyssa - For (Email 9/17/21)

Amber - For (Email 9/17/21)

Michael - For (Email 9/17/21)

Jenna - For (Email 9/17/21)

Stephanie - For (Email 9/20/21)

The motion was approved by 2/3 of the Committee.

5. New Business

No new business.

6. Next Meeting and Close

The next regular meeting will be on December 13, 2021 at 1pm Eastern by teleconference.

Debbie adjourned the meeting at 2:21pm 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 Gumper (Vice-Chair) Present – Added 1:37	ChemVal Consulting	2024	Other	kgumper@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@dhsosha.state.or.us
Stephanie Atkins Present	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 Present – sound issue.	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