Quality System Expert Committee (QS)
Meeting Summary

October 11, 2021

1. Roll Call:

Debbie Bond, Chair, called the meeting to order at 1pm Eastern by webinar on September 13, 2021. Attendance is recorded in Attachment A – there were x members present. Associate Members present: Paul Junio (only on phone), Carl Kircher (joined 1:22 Eastern – only on phone),

There were not enough voting members available to do any business today. The minutes will be reviewed and approved during the November meeting.

Debbie would like everyone to complete their Committee training by the end of October.

2. SIR 412

Debbie decided to have an informal discussion to continue the conversation started by email.

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?

Debbie received the following from Lynn Bradley, Program Administrator for LASEC:

Response: The use of the solvent at analysis requires that all data necessary for the historical reconstruction of the data be available (see 4.13.3 f). The lot number is created at a point in time when the reagent, standard or material is prepared and is unique to that preparation. Housing the prepared standard, reference material, and reagent in multiple containers does not require assigning each container a unique ID, but they must each bear the assigned identifier of the preparation.

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: The lot number is a unique ID for a preparation of purchased reagents. No additional unique identifier is required. Housing the prepared standard, reference material, or reagent in multiple containers does not require assigning each container a unique ID. Section 5.6.4.2.d does require that each container bear the unique identifier.

As of September 28, we have 5 "against" votes on this SIR – enough that it cannot pass. Please revise the response to address the comments, which are as follows:

- What does this mean? "but they must each bear the assigned identifier of the preparation." You want the preparer of a purchased solvent listed?
- The Lot number is for that specific group of 4 bottles, but if they go to four different areas of the lab, using one unique identifier would not prove logical. All four could be handled in totally different manners. This is too vague to address that scenario.
- The Lot number is for that specific group of 4 bottles, but if they go to four different areas of the lab, using one unique identifier would not prove logical. All four could be handled in totally different manners. This is too vague to address that scenario.
- Agree with the sentiment [the answer is "no"] and agree with the comments that the final phrase [as well as the first sentence] of the response is confusing and starts to mettle into what someone thinks the lab's 'system' is. Simplify the answer to prevent further confusion.
- needs to be reworded; is confusing as written.

Email Input:

Nicole (10/8/21):
I will not be on the call on Monday, but I wanted to provide some feedback on SIR 412.

As I believe we discussed previously, clause d) refers to "prepared" standards, reference materials, and reagents, NOT original containers provided by the manufacturer. In fact, clause b) states to use the expiration date on the original container and if one is not provided on the original container than one is not required. Therefore, if clause d) is now applied to original containers it will be in direct conflict as clause d) requires an expiration date no matter what. In addition, the previous clause c) is all about what needs to be included in preparation records and discusses traceability to purchased materials. This clause is then followed by clause d) which provides the requirements for the containers of these prepared items.

I think it might be easier to respond to this SIR with this concept of original container vs. container used to hold a prepared item. I've provided a simple draft response for discussion.

"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."

I disagree with the comment that if 4 bottles of solvent received under one Lot are sent to different areas of the lab that they need unique identifiers. I don't see that requirement in 5.6.4.2.

TNI V1M2
5.6.4.2 Documentation and Labeling of Standards, Reagents, and Reference Materials

Documented procedures shall exist for the purchase, receipt and storage of consumable materials used for the technical operations of the laboratory.
a) The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.
b) For original containers, if an expiration date is provided by the manufacturer or vendor, it shall be recorded on the container. If an expiration date is not provided by the manufacturer or vendor, it is not required.
c) 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.
d) All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date.
e) Procedures shall be in place to ensure prepared reagents meet the requirements of the method.
f) Standards, reference materials, and reagents shall not be used after their expiration dates unless their reliability is verified by the laboratory.

From Robert Waite (10/8/21):

I agree with Nicole on the argument the solvent received under one Lot are sent to different areas of the lab that they need unique identifiers is not a requirement of 5.6.4.2.

This is a little long so allow me to send my thoughts to the group in this email.

"All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date."

To me the question is, "unique identifier" of what? Is it the container(s) or the content(s) within the container(s)? At first the mind naturally focuses on unique identifier of the containers because the sentence starts out talking about containers. The "expiration date" in the requirement adds clarification that the standard is actually talking about contents rather than containers related to the unique ID. Containers generally don't expire, but content does. So weather the content(s) upon creation are aliquoted into a single container or multiple containers it's still the same content. The "unique identifier" is the tie to the content's creation and those associated records.

If we come at it with this perspective it really does not matter if we are talking about an internally created standard, a purchased standard, or bottles of a purchased reagent. The requirement is to uniquely identify the content(s)/creation. If the content of a container is the same from container-to-container for multiple containers as evidenced by them all have the same lot number (however named) then the "unique identifier" requirement is met with the lot number or with a uniquely generate lab ID tied to its specific creation or lot.

So my suggestion for a response is something like: "*The unique identifier requirement refers to the content(s) of the container rather then the container itself. 5.6.4.2(d) does not differentiate between content created internally within the laboratory or content purchased. Section 5.6.4.2 however does not prohibit storage of specific content(s) 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 unique identifier used must be traceable back to the information specified in 5.6.4.2(b) or to 5.6.4.2(c) as applicable."

From Tina Buttermore (10/8/21):
My only suggestion is to keep a reference to the historical reconstruction of data requirement in the response as a reminder that the requirements of that standard must still be met. Consider dehydrated micro media where the expiration date changes with the date opened. If multiple containers are received given the same lot number but opened on different dates you'd still need to be able to trace to different expiration dates. Most labs would do that by assigning unique IDs to each container. I think keeping that caveat regardless of the rest of the response does no harm and may prevent some confusion.

The Committee started working on a reply that combines what Nicole and Robert suggested.

Carl expressed some concerns that other modules might have conflicts with what is being worked on, but Paul pointed out that those other sections clearly state their requirements for their special circumstances so that those procedures are followed.

John Gumper – Not an issue with Radiochemistry. Has to do with when it was certified and not when it was opened.

The response in yellow above has been changed to:

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 comments in yellow will stay as they are.

Debbie will send this out by email to the voting members to vote. If she gets lots of comments back back from the voting members she will hold off and revisit this during the November meeting.

Debbie would like everyone to complete their Committee training by the end of October.

3. New Business

No new business.

4. Next Meeting and Close

The next regular meeting will be on November 8, 2021 at 1pm Eastern by teleconference.

Debbie adjourned the meeting at 1:39pm 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) **Absent**	ChemVal Consulting	2024	Other	kgumpper@chemval.com
Nicole Cairns **Present – 1:20pm Eastern**	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 **Absent**	Oregon Dept. of Environmental Quality	2022	Accrediting Body	LIZBETH.GARCIA@dhsoha.state.or.us
Stephanie Atkins **Present**	Pace Analytical	2024*	Lab	stephanie.atkins@pacelabs.com
Nicholas Slawson **Absent**	A2LA	2023*	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
William Ray **Absent**	William Ray Consulting	2023	Other	Bill_Ray@williamrayllc.com
Amber Ross **Present**	PA DEP/Bureau of Laboratories	2022*	AB	ambross@pa.gov
Amy Schreader **Absent**	UC Laboratory	2024*	Lab	amy@uclaboratory.net
Alyssa Wingard **Present**	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