Quality System Expert Committee (QS) Meeting Summary

September 13, 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 8 members present. Associate Members present: Brian Lamarsh, Carla McCord, Cindy Redmond, Debra Zeller, Douglas Kablik, Elizabeth Turner, Halley Hastings, Jeanette Hernandez, Joe Manzella, Karina Blanton, Karna Holquist, Kelvin Yuen, Kristin Brown, Linda O'donnell, Michelle Wade, Paul Junio, Rachel Van Exel, Renee Jernigan, Robert Waite, Tiffany Shaw, Ty Atkins, and Carl Kircher.

Intitially there were not enough voting members present to do Committee business and the group decided to cancel the meeting, but Nicole added in at 1:20pm Eastern so the Committee did decide to still review and vote on the minutes and SIR 416 before ending the meeting.

The July and August minutes were distributed by email and reviewed on Webex. Earl made a motion to approve the July 12, 2021 and August 9, 2021 minutes as written. The motion was seconded by Ashley. There was no further discussion and the motion passed.

2. SIR 416

SIR 416 was discussed by email and Kathi made some suggested changes. The Committee reviewed these changes and provided the response in the table below.

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 expiration date and "reference to" preparer's initials?

Committee Comments: The standard does not state a requirement for a single record. 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: 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.

A motion was made by Earl to approve the Response in the table above. The motion was seconded by Nicole and there was no further discussion. The motion was unanimously approved. Debbie will forward the response to Lynn Bradley, Program Administrator for LASEC.

3. New Business

No new business.

4. Next Meeting and Close

The next regular meeting will be on October 11, 2021 at 1pm Eastern by teleconference.

Debbie adjourned the meeting at 1:32pm Eastern.

Attachment A

Participants Quality Systems Expert Committee (QS)

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