The NELAC Institute (TNI) Quality Systems for Radiochemistry Expert Committee Meeting Minutes

The Quality Systems for Radiochemistry Expert Committee of The NELAC Institute (TNI) met on November 29, 2012 via teleconference.

The committee meeting began at 11/29/2012 at 2:00 ET.

Participants:

Committee Members: Bob Shannon, Sreenivas Komanduri, Dave Fauth, Carolyn Wong, Todd Hardt, and Larry Penfold.

Associates: Joe Pardue

The agenda was distributed by email along with the following documents:

1. The NELAC Institute (TNI) Quality Systems for Radiochemistry Expert Committee Meeting Minutes (9/28/12)
    a. Attachment 1 – Decision Making Rules for Quality Systems for Radiochemistry Committee - as Considered and Adopted on 10/26/2012 Committee Conference Call
    b. Attachment 2 – Minutes from Past Meetings – As considered and adopted in the October 26, 2012 Committee Conference Call
    c. Attachment 3 - Minutes from the September 28, 2012 Meeting – As considered and adopted on the October 26, 2012 Committee Conference Call

The meeting was called to order.

Bob indicated that our first working meeting will be at the NELAC Meeting in Denver the week of January 14. The meeting time January 16, 2013 at 1:30 pm (all afternoon). All committee members should respond to Bob to let him know whether they will be attending the meeting or not. If they cannot attend, they should indicate whether they will be able to participate via teleconference.

The minutes from the previous meeting were approved by email vote of the committee *(Yes 9; No 0; Abstain 0; Associate negative 0)*

Attachment 2 – Final Minutes of 10/29/2012 Teleconference

Bob will send out an email looking for a regular time for our meetings beginning January 2013. Consistent with the last several meetings, he will be targeting the fourth week of each month. Please respond to him as soon as you get this email.

Batching

The committee continued the previous meeting's discussion on batching. Bob pointed out that this requirement does not just affect small labs, but it affects every lab for tests that they perform infrequently. He reported that he has discussed the topic with quite a few people and does not sense much support for redefining the batch concept. He also consistently hears concerns about lowering the bar for quality. He believes that there is utility in providing clarification about what to do when resources limit the number of samples that can be simultaneously processed so that the integrity of the QC batch is preserved. Vas indicated that labs need to maintain adequate resources for processing samples for tests they intend to run so that they can comply with the limitations of the 24-hour batch requirement. Carolyn mentioned that we could provide clarification for necessary exceptions. Other committee menbers indicated that they agreed with previous comments. Since Tom Semkow and other committee members were not present, Bob noted that he planned to vote by email on the following questions:

1) Should the committee strive to redefine “batch” from the current NELAC definition

2) Is the committee open to adding clarifying language to the standard that addresses how batches can be managed to ensure the integrity of batch QC relationships *(this assumes that someone is willing to put something in front of the group)*.

There was limited discussion on work cell concept (multiple step/multiple analyst) DOC process that was in the 2003 standard. Larry provided context on this. This concept was dropped because the analyst qualification process that resulted was overly complicated and personnel changes required qualification of numerous, complex constellations of analysts. There was not much added value over requiring all analysts who work on samples to be qualified individually.

Section 1.5 Method Validation and Section 1.6 Determination of Capability

Discussion began covering the 2012 draft and the August 24 group comments. It was agreed that we will maintain the format of referencing other sections of the standard whenever we can to maintain continuity. Bob will also bring the issue up with the TNI Consensus Standards Development Executive Committee since the current system of referring to a second section only to refer to a third section are not very "customer friendly" and could be quite confusing to auditors and labs.

Comments on Section 1.5.

- Section 1.5.2
    - Recognize different requirements, radiochemistry versus, drinking water act, non-radiometric methods
        - The section currently addresses MDA and SDWA MDL
        - Need to add critical level
            - Need to specifically address what validation is required to include:
                - absolute bias at background
                - relative bias at MDC?
                - relative bias at higher levels surrounding levels where decisions will be made
                - combined standard uncertainty

        - For radionuclides measured by non-radiometric methods where results will be censored
            - need to add a statement that points to Module 4 for determining detection capability and validation
            - Add the critical level
    - Determination of Capability (DoC) is addressed in 1.6 and refers to initial and periodic certification process for each analyst that will run a method
        - Section 1.6 should apply to blanks and spiked blanks
- Carolyn will work on updated language to address sections 1.5 (and related sections of 1.6). We will circulate this via email for comments and discuss on a future conferernce call once it has reached a reasonably stable form.
    - The table on method validation requirements that Carolyn submitted (see Collected Comments document line 135-136) should be included. After some discussion, it was agreed that the table should be in section 1.6.
    - Section 1.5.1.c refers to Module 5.4.5
    - Expand to address validation

    [RTS Note: right now there is more in detail 1.6 than in 1.5 even though some of it belongs in 1.5]

Our next meeting will be December 11 at 2:00 ET. We will begin at Section 1.6 of the Module 6.

The meeting adjourned at 3:09 PM ET.

Committee Action Items

Send out email to vote on batching questions	Bob
Vote on batching questions before next meeting	Committee
Re-word Section 1.5 (and possibly 1.6)	Carolyn
Send out email asking for feedback on regular meeting day/time	Bob
Respond to Bob about regular date/time for our meeting	Committee
Send out email asking who is attending Denver NELAC Meeting or not	Bob
Respond to Bob on January NELAC Conference	Committee
(if not attending, indicate if you would be available for teleconference)	

Respectfully submitted,

David Fauth

Attachment 3: Summary of Voting on Batching Questions

From: Bob Shannon [mailto:bobshannon@boreal.org]
Sent: Thursday, December 13, 2012 2:43 PM
To: BobShannon@boreal.org
Subject: Results of Email Votes about Batching

To all:

Here are the results of the two votes about batching.

1) Should the committee strive to redefine "batch" from the current NELAC definition?

Affirmative: 1
Negative: 10
Abstain: 1

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2) Is the committee are open to adding clarifying language to the standard that addresses how batches can be managed to ensure the integrity of batch QC relationships *(this assumes that someone is willing to put something in front of the group)*?

Affirmative: 8
Negative: 1
Abstain: 3

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Accordingly, if anyone has good ideas on how to clarify what constitutes apprproaite handling of a batch (when can steps be broken out and what is the line beyond which a group of samples is no longer being handled as a batch). Consider that I think we will be able to revisit some of this issue again when we get to QC. Gamma spec, especially, comes to mind. Anything you have, please send to me and we will circulate via email. If we get something that looks like it will get consensus, we can then discuss on a conference call.

Best regards,

Bob Shannon
QRS
218-387-1100