HASQARD Focus Group
Meeting Minutes
August 20, 2013

The meeting was called to order by Huei Meznarich, HASQARD Focus Group Chair at 2:05 PM on August 20, 2013 in Conference Room 308 at 2420 Stevens.

Those attending were: Huei Meznarich (Focus Group Chair), Cliff Watkins (Focus Group Secretary), Taffy Almeida, Glen Clark, Robert Elkins, Scot Fitzgerald, Joan Kessner, Steve Smith, Rich Weiss and Eric Wyse.

I. Huei Meznarich asked if there were any comments on the minutes from the July 23, 2013 meeting. No Focus Group members stated they had comments on the July meeting minutes and, after hearing a motion and second for approval, the minutes were approved.

II. A discussion of the latest efforts to complete Revision 4 of HASQARD Volume 1 was held:

a. After the July meeting, Rich Weiss had taken an action to address comments on his proposed revision to Section 4. Rich provided his proposals to address the comments received. The proposed comments resolutions included:

A paragraph that had been proposed for deletion was retained to say: "HASQARD recognizes that if a consensus standard or standard method is written in a way that it can be used as published by the operating staff in a laboratory, it does not need to be rewritten as an internal procedure. However, it requires the same procedural approval process as normally implemented in the laboratory."

The relationship of this section to research and development (R&D) activities that are under the purview of the HASQARD scope was discussed. Eric Wyse asked whether it is possible some organizations are conducting R&D without specific procedure or documentation. Taffy Almeida stated that in the case of PNNL, they typically have approved test plans under which they conduct R&D. Therefore, the intent of the language in the section should be able to be met by R&D organizations.

Rich added the applicable references to the Washington Administrative Code for when a method defined parameter must be determined using a method specified by regulation.

The Focus Group agreed to add text concerning

"method-defined-parameters" to the Method Modification section of Section 4 of Volume 1 to clearly identify the methods that are relevant to the discussion and define what is meant by "modification." Rich Weiss will add a few sentences to address identification of deviation for the non-method-defined-parameters method, such as omission or addition of hydrogen peroxide during sample digestion. Rich would also like to add language to this section stating that when a referenced method is used "as published" but the laboratory revises something relatively minor (e.g., the reagents used) the scope of the changes needs to be discussed in the procedure. As another example, if the amount of sample used is different than as published, it is not an issue unless the ratios of sample to reagents used in digesting the sample are not held consistent with the method.

b. After discussing the revisions Rich made to Section 4 as a result of actions received at the July meeting, the Focus Group picked up review where they left off at the end of the July meeting, in Section 6. In discussing the proposed language for revising procedures, Eric Wyse provided input from recent inquiries he has made regarding the document control practices in place at the various Hanford Contractors. Eric's concern has been language n HASQARD that states: "Revisions to instructions, procedures, and drawings that affect the process or are technical in nature shall receive the same level of review and approval as the original document." Eric stated that document control procedures among the Hanford contractors do not require a review unless the scope of the procedure has changed. Therefore, many revisions that would not be considered only editorial, and could be interpreted as to applicable to the HASQARD language of "affect the process or are technical in nature," are not required to be reviewed by all organizations that were originally required to conduct the review. As a result of this discussion, the sentence in HASQARD was revised to say, "Revisions to instructions, procedures, and drawings that affect the process or are technical in nature shall receive a documented level of review by impacted organizations to ensure that that the changes are appropriate."

c. The Focus Group reviewed Section 7, "Software Systems Quality Assurance" and saw that there were no changes tracked in this section indicating no changes had been made. Steve Smith indicated that this section should have some new requirements and asked if the new write-up was available. The file was not available at the meeting. The Secretary took an action to find the file and send the revised Section 7 out for separate review and comment via e-mail submittals to the Secretary. Steve Smith stated he would also look for the file to ensure the Secretary distributed the correct version for review.

d. The Focus Group reviewed Section 8.0 and had no comments. A new Section 8.1 was added by the QA Working Group titled, "Contract

Review." The Focus Group discussed what the Section was aimed at. The on-site laboratories are not under contract so it was not clear if this section was applicable or even appropriate from the view of the on-site laboratory participants. Other members of the Focus Group expressed the opinion that because there is some type of work order given to on-site laboratories that serves the purpose of a client/laboratory contract, this section was applicable. The title of the Section was revised to, "Review of Requests, Tenders and Contracts." Another point of confusion was whether this section was specifying requirements for laboratories that are subcontracting work to other laboratories. The proposed section includes a sentence saying, "The review shall cover any work that is subcontracted by the laboratory." Several members of the Focus Group felt this sentence meant that if any laboratory received a work order from a client and could not do all the work and some scope would have to be subcontracted, the review of requirements in the original work order needed to be reviewed to ensure appropriate flow-down to the subcontracted laboratory. After discussion, Rich Weiss felt that this section did not fit in the "Procurement" section and should be its own stand-alone section of Volume 1. The members present pointed out that this section is a stand-alone Section in the ISO 17025 standard. The Secretary took the action to move the proposed wording from Section 8.1 in the draft being reviewed to its own Section.

e.   The Focus Group reviewed Sections 9, 10 and 11 with no comments to the proposed revisions to these sections. Section 12 of Volume 1, Rev. 3 is titled "Clarifications and Interpretations." This section is currently empty. The Focus Group recognized that the process for clarifications and interpretations in HASQARD is now done using the deminimus process and the HASQARD web site. There was no suggestion to add language explaining this fact in Section 12. Rather, the Focus Group members present suggested this Section be deleted entirely.

III.   A discussion of the latest efforts to complete Revision 4 of HASQARD Volume 4 was held:

a.   There were two comments remaining in the Volume 4 working copy that required final review once a draft-final version of Volumes 1 and 2 was available. The first action was to ensure the required elements to be provided on a chain of custody form was consistent between the language in Volume 2 and Volume 4. The Focus Group concurred that this was the case and the comment was deleted. The second remaining action for Volume 4 involved Section 5.1 "Data Collection." The draft of Section 5.1 had a place holder comment stating it needed to be reconciled against the final language the Focus Group concurred with in Volume 1, Section 6.3.3, "Notebooks/Logbooks." Rich Weiss accepted an action to propose

language for Volume 4, Section 5.1 that will ensure its consistency with Volume 1.

The Focus Group Chair asked if the remaining reviews should be done over the next month months via e-mail communications rather than holding a Focus Group meeting in September. The membership agreed with this approach and committed to discussing any comments that could not be resolved via e-mail communications at a meeting in October. Even if comments are successfully addressed via email communications, a meeting will be held in October to identify any new business and discuss the process for technical editing and final review of Revision 4 to HASQARD. With these agreements in place, the Chair suggested that the meeting be adjourned. Hearing no objections, the Chair adjourned the meeting at 4:05 PM.

The next meeting is scheduled for October 15, 2013 at 2:00 PM in 2420 Stevens, Room 308.