

HASQARD Focus Group

Meeting Minutes

October 15, 2013

The meeting was called to order by Huei Meznarich, HASQARD Focus Group Chair at 2:05 PM on October 15, 2013 in Conference Room 308 at 2420 Stevens.

Those attending were: Huei Meznarich (Focus Group Chair), Cliff Watkins (Focus Group Secretary), Lynn Albin, Taffy Almeida, Glen Clark, Robert Elkins, Mary McCormick-Barger, Noe'l Smith-Jackson, Chris Sutton, Amanda Tuttle, Rick Warriner, Rich Weiss and Eric Wyse.

- I. Huei Meznarich asked if there were any comments on the minutes from the August 20, 2013 meeting. No Focus Group members stated they had comments on the August 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. In the August meeting the fact that 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 was discussed. One of the remaining actions 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, "Data Collection" that will ensure its consistency with Volume 1. This language was presented by Rich. The resolution was to minimize the specification of requirements for completion of logbooks in Volume 4, Section 5.1 and retain the language proposed in Volume 1, Section 6.3.3. In addition, the Focus Group agreed to move a sentence from Volume 4, Section 5.1 that said, "Electronic notebooks are permitted and shall meet the same requirements for change protection and controls as hand-written hardcopy notebooks" to Volume 1, Section 6.3.3. The text of Volume 4, Section 5.1 will now read:

"Raw data includes all parameters used to calculate a final reportable result. Raw data can be generated by manual and/or electronic means. Manual data generation shall be collected and recorded by the analyst according to applicable procedures. Many analytical instruments are interfaced with computers and/or integrators and are able to generate or reduce the raw data into reportable results."

Observations, records and results recorded by the laboratory shall be on pre-printed forms, electronic media, or entered into permanent laboratory logbooks. Entries into logbooks shall be made in a manner such that they can be easily read, understood, and reproduced with a standard photocopier.

Raw data output shall be retained as a part of the records (see Volume 1, Chapter 6.0). Sufficient raw data should be retained to allow reconstruction of the analytical run. Information on date of sample collection, sample preparation, and analysis run; sample identification numbers; analyst or instrument operator; instrument identification and operating parameters; type of analysis; and procedure number, including revision number, shall be traceable to the raw data output.”

At the August meeting of the Focus Group, Rich Weiss accepted an action to provide additional language regarding when a method has been “modified” to the point it must be documented in procedures, approved, etc. Rich provided a proposed revision to Section 4.5 to attempt to address the method modification for the methods that are not required for method-defined parameters. The term “modified method” caused some confusion. The discussion held focused on the confusion the Focus Group had concerning the terminology used in Section 4.5, 4.6 and 4.7. Of specific concern were the terms “modification” and “qualification.” The term qualification is defined in the HASQARD document but the term modification is not well defined for the methods that are not in the category of the method-defined-parameters (identified in Section 4.7). Also of concern is how much documentation is required when a method is modified and in which instances that documentation is required or when a modification is so minor it need not be documented. Rich stated that he acknowledges that even in the proposed language he provided, we still do not have a definition of the term “modified method” that everyone can accept. The intent of the language he provided was to say that if you deviate from the performance parameters specified in published methods as a result of a modification, the method has been modified. If the performance parameters can still be met with minor adjustments from the published method (e.g., which solvents or reagents are used), then identifying the changes in the laboratory procedure and with qualification is sufficient.

The Focus Group agreed to add the word of “Procedure” to the title of Section 4.6, “Qualification of Method” making the title “Qualification of Method/Procedure.”

Eric Wyse suggested that perhaps a greater frequency of meetings is necessary until this issue of method modification can be resolved to everyone’s satisfaction.

The fact that method modification has a regulator acceptance connotation was discussed. Glen Clark requested input from Ecology on the appropriate use of the words “method modification or modified method.” Noe’l Smith–Jackson stated that the HASQARD document is the work of the Focus Group not Ecology and that everything concerning method modification in Revision 3 of HASQARD was acceptable to Ecology. She also indicated Ecology will review and comment on any of proposed revision to the language on this subject.

Rich Weiss pointed out that Revision 3 of HASQARD had details on modification, deviation and substitution of methods. Deviation and substitution have been proposed for elimination from Revision 4 because the definitions were too specific and did not add value. The concepts are all still retained in the proposed relevant sections in Revision 4. Rich has tried to propose language concerning these concepts that is agreeable to all. This is difficult because the word “modification” has a certain amount of “baggage” associated with it. Therefore, if the words “modification of regulatory method” are used in the proposals for Revision 4 of HASQARD, all of the baggage associated with the term comes with it. Rich believes that we cannot get something that is “perfect” on the subject of method modification in HASQARD without writing something so prescriptive that it has unintended implications.

Huei Meznarich provided some clarification about the use of the term modification. Modification has not been removed from the proposed revision to Volume 1. In the proposed revision, modification is used only when discussing methods used for analysis of “method-defined-parameters” in the proposed language used in Volume 1, Section 4.7. Definitions for method-defined-parameters, modification, and the specific requirements for when the term modification is applicable for these method-defined-parameters are provided in Section 4.7.

The Chair also recommended replacing the term “regulatory method” in Section 4.7 with the term “method-defined-parameters” to eliminate confusion about which actions need to be taken when a modification is applied to the method-defined-parameter or to the regulatory method (e.g., SW-846).

With some proposed new language, but no final resolution on the matter, the Focus Group agreed to address this issue again at an upcoming meeting.

- b. The Focus Group had received the latest draft of Section 7, “Software Systems Quality Assurance” from Steve Smith for review. Because little

time was left in the meeting and Steve Smith was not present to provide input, the Focus Group review and comment on this section was tabled until the November meeting.

- c. Taffy Almeida had completed a review of Volume 1 and had provided comments to the Focus Group Secretary. A discussion of her comments was held with all Focus Group members agreeing to the comments Taffy provided. As they were discussed and accepted, Taffy's comments were incorporated in the working version of Volume 1 that will be used to produce the final review copy of Volume 1, Revision 4. The Focus Group reiterated their recognition that the Glossary needs to be reviewed and possibly revised also.

The Focus Group Chair asked if there was any new business to discuss. The members present discussed the status of the document that is being implemented by DOE to replace the Quality Systems for Analytical Services (QSAS) document. The QSAS has been the basis for DOECAP audits. The implementation schedule for the new document and DOECAP's use of it was also discussed. Although of technical interest to the HASQARD Focus Group, the participants agreed that there is no impact to the efforts to produce Revision 4 of HASQARD introduced by the DOECAP moving to a new QA standards document. The Chair suggested that the meeting be adjourned. Hearing no objections, the Chair adjourned the meeting at 4:25 PM.

The next meeting is scheduled for November 19, 2013 at 2:00 PM in 2420 Stevens, Room 308.