

HASQARD Focus Group
Meeting Minutes
March 15, 2011

The meeting was called to order by Jim Conca who was acting for the absent Dave Crawford, Focus Group Chairman at 2:01 PM on March 15, 2011 in Conference Room 208 at 2425 Stevens.

Those attending were: Jim Conca (Acting Chair), Cliff Watkins (Secretary), Heather Anastos, Jeff Cheadle, Glen Clark, Kathie Dunbar, Robert Elkins, Scot Fitzgerald, Greg Holte, Larry Markel, Huei Meznarich, Karl Pool, Dave Shea, Steve Smith, Noe'l Smith-Jackson, Chris Sutton, Cindy Taylor, Amanda Tuttle, Rich Weiss, Eric Wyse.

- I. Jim Conca requested approval of the minutes from the February 15, 2011 meeting. The Secretary noted that the comments made were shown in the text of the minutes distributed. No objections were raised to the February meeting minutes and, after hearing no objections, the minutes were approved.

- II. The Action Tracking matrix was discussed:
 - a. The action item related to organizing a working group to address the HASQARD language regarding independent assessments to ensure the language addresses all organizations requiring assessments (i.e., sampling organizations and laboratories), acceptable methods for meeting the independent assessment requirement, the thoroughness of the assessment and the frequency required was discussed. On February 24, the secretary provided proposed language to Huei Meznarich. Huei provided the secretary with comments on his proposed language on March 14. Due to time constraints between March 14 and the March 15 date scheduled for the next HASQARD Focus Group meeting, the secretary had no time to resolve Huei's comments prior to the meeting. The action was deferred one more month.
 - b. The issue of the posted deminimis language for use of custody seals was not discussed because Huei Meznarich and Jim Conca have the action to present new proposed language to the Focus Group at the April meeting.
 - c. The schedule for presentation of the subcommittee recommendations for revision to the HASQARD document was discussed. The schedule will be updated based on input at this meeting (see item IV below) and provided in hard copy form at the April meeting.
 - d. At the January 18 meeting, Huei Meznarich and Rich Weiss agreed to collaborate on revised language for consideration for Volume 4, Section 6.7.1 on requirements for confirmation analyses and documentation required in run logs. Rich and Huei provided a proposed revision to Glen

Clark on March 15, 2011. Glen projected the proposed revision for the Focus Group to review. There were no comments and no issues raised with the revised language. This language will be included in the organic analysis subcommittee's final product. This action is closed and will be moved to the completed actions list.

This time was also used to discuss proposed language for run log exceptions. The Focus Group requested that this language be forwarded to the Secretary for distribution to the entire Focus Group for a more detailed review and consideration.

- e. At the February 15 meeting, Glen Clark took the action to contact AVS and request audits of PNNL and WSCF offering HASQARD Focus Group personnel as auditor resources for the audits. Glen reported that he had contacted Carl Wallskog at AVS. Glen told Carl he could obtain the names of personnel that could support the audits required. The Focus Group indicated that two laboratories at PNNL require audits to get them on the active Evaluated Suppliers List (ESL). Huei Meznarich inquired on the schedule for the AVS audit at WSCF. Glen said that the ESL expires for WSCF at the end of August, which means the on-site visit portion of the audit is needed in May or early June to allow time for a report to be produced, concerns responded to and approved in corrective action plans. Glen said he would take e-mail volunteers for conducting the audits of the Hanford laboratories and forward those volunteers to Carl Wallskog along with the area of technical expertise these personnel would cover in an audit. This action is closed and will be moved to the completed actions list.
- f. At the February 15 meeting, Rich Weiss took the action to determine if language concerning customer complaints proposed for Section 5.1 by the QA subcommittee should be placed elsewhere in the HASQARD. Rich requested this action be deferred to the April 19 meeting.

III. No new business was identified by the Focus Group.

IV. The schedule status of the subcommittees established to compare the QSAS and HASQARD requirements and propose revisions to the HASQARD accordingly was discussed.

- a. Organic: Glen Clark (Coordinator), Robert Elkins, Cliff Watkins

Glen Clark requested one additional month to complete the commitments listed on the schedule.

- b. Sampling: Chris Sutton (Coordinator), Wendy Thompson;

Chris Sutton reported that the draft of the revision to Volume 2 has been

completed and has been sent to the document preparation team for one final review and comment prior to presenting it to the Focus Group.

- c. Inorganic Analysis: Heather Anastos (Coordinator), Chris Thompson, Jim Jewett, Eric Wyse

Heather Anastos reported that the inorganic subcommittee is on schedule to meet all milestones shown on the last updated schedule.

- d. Radiochemistry: Joan Kessner (Coordinator), Rich Weiss, Huei Meznarich, Karl Pool, Eric Wyse

In Joan's absence, Rich Weiss and Karl Pool reported that the radiochemistry subcommittee is on schedule to meet all milestones shown on the last updated schedule.

- e. Quality Assurance/Management Systems: Steve Smith (Coordinator), Taffy Almeida, Cindy Taylor, Greg Holte, Larry Markel, Kris Kuhl-Klinger, Amanda Tuttle and Kathi Dunbar:

Steve Smith reported that the QSAS Section 5 material will take as much time or more to review as the QA material currently being reviewed by the Focus Group. Therefore, two months additional time should be added to the QA subcommittee's schedule.

V. New Business

There was no new business brought to the Focus Group this month other than that detailed in item III above.

VI. HASQARD Revision 4 Proposals:

Steve Smith, the HASQARD QA and Management Systems Subcommittee Chairperson, continued his presentation of the proposed revisions to HASQARD Volume 1 as a result of the DOECAP/QSAS/HASQARD gap analysis conducted by the subcommittee.

Steve Smith began with follow-up actions he had as a result of feedback received during the February Focus Group meeting. Steve has done some research on the term "data integrity" due to confusion expressed about that term at the February meeting. The term has a variety of definitions that seem to be applicable to the context of the document in which they are used. Steve's group proposes to delete the use of the term "data integrity" in HASQARD and use the phrase "data of known quality" instead.

The Focus Group discussed what the term data integrity meant to them. This

discussion highlighted the issues associated with expecting this term to be used in an unambiguous context.

Eric Wyse noted that data integrity has a connotation of traceability of the data to allow for complete data validation and data verification. That is, data integrity means that records include all information or pedigree about the data.

Chris Sutton added that his understanding of data integrity has more to do with managing data in a database or document control system. That is, maintaining data integrity means managing it in a fashion that assures it doesn't get corrupted, erroneously erased or altered.

Steve Smith mentioned that the NELAC definition discussed earlier related to the entire measurement/data collection system, not just the maintenance and storage of data. That alone results in data integrity meaning many things depending on who you talk to.

Eric Wyse mentioned that the ISO standard on data traceability requires specific procedures to maintain data traceability.

In discussion of the paragraph being displayed on the screen, Rich Weiss noted that the last sentence which says, "The use of the HASQARD will ensure data of known quality and technical defensibility of the methods used to obtain that data" is erroneous. That is to say, use of the HASQARD cannot ensure data of known quality. Use of the HASQARD is intended to maximize or enhance the probability that data of known quality will be produced.

The end result of the discussion was Steve Smith agreed to look further into data integrity language from QSAS and how to incorporate the term appropriately into HASQARD.

Steve then discussed the revisions to the draft proposed by the QA subcommittee as a result of comments received at the February Focus Group meeting:

The requirements concerning contract review were removed.

In the February meeting, the Focus Group requested that a proposed additional laboratory procedure addressing "Reporting Analytical Results" be removed from the list of those required by HASQARD. The QA subcommittee met again and asked that this procedure topic not be removed since nothing similar could be found elsewhere in the HASQARD document. No members of the Focus Group had issue with keeping this procedure topic in the list.

The Corrective Action and Quality Improvement Section contained reference to the word "immediately" which has been changed to "as soon as

practicable.”

Steve Smith then continued to present other proposed revisions to the document that the Focus Group body had not yet reviewed.

Changes to the document control section allowing hand corrections and requiring all such changes to be initialed and dated were approved by those in attendance.

The Focus Group requested striking some proposed revisions regarding changes to data, since this section was addressing document control. Heather Anastos pointed out that the struck material needs to be retained somewhere, just not in the document control section.

The title of Section 6.1 in HASQARD is “Quality Records.” The Focus Group members discussed the fact that some of the records listed in this section were not quality records. Eric Wyse noted that the terms “records” and “quality records” seem to be used interchangeably in HASQARD, therefore removing the modifier “quality” before the term “record” might be appropriate. Huei Meznarich accepted the **Action Item** to research the difference between quality records and records and propose a resolution to the words used in this section to clarify requirements associated with records.

The Focus Group felt that the language requiring NELAP-related records to be available to the accrediting authority could be struck from HASQARD.

The Focus Group suggested that the words in the Quality Records and Records section that were suggested as: “When corrections are due to transcription errors...” be changed to “When data corrections are...”

The Focus Group discussed the proposed requirement that says: “All generated data, except those that are generated by automated data collection systems, shall be directly, promptly and in permanent ink.” Rich Weiss noted this is an antiquated requirement and does not apply to an automated world because data can be collected in other than automated data collection systems. The Focus Group felt like the reference to permanent ink may not be necessary in this section regardless of its presence elsewhere in the document. Steve Smith accepted the **Action Item** to determine if the requirement to record entries in permanent ink is found elsewhere in HASQARD (e.g., the notebooks/logbooks section). Heather Anastos stated that any reference to entry of data by hand in HASQARD probably does not require that entry to be “directly and promptly” and that there would be value in using those words. Eric Wyse noted that words “directly and promptly” may not be practicable in high radiation laboratories where hand entries may be delayed by conditions under which work is performed. The bottom line of the discussion was that there are several issues with this proposed language that require resolution.

Another proposed requirement states, “Entries in records shall not be obliterated by methods such as erasure, overwritten files, or markings.” The group discussed this for a while, discussing how this can happen in modern integration systems, etc. Rich Weiss suggested making the requirement more generic by saying, “Entries shall not be obliterated, examples of inappropriate obliteration include but are not limited to erasure, overwritten files, or markings.” Steve Smith suggested adding a list of bullets of how entries might be obliterated.

The proposed requirement stating: “Records that are stored only on electronic media must be supported by hardware and software necessary for the retrieval” was discussed. This one is a difficult issue because of the constant advance of technology begging the question “for how long?” Many felt it may be unreasonable to expect a laboratory to maintain antiquated electronic data reading systems just for the off chance that a very old data file is needed. Rich Weiss suggested that if the words “until they are approved for disposal” were added to the end of the sentence, a laboratory could inform Hanford clients that they are going to get rid of a data reading device and that they are requesting disposal of the records that would be read by the device.

Another proposed requirement specifies that written approval must be received prior to disposal of any record associated with DOE analytical data. Huei Mezmarich thought this is covered in HASQARD by reference to the 75-year Records Inventory and Disposition Schedule (RIDS) requirements. Chris Sutton pointed out that HASQARD, Volume 1, Section 6.3 contains this reference to RIDS. The Focus Group felt that the text of Section 6.3 covered records retention adequately and suggested the new proposed language not be used.

The Focus Group spent the end of the meeting trying to determine a more productive method to address the large volume of proposed changes being suggested by the QA subcommittee. One suggestion was to distribute the draft revision ahead of the meeting to all Focus Group members so they could come to the meeting with their thoughts on each proposal prepared (including research on whether the new language is already adequately addressed in some other fashion in Rev. 3 of HASQARD). Steve Smith suggested preparing a cross-walk showing new material that is brought in to HASQARD by including QSAS requirements and a reference to the closest thing that can be found in Rev. 3 of HASQARD. Larry Markel suggested presenting a list of all the gaps between QSAS and HASQARD found by the QA subcommittee in list form and then the list could be addressed with the Focus Group determining if adding text to address the gap adds value to the HASQARD. Rich Weiss suggested that the QSAS could just be incorporated in HASQARD by reference to allow for additional QA requirements that some may find applicable and appropriate adding that the commercial

laboratories used by Hanford companies are being audited by DOECAP and are therefore living with the QSAS already.

Because the end time for the meeting was reached, and hearing neither additional new business nor objections to the proposal to adjourn, the meeting was adjourned at 4:08 PM. The next meeting is scheduled for April 19, 2011 at 2425 Stevens, Room 208.