

**HASQARD Focus Group**  
Meeting Minutes  
September 21, 2010

The meeting was called to order by Dave Crawford, Focus Group Chairman at 2:07 PM on September 21, 2010 in Conference Room 208 at 2425 Stevens.

Those attending were: Dave Crawford (Chair), Cliff Watkins (Secretary), Heather Anastos, Doug Duvon, Kathi Dunbar, Kris Kuhl-Klinger, Larry Markel, Huei Meznarich, Karl Pool, Noe'l Smith-Jackson, Andrew Stevens, Cindy Taylor, Chris Thompson, Eric Wyse and Jerry Yokel.

- I. Dave Crawford requested approval of the minutes from the August 24 meeting and, hearing no objections to the minutes as presented, they were approved.
- II. The Action Tracking matrix was discussed. The following updates were provided:
  - a. The process for handling inclusion of interpretations to HASQARD by posting them on the HASQARD web-site has been completed. The Secretary has made contact with the personnel that manage the web site that currently hosts the HASQARD document (<http://www.hanford.gov/orp/?page=141&parent=14>). The Secretary provided the web site administrator with the files the Focus Group requested be placed on the web site (Charter, Meeting Minutes, Interpretations and Meeting Schedule). The site is up and running using a link to the HASQARD Focus Group from the url specified. This action item will be moved to the completed actions matrix.
  - b. The issue concerning the required frequency for quality systems assessments in HASQARD was presented by Dave Crawford. Dave has reviewed the MSA contract to determine if there is an assessment frequency requirement for the WSCF laboratory contained in that document. There is no requirement for frequency of assessments of the WSCF laboratory in the MSA contract. Dave is of the opinion that this means the WSCF, as a Hanford laboratory, falls under the same frequency requirement as all other laboratories at the site. Dave asked the regulators present if there is any required frequency from their perspective. No'el Smith-Jackson stated that State laboratories are audited every three years. Huei Meznarich and Kathi Dunbar added that assessments of some type are typically done annually, but a desk evaluation of some sort is done on the years an on-site assessment is not completed. Karl Pool wanted the group to ensure language requiring a frequency of assessment in the HASQARD was specific so as not to confuse management self assessments, internal assessments and external assessments. Kathi Dunbar

stated that the MSA Acquisition Verification Services (AVS) organization uses a team of the Hanford contractors to conduct the audits they do at the laboratories. Heui Meznarich stated she believes that the AVS required frequency is every three years. No'el Smith-Jackson and Cliff Watkins agreed to team on the **Action Item** to take a look at the current frequency requirements in HASQARD and determine if the language needs to be changed and if so to propose alternative language to the focus group. Doug Duvon added that at the laboratories he has audited, every customer has their own requirement for frequency of assessments. Dave Crawford acknowledged that this is the case but stated that this is a separate issue. Eric Wyse added that any revised language would need to make clear who the responsible party is for ensuring the frequency is met. That is, is it the laboratories responsibility to ensure someone has done a triennial independent assessment of them against the HAQARD requirements? Heui Meznarich volunteered to send the current language for assessment frequency used by AVS to Cliff Watkins to support the action item discussed above. The matter was deferred for discussion at the next HASQARD Focus Group meeting under the context of the new action item opened. The existing action item for Dave Crawford to review the MSA contract is completed and will be moved to the completed actions matrix.

- c. The Secretary had the action to ensure the newly revised language regarding the use of custody seals was posted to the HASQARD web site. The language This action item is closed and will be moved to the completed actions list.
- d. From the August 24 meeting the Secretary was assigned the action to research whether refrigerator blanks are required in any other program besides the EPA CLP and if any guidance exists for use of the data generated from the analysis of refrigerator blanks. The QSAS currently requires refrigerator blanks be present and the Focus Group is interested in the merits of adding this requirement to HASQARD. The Secretary requested an additional month to research this matter.
- e. From the August 24 meeting, Kris Kuhl-Klinger accepted an action to present some of the items the QA subcommittee was finding and will be recommending for inclusion in Rev. 4 of the HASQARD. Kris requested an additional month to prepare this presentation. Dave Crawford, having missed the organic analysis subcommittee's presentation at the August meeting, asked if these presentations are useful for the effort. The members of the Focus Group indicated they are useful. Kris added that not only do they provide the other subcommittees with an idea of the level of detail being explored by the presenting subcommittee, the subcommittee doing the presenting gets "mid-course" feedback on their efforts by making these presentations also.

- f. From the August 24 meeting, Chris Sutton accepted an action to determine if language pertaining to storage of sample containers in a “contaminant-free” environment has been revised in the Volume 2 revision being prepared by the sampling subcommittee. Chris was not present at this meeting, so the matter was tabled for the October meeting.

III. The status on the subcommittees established to compare the QSAS and HASQARD requirements was provided by the coordinator for each subcommittee:

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

Chris Sutton reported (via e-mail to the Secretary) that due to demands on sampling personnel no progress had been made since the last HASQARD meeting.

- b. Organic Analysis: Glen Clark (Coordinator), Robert Elkins and Cliff Watkins

The organic group is working on incorporating the material from their presentation at the August 24 meeting in the “track changes” version of the HASQARD Word file.

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

Heather Anastos reported that the inorganic group found the presentation by the organic group at the last HASQARD meeting to be beneficial. Heather’s group has identified that it will be important to document those items that are in QSAS or DOECAP checklists that are conscientiously recommended to not be included in HASQARD and the basis for this recommendation. The idea of a matrix showing all changes that were considered and their status (e.g., included or not included) was discussed. The inorganic group intends to make it’s recommendations to the Focus Group also using a mark-up of the HASQARD Word file along with the complete list of items not included but considered and the rationale for not including those items.

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

Karl Pool stated there was nothing new from the last meeting to provide.

- e. Quality Assurance/Management Systems: Steve Smith (Coordinator), Taffy Almeida, Cindy English, Larry Markel, Kris Kuhl-Klinger, and

Kathi Dunbar:

Kris Kuhl-Klinger stated that she is happy with the progress being made on the QA Management section and the group has not dealt with the QSAS Section 5 material in as great a detail. Kris accepted the **action item** to present a summary of examples of the group's work at the next HASQARD meeting.

Doug Duvon asked if the QA subcommittee was finding any areas where the HASQARD was more prescriptive than the QSAS. Kris and Huei Meznarich stated that if there are any there aren't many. Someone in the group commented that there has not been an effort to look at HASQARD from that perspective. The effort to address the DOECAP/QSAS gap analysis in revising HASQARD is uncovering some of these differences.

Larry Markel stated that HASQARD allows flexibility for laboratories to direct the required processes through implementation of laboratory-specific procedures. The QSAS puts many elements that are often specific enough to be considered "laboratory procedure" level requirements in the document. Larry commented that we likely don't want that much specificity in HASQARD.

Doug Duvon added that we need to look at HASQARD to ensure it passes down all requirements to laboratories that it should. For example, the software design requirements of NQA-1 are not addressed in the document at all. It is understood that this document is implemented as part of the graded approach to quality assurance and perhaps software design was deemed inapplicable at the time HASQARD was originally written. But, on a recent assessment at a commercial laboratory, Doug noted that the laboratory claimed to have an NQA-1 compliant program but did not know what software design requirements were. This became an issue because the laboratory designed all of its software for the radioanalytical systems in use at the laboratory. As a result, WCH temporarily paused sending samples to this laboratory until the software quality assurance issues were resolved.

Several people stated that DOECAP audits to the QSAS requirements and those audits are conducted only at off-site laboratories and HASQARD is used to audit the Hanford on-site laboratories and by some Hanford contractors to audit their off-site commercial laboratories.

Eric Wyse stated we better be careful in assuming that position because we may find ourselves defending the existence of HASQARD if DOECAP/QSAS is used at off-site laboratories and HASQARD only applies to on-site laboratories. That is, why two standards for laboratories

doing environmental testing for Hanford contractors?

Dave Crawford added that it is not inconsistent with the Charter of this Focus Group to address the topic of appropriate requirements flow-down to the laboratories used by the Hanford contractors.

The group discussed applicable QA standards for laboratories using records management as the case example for much of the discussion.

Karl Pool added that we don't want the laboratories to have to comply with NQA-1 records retention requirements or they will be storing records far too long. Rather, we want them to return the records to the applicable Hanford contractor for storage in their records system.

Dave Crawford added that the subject of records management in the HASQARD should look at not only retention of records but the form the records may be maintained in (i.e., hard copy versus electronic). He also added that if the Focus Group believes software quality assurance raises enough concern because DOECAP audits cannot be relied upon to adequately assess them it is an appropriate thing for this group to address.

Doug Duvon took the **action item** to share the issues that resulted in WCH deciding to halt use of the commercial laboratory in question with Kris Kuhl-Klinger so she could address the gaps in the QA subcommittee's efforts.

f. Section 5:

Steve Smith was not present but had previously reported that efforts have not focused on Section 5 specifically. They intend to incorporate the material required from Section 5 in the HASQARD revisions they propose as a result of the QA subcommittee efforts. If an analysis-specific requirement or revision is identified, it will be discussed with the applicable sub-group prior to incorporating it in the final HASQARD revision proposals.

- IV. Dave Crawford commented that it is likely the schedule for completion of the DOECAP/QSAS/HASQARD Gap Analysis activities that we have been working from needs to be revised. Dave took the **action item** to go over the schedule and try to reformat it into something more accurate and usable. Cliff Watkins stated that if the same set of products was required from each subcommittee the overall percent complete for the tasks associated with the schedule might be easier to define. It was recognized that this would not apply to the Volume 2 effort since that subcommittee is proposing an entire revision of the document.

V. New Business

- a. Dave Crawford stated that he and the Secretary should plan on preparing an annual report of the HASQAD Focus Group's accomplishments and upcoming activities. Dave requested input from the entire Focus Group to ensure completeness in the report.
- b. Dave Crawford polled the group to determine if the scheduled meeting time and dates are acceptable for the members. Most members were ambivalent, but No'el Smith-Jackson and Kathi Dunbar expressed favor in the date/time proposed for upcoming meetings.

Hearing no additional new business, Dave Crawford adjourned the meeting at 3:24 PM.