HASQARD Focus Group
Meeting Minutes
October 19, 2010

The meeting was called to order by Dave Crawford, Focus Group Chairman at 2:07 PM on October 19, 2010 in Conference Room 208 at 2425 Stevens.

Those attending were: Dave Crawford (Chair), Cliff Watkins (Secretary), Heather Anastos, Steve Chalk, Jeff Cheadle, Glen Clark, Doug Duvon, Kathi Dunbar, Robert Elkins, Al Hawkins, Joan Kessner, Larry Markel, Huei Meznarich, Steve Smith, Noe'l Smith-Jackson, Eric Wyse.

I. Dave Crawford requested approval of the minutes from the September 21 meeting. A discussion was held regarding the wording in the minutes on which laboratories are audited by DOECAP to the QSAS requirements versus those that are audited to HASQARD requirements. The wording in the minutes was revised and the minutes were approved.

II. The Action Tracking matrix was discussed. The following updates were provided:

a. The Organic subcommittee had proposed the addition of requiring the use of refrigerator blanks in Rev. 4 of HASQARD. Prior to determining the usefulness of these blanks, the Secretary was requested to research whether storage blanks (or refrigerator blanks) have a use in the data validation and/or data usability decision processes. The Secretary reported that the EPA CLP *National Functional Guidelines for Organic Data Review* refers to "Storage Blanks." That document uses storage blank data to qualify sample results. The document lists method blanks, storage blanks, and instrument blanks as being required using "must" language because the CLP SOW requires laboratories under that contract to use these blanks. Equipment blanks and trip blanks are excluded from the list of blanks used to qualify sample data associated with them presumably because the CLP SOW has no control on the field samplers and whether or not these blanks are used. SW-846 Method 8260B refers to trip blanks as "can be used" to detect contamination introduced during all processes including storage. SW-846 Chapter Four "Organic Analytes" says a trip blank "should be carried through the sampling, shipping and storage process." There is a mention of a field blank (basically an equipment rinsate blank) but no mention of a storage or refrigerator blank in this Chapter. The Focus Group will base their ultimate decision on whether to add the use of a storage blank to HASQARD as a requirement based on this input. The action was closed and will be moved to the completed actions table.

b. The action to present a summary of the QA subcommittee's efforts to date was tabled after review of the group's progress was discussed as part of item III below. This action will be closed since the QA subcommittee's work will be presented when their presentation on how HASQARD Rev. 4 should address the DOECAP/HASQARD gaps is provided to the Focus Group.

c. 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 November meeting.

d. At the September 21 meeting, Dave Crawford and Cliff Watkins accepted the action to produce an annual report of the HASQARD Focus Group's activities. Dave and Cliff will schedule a meeting in the coming weeks to discuss the outline and content for the report.

e. At the September 21 meeting, Dave Crawford accepted the action to revise the DOECAP/HASQARD gap analysis and HASQARD revision schedule into something closer to what the activity looks like at this time. The schedule was not available at this meeting but based on discussions at this meeting, a new version of the schedule will be available by October 22. The schedule of upcoming activities was discussed. The Organic subcommittee is essentially ready to begin presenting their final recommendations to the Focus Group and the QA subcommittee is close to being ready. Dave Crawford asked how many Focus Group meetings each group thought it would take to get though their material entirely. It was agreed that an average of two meetings would be needed for each group. With this information, Dave and Huei Meznarich will revise the schedule showing the organic group beginning with their recommendations at next month's meeting, the QA group following, the inorganic group after that and the radiochemistry group going last.

f. At the September 21 meeting, Cliff Watkins and No'el Smith-Jackson took the action to take a look at the current frequency requirements in HASQARD and determine if the language could be changed and if so to propose alternative language to the focus group. They completed the action by proposing the following revision:

Current Language: Section 10.4 Quality System Assessments says: "The adequacy of the quality system and its implementation shall be assessed annually as an independent assessment. An external assessment may be used to fulfill this requirement."

Proposed Revision: "The adequacy of the quality system and its

implementation shall be assessed every two years as an independent assessment. Any audit, surveillance or assessment by an organization external to the laboratory (i.e., not the laboratory's internal QA organization) is considered independent for the purposes of fulfilling this requirement."

No'el Smith-Jackson met with Ecology personnel and they agreed that a frequency of every two years would be acceptable.

Eric Wyse stated a concern that meeting this requirement also poses challenges. Specifically, he stated that the current schedule for the Acquisition Verification Services (AVS) audits of the on-site laboratories only results in an independent assessment of the quality system to the HASQARD requirements occurring every three years. He stated that the 222S laboratory is audited by the American Industrial Hygiene Association (AIHA) for compliance with ISO 17025 every two years. He asked if this audit would count.

Joan Kessner provided some historical perspective of where the annual requirement in HASQARD came from. When that requirement was adopted in the document, the Environmental Restoration Contractor (ERC) was performing annual audits of all of the laboratories they used. Now, the MSA Evaluated Suppliers List (ESL) is used by all companies that have a memorandum of agreement with MSA to provide these services for them. The MSA ESL uses a triennial assessment conducted by AVS for maintaining approval of the on-site laboratories and recognizes the DOECAP audits for the commercial laboratories. The AVS utilizes representatives from multiple Hanford contractors in conducting their assessments.

Steve Smith asked if the proposed revised language would be acceptable for the field sampling organizations that are also independently assessed to the HASQARD requirements. He mentioned that CHPRC is performing annual assessments of the sampling organizations to these requirements, but asked if Ecology and all the other contractors would be OK if that frequency was reduced to every two years.

Larry Markel mentioned that WRPS QA will be auditing the WRPS 222S laboratory this year, so the two-year requirement will be met for the next two years for WRPS.

Steve Smith asked if for the laboratories used by Hanford Contractors it should be a role of the HASQARD Focus Group to track whether the two-year frequency for independent assessments was being maintained. Other members stated that this was not in the Charter of the Focus Group and is likely more appropriately a function of each Contractor's QA

organization.

Al Hawkins mentioned the RL Integrated Evaluation Plan (IEP) and/or the QA component of the Integrated Safety Management report (ISM) could be used to track the frequency of independent assessments at laboratories and field sampling organizations.

Eric Wyse mentioned the concern that if the proposed language of "Any audit, surveillance or assessment by an organization external to the laboratory…" is adopted, a complete assessment of "the adequacy of the quality system and its implementation…" may not occur every two years. This is because surveillances may only look at one aspect of the quality system (e.g., records management).

Larry Markel mentioned that the documentation of all assessments and what was covered in them should be captured by laboratories as part of meeting the HASQARD requirements for QA Reports to Management. This would allow an organization to evaluate whether all aspects of the quality system and its implementation were being assessed every two years.

Al Hawkins added that for the prime contractors, the QA piece of the annual ISM report requires all elements of the implementing QA standards to be covered. It does not require that each element be assessed annually, but does require the contractors to report on the status of each element of the implementing standards.

Huei Meznarich stated support for a team from the Focus Group being formed to assure the two-year frequency for independent assessments is met.

During this discussion, the Integrated Contractor Assessment Team (ICAT) was mentioned. Joan Kessner clarified that the ICAT does not exist anymore. In the conduct of AVS audits, the AVS uses representatives from the companies that have a support agreement with MSA to use the AVS, but the ICAT as it was known in the past does not exist today.

Eric Wyse suggested that the language be changed to something requiring annual assessments (accepting that <u>any</u> audit, assessment or surveillance of any aspect of the quality system can be used to meet the annual requirement) and within every three years all aspects of the quality system will have been covered by one or a combination of the annual independent assessments.

Dave Crawford concluded that this issue could not be readily resolved in

this meeting of the Focus Group and suggested a smaller group be formed to address the nature and frequency of independent assessment requirements in the HASQARD. The goal of this group would be to provide another proposal to the Focus Group for consideration. The Secretary took the **Action Item** to solicit interest in serving on this smaller group and coordinating the effort.

g. From the September 21, Doug Duvon had the action to provide Kris Kuhl-Klinger with the software QA issues that resulted in WCH pausing sample shipments to one of their commercial laboratories so the issues could be addressed in the QA subcommittee's work on HASQARD. That transfer of information occurred and the action is closed.

III. With Kris-Kuhl Klinger absent from the meeting, no presentation of the summary of recommendations the QA group was considering based on their review of the DOECAP/QSAS requirements versus those in HASQARD occurred. Rather, Steve Smith handed out a product the QA subcommittee has produced for the Focus Group's consideration. This product was a revision of Volume 1 of the HASQARD to align the sections with those on DOE Order 414.1C. Steve explained the same material was in this document as that contained in the current Volume 1. Only the order of presentation and sections where certain material is included was changed. Steve was requesting a review and comment on this approach before the QA subcommittee presents its recommendations for HASQARD Rev. 4.

IV. 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:

Steve Smith reported 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

Glen Clark reported 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 is meeting every other week and is making progress toward an ultimate goal of presenting their

recommendations to the Focus Group at the meeting that they are scheduled to begin doing so.

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

Joan Kessner stated that the group started meeting again and has scheduled a meeting for November. The team members have completed providing recommendations on the sections they were assigned to evaluate against the DOECAP and QSAS requirements. The subcommittee will begin preparing finalized recommendations as the subcommittee evaluates and reaches concurrence on each individual's set of recommendations.

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

Steve Smith reported for the QA group and stated that good progress is being made on the QA Management section and that the group has not dealt with the QSAS Section 5 material in as great a detail.

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 for the off-site laboratories and HASQARD is used to audit the Hanford on-site 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 stated that the efforts of the group have been focused on producing the product he distributed as discussed in item III above. They hope to start working on the Section 5 material next week or the week after that.

V. Dave Crawford commented that based on what he has heard in the meeting today, he has a concept for how to revise the schedule for completion of the HASQARD/DOECAP comparison activities. Dave took the **action item** to revise the schedule and get it out for comment by October 22. He stated that once completed, the subcommittees should be able to report on their progress toward meeting the dates reflected on that schedule at future Focus Group meetings.

VI. New Business

a. Eric Wyse brought up the topic of semi-quantitative analysis and whether it should be covered in HASQARD. Of specific interest were ICP-MS analyses for isotopes for which no available standard exists. Eric decribed what techniques the laboratory uses to quantify these isotopes but recognizes that without a standard and a secondary standard for preparation of a Laboratory Control Sample, the results are viewed as semi-quantitative. Dave Crawford said we should list an action item to determine if these methods should be covered in HASQARD.

Post-Meeting Note: Following the meeting, Eric shared some correspondence on this subject with Heather Anastos. Heather committed to covering ICP-MS analyses (including the semi-quantitative analyses for isotopes for which no standard is available) as part of the inorganic analysis subcommittee's HASQARD efforts.

b. Dave Crawford polled the group to determine if the scheduled meeting times and dates for upcoming meetings are acceptable for the members. The date of the regularly scheduled meeting in November (November 16) was determined to be acceptable. However, the Focus Group determined that a meeting date of December 13 would be better than third Tuesday date of December 21. Dave Crawford took the **Action Item** to secure a location for the December 13 meeting.

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