

HASQARD Focus Group
Meeting Minutes
April 16, 2013

The beginning of the meeting was delayed due to an unannounced loss of the conference room scheduled for the meeting. After securing another meeting location, the meeting was called to order by Huei Meznarich, HASQARD Focus Group Chair at 2:18 PM on April 16, 2013 in Conference Room 156 at 2420 Stevens.

Those attending were: Huei Meznarich (Focus Group Chair), Cliff Watkins (Focus Group Secretary), Jeff Cheadle, Glen Clark, Joan Kessner, Larry Markel, Mary McCormick-Barger, Karl Pool, Dave St. John, Chris Sutton, Chris Thompson, Steve Trent, Sam Vega, and Eric Wyse.

- I. Huei Meznarich requested comments on the minutes from the March 19, 2013 meeting. The Focus Group Secretary highlighted the comments he had received since sending out the draft minutes for review. No HASQARD Focus Group members present stated they had any additional comments on the March meeting minutes and, after hearing no objections, the minutes were approved.

- II. Because no overhead projector was available in Room 156, specific suggestions for technical or editorial changes to HASQARD could not be discussed interactively as the document was being edited real-time. Therefore, a general discussion of the activities to complete Revision 4 of HASQARD was held:
 1. At the February HASQARD Focus Group meeting the fact that the WRPS QAPD did not require HASQARD flow-down to commercial laboratories was discussed. Between the February and March meetings, Glen Clark provided a proposed revision to the Introduction to Volume 1 that would specify that HASQARD was the standard for environmental analyses conducted by laboratories operated by Hanford Site contractors and adding a sentence to allow WRPS to conduct business as specified in their QAPD. In response to input received from the Focus Group in March, Glen determined a meeting with ORP QA personnel was necessary to address the concerns raised. Glen reported that this meeting has occurred and the results are that the WRPS QAPD will be revised to conform with HASQARD and he will withdraw his proposed change to the Introduction to Volume 1. Glen stated that WRPS will likely utilize DOECAP audits in their supplier evaluation process, but will ensure HASQARD requirements are flowed-down to the commercial laboratories utilized by WRPS.

Chris Sutton stated that he has now had a chance to read the draft revisions to Volume 1 and Volume 2 from beginning to end and, in also considering

some of the recent comments made at Focus Group meetings, has identified some comments that should be discussed. Chris believes that some of the recent discussions on the relationship of the Quality System for Analytical Services (QSAS) document, the Department of Energy Consolidated Audit Program (DOECAP) and HASQARD should be stated in the Introduction to Volume 1. The HASQARD Focus Group spent a great deal of effort conducting a gap analysis looking at those elements of QSAS that should be included in HASQARD. The early efforts to produce Rev. 4 of HASQARD focused on what elements of the QSAS should be included and which, by conscious and deliberate decision, should be excluded. Chris is concerned that this has been lost in the last six months as we polish the final Revision 4 documents for publication. The relationship of the QSAS/DOECAP has been discussed in the last two HASQARD Focus Group meetings a lot. Chris has no specific text to suggest, but believes some acknowledgement that shows the authors of HASQARD are aware of these other programs and to describe the relationship of them is appropriate.

Chris recommended including a short section to discuss the comparison performed between HASQARD and QSAS.

Chris also raised a concern regarding one of the passages in HASQARD. Specifically, the text of Volume 1, Section 8.0 addressing “Procurement Controls” includes the statement:

“Procurement controls shall describe provisions for the following:

- Identifying applicable technical and administrative requirements from HASQARD for subcontracted services and items, including acceptance criteria.”

Chris has a concern that while there are several references to requiring flow-down of HASQARD to subcontractors, this statement allows an individual that is preparing to procure analytical services to determine what the “applicable” technical and administrative requirements from HASQARD” are including a determination that none apply. Chris believes that it is not good QA to allow something that is supposed to be a requirement to be interpreted “as applicable.”

Chris stated that he has provided this comment to Steve Smith and the HASQARD Focus Group Secretary for consideration in preparing the final draft of Revision 4 to HASQARD Volume 1.

Joan Kessner stated that this language was never meant to differentiate between on-site and commercial laboratories. Rather, it has always been intended to apply to all environmental laboratory services. The words “as

applicable” in Section 8.0 of Volume 1 are there to allow the HASQARD requirements that are unique to, for example, radiochemistry analyses to not be applied to a laboratory from which an entity is procuring organic or inorganic hazardous constituent analyses. The words “as applicable” in that section were never meant to indicate someone can pick and choose which requirements from HASQARD stated for the analysis type being procured that individual wants to apply.

Chris Sutton acknowledged that there is a great deal of “historical knowledge” of intent of these statements present in the HASQARD Focus Group. However, if an individual was to begin using HASQARD that did not have this historical perspective, they could misread and erroneously apply the wording in this section.

Mary McCormick-Barger pointed out that the Introduction to HASQARD Volume 1 includes the statement, “The HASQARD serves as the quality basis for all sampling and field/laboratory analytical services provided to support the Hanford Site environmental clean-up mission. This includes work performed by contractor and commercial laboratories and covers both radiological and non-radiological analyses.” Mary suggested that the language in Section 8 be revised to say, “Procurement controls shall describe provisions for the following: Identifying technical and administrative requirements from HASQARD for subcontracted services and items, including acceptance criteria applicable to the services being procured.”

Sam Vega echoed Chris Sutton’s concern in saying that the language of Section 8.0 isn’t good. Sam stated that in his experience, introducing the words “as applicable” to a requirements document allows a manager to assume that for the element to which “as applicable” is applied they can do whatever they want including nothing.

Mary McCormick-Barger also suggested that simply dropping the words “as applicable.”

The Focus Group Secretary had a copy of a page from the MSA Contract Statement of Work (SOW) and read the requirement, “Contractor shall compare and contrast both the DOECAP and HASQARD to ensure that all applicable DOECAP quality criteria have been included in the HASQARD.” The Secretary noted that the word “applicable” was actually used in the contract SOW.

The discussion returned to the applicability of DOECAP and/or the QSAS to the Contractors. Many years ago, a letter from DOE-HQ EM Management was received and was forwarded by the DOE-ORP Manager to the ORP Contractors indicating that participation in the DOECAP was

encouraged. Larry Markel stated that when this was done, if DOE-RL and DOE-ORP wanted complete implementation of DOECAP, they should have modified the Hanford Site Contracts to release the Contractors from the requirement to comply with HASQARD. As we know, this was not done which results in the Contractors being required to use HASQARD and grapple with the existence and how to use the DOECAP at the same time.

There was a brief discussion about HASQARD flow down to commercial laboratories. There were some miscommunications between MSA and the CHPRC Sampling & Groundwater Remediation Program on implementing this requirement. All procurement of subcontracted analytical services conducted by MSA has included compliance with HASQARD as being required. Huei also pointed out that DOE directs MSA in writing to use DOECAP to audit commercial laboratories.

Sam Vega stated that for HASQARD to be NQA-1 compliant, HASQARD must contain a reference to the recognized QA standard that is being implemented.

Mary McCormick-Barger stated that it is also clear that if HASQARD is called out in a Contract, it is required that the Contractors use it.

Joan Kessner reminded the group that the QSAS versus HASQARD comparison effort was to incorporate those elements of the QSAS that were found to add value to HASQARD and not an effort to fill all the gaps.

Sam Vega stated that his review of the current draft of Revision 4 to Volume 1 of HASQARD has brought a large question to his mind. Sam stated that he needed to leave the meeting very soon, but wanted the Focus Group to consider these comments. Specifically, the current version of the draft he reviewed differs from Revision 3 in that the statement, "The HASQARD establishes quality requirements in response to DOE Order 414.1C, *Quality Assurance*" has been deleted from the document. Someone had told Sam this is because DOE Order 414.1C and 10 CFR 830 apply to nuclear and non-nuclear applications and HASQARD does not always apply to nuclear facility applications. Therefore, the need for an NQA-1 compliant program is not required. Sam stated that both Order 414.1C and 10 CFR 830 require that QA documents be prepared to implement a recognized QA Standard. Therefore, if neither 414.1C nor 10 CFR 830 apply, there is no flow-down requirement for which HASQARD is required. Sam suggested that the reference to Order 414.1C be put back in Volume 1 and that NQA-1 be specified as the standard being implemented using HASQARD.

The chair pointed out that removing 414.1C was discussed in the group during review of Volume 1. None of the Focus Group members present could remember the specific reason(s) why the reference to Order 414.1C was removed.

Mary McCormick-Barger stated that it would also be acceptable to replace the reference to Order 414.1C which tells you that for nuclear facility applications, NQA-1 is the implementing standard. Other standards are used for non-nuclear facilities. Mary stated that Order 414.1C has been replaced by Order 414.1D but that this newer Order may not be in all the Hanford contracts. Where Order 414.1C is applicable, it calls out NQA1-2000 whereas Order 414.1D calls out NQA-1-2008 and its addenda. It was noted that some of the contracts have been revised to require Order 414.1D compliance.

Karl Pool stated that HASQARD was never designed to be solely an NQA-1 implementing document. It is a document that draws from several QA standards and guidance documents including those published by EPA.

Sam Vega stated that while this may be true, if the Focus Group designs HASQARD to be compliant with NQA-1 they will have complied with the most strict standard and compliance with Order 414.1C or Order 414.1D will be assured.

Karl Pool added that HASQARD was never intended to comply with the strictest standard (e.g., NQA-1) but rather was written to define best commercial or EPA's good laboratory practices (GLP) as the standards applicable to environmental sample analyses for Hanford.

Eric Wyse stated that we probably don't want HASQARD to flow-down NQA-1 requirements to commercial laboratories that do not work in nuclear applications. This would add undue costs to commercial analytical services as they implement a program more restrictive than is required for obtaining quality data. Therefore, HASQARD was developed as a stand-alone document to define minimum QA requirements for analytical laboratories.

Karl Pool recalled that it was the fact that HASQARD was not designed to be compliant with NQA-1 that resulted in Bechtel National Inc. (BNI) refusing the invitation to participate in the HASQARD Focus Group. The BNI's specific reasoning was that the Waste Treatment Plant was required to implement NQA-1 and the Quality Assurance Requirements Description (QARD) (DOE/RW-0333P) issued by the now defunct DOE organization known as the Office of Civilian Radioactive Waste Management (OCRWM).

NOTE: Communications with Dr. Larry Perkins of the DOE-HQ EM-23 organization indicates that EM has determined that after elimination of the OCRWM organization, the High Level Waste and Spent Nuclear Fuel sites will continue to use the QARD per a memo direction from EM-1. EM-43 performs audits of the EM programs to ensure they are maintaining their programs consistent with the QARD. Although DOE-HQ requires continued use of the QARD, EM-43 does not “own” the QARD and there is no other office that manages compliance or “owns” the document.

Glen Clark stated that several years ago BNI did not believe HASQARD was NQA-1 or QARD compliant. Because of this, and the fact that they needed some testing done at the 222S laboratory, the BNI QA personnel came to the 222S laboratory to conduct a commercial grade dedication (CGD) survey. This survey was done to ensure the 222S laboratory met their needs for the services to meet NQA-1 requirements. The results of a later BNI survey were that the 222S laboratory did meet NQA-1 requirements with their QA program.

Mary McCormick-Barger added that the direction from DOE-ORP QA management is to ensure that nothing that is required by NQA-1, and is presently included in HASQARD, gets removed as Revision 3 is replaced by Revision 4.

Note: This clarification addresses all preceding discussion of the relationship of HASQARD to NQA-1. Following the April 16, 2013, HASQARD Focus Group Meeting, a meeting was held involving ORP staff and the ORP QA Supervisor. Based on the ORP meeting, it was determined that HASQARD does not need to meet NQA-1, but cannot conflict with it.

Larry Markel pointed out that NQA-1 is for nuclear facilities, not for analytical samples. Larry posed a question regarding whether “nuclear facility” or “samples from a nuclear facility” are being confused when “NQA-1” was mentioned in the conversation. HASQARD addresses analytical methods and quality control associated with analytical methods. NQA-1 does not address any requirements for analytical processes. For analytical data, EPA provides the requirements and/or the regulatory drivers, not NQA-1.

Eric Wyse stated that HASQARD provides technical requirements for analytical services plus QA requirements that must be implemented as a minimum. The laboratories are expected to have a QA Plan that implements HASQARD and any other contractual requirements specified for the QA program.

Glen Clark added that for safety significant or safety class projects, the 222S laboratory implements NQA-1 in addition to HASQARD.

Mary McCormick-Barger stated that she always assumed HASQARD was consistent with NQA-1.

Eric Wyse stated that if NQA-1 is required there are more supplemental evaluation requirements imposed on the laboratory.

Mary McCormick-Barger stated that she believes a thorough review of HASQARD for consistency with NQA-1 was completed. Huei Meznarich asked if the results of that review could be shared with the Focus Group. Mary McCormick-Barger said she would check to see if that would be allowed.

Larry Markel stated that he reviewed the WTP analytical laboratory QA Plan and made comments asking why HASQARD isn't being applied at the WTP laboratory. Larry was told that HASQARD will apply to the waste up until the point that it crosses the fence line of the WTP. At that point, the internal QA Plan will apply to the waste testing conducted. Therefore, the result is that HASQARD applies to WRPS operations in the tank farms and ends at the fence line. Larry was told that the WTP analytical laboratory will comply with the QARD (DOE/RW-0333P) rather than NQA-1.

Eric Wyse reiterated that Sam Vega was talking about using the most stringent standard in implementing QA at the laboratories. But, it was not Eric's understanding that HASQARD is designed to be the most restrictive set of requirements. It would be analogous to looking at all of the analytical methods for a given analyte and imposing the most restrictive QC limits of acceptance regardless of sample matrix, analytical method used, etc. The purpose of HASQARD is to state that in the absence of other QA and/or QC criteria, apply these.

Chris Sutton added that on top of all this confusion, DOE has issued a draft of the replacement document for the QSAS for comment which is based on ISO 17025. The DOECAP audits will use this new document for their requirements basis when the document is officially released/implemented.

Mary McCormick-Barger reiterated that she has been asked by DOE-ORP management to ensure the reference to Order 414.1C is retained in Volume 1.

Eric Wyse added that reinserting the statement about Order 414.1C as it

was written in Revision 3 of HASQARD would not mean that 414.1C and/or NQA-1 are now required.

The Focus Group briefly discussed the non-editorial comments from Eric Wyse on Volume 2. Eric Wyse will forward his written comments to Steve Trent.

The meeting was adjourned at 4:15 PM.

The next meeting is scheduled for May 21, 2013 at 2:00 PM in 2420 Stevens, Room 308.