

HASQARD Focus Group
Meeting Minutes
February 28, 2017

The meeting was called to order by Jonathan Sanwald, HASQARD Focus Group Chair at 2:08 PM on February 28, 2017 in Conference Room 328 at 2420 Stevens.

Those attending were: Jonathan Sanwald (Mission Support Alliance (MSA)), Focus Group Chair), Cliff Watkins (Corporate Allocation Services, DOE-RL Support Contractor, Focus Group Secretary), Lynn Albin (Washington State Department of Health), Taffy Almeida (Battelle - Pacific Northwest National Laboratory (PNNL)), , Jeff Bramson (CH2M HILL Plateau Remediation Company (CHPRC)), Jeff Cheadle (U.S. Department of Energy – Office of River Protection (DOE-ORP)), Glen Clark (Washington River Protection Solutions (WRPS)), Jim Douglas (CHPRC), Fred Dunhour (DOE-ORP), Sarah Nagel (CHPRC), Karl Pool (PNNL), Noe'l Smith-Jackson (Washington State Department of Ecology), Chris Sutton (CHPRC), Chris Thompson (PNNL), Wendy Thompson (MSA).

- I. Jonathan Sanwald requested review and approval of the meeting minutes from the last meeting of the HASQARD Focus Group held on January 31, 2017. The draft minutes from the January 31 meeting showed the incorporation of several comments that were provided to the Focus Group Secretary after the draft minutes had been distributed for comment. Hearing no additional comments on the draft meeting minutes, the minutes were approved.

- II. The status of action items from previous meetings were discussed:

Jonathan Sanwald stated he has received checklists for assessing compliance with HASQARD Revision 3, Volumes 2 and 3 from Jeff Bramson. The next effort will be to update these checklists to be applicable to HASQARD Revision 4. Wendy Thompson stated she has a draft checklist for HASQARD Volume 2 for Revision 4. Jonathan said he would like to review that checklist. Wendy Thompson added that her version of the checklist includes statements from HASQARD that are suggestions (i.e., are stated as “should” statements in HASQARD). It was asked whether the checklists should be worded such that all “should” statements in HASQARD are treated as requirements (i.e., as “shall statements). Jonathan Sanwald said he believes it should be up to the users of the checklist to determine the applicability of “should statements” to their work and use checklist accordingly.

- III. The Focus Group began discussing the concept of adding an expectation that DOECAP be the auditing entity for commercial laboratories that are subcontracted by Hanford Contractors and are routinely audited by the DOECAP program.

Prior to the meeting, Chris Sutton had provided a suggestion on where language to specify the DOECAP interfaces should be placed in HASQARD. The Focus Group members present listened to the proposal Chris presented and discussed the implications. The suggestion Chris provided was:

1. Leave the introduction alone and retain the current wording.
2. In Section 2.2, add a bullet or a sentence somewhere that says that commercial laboratories must comply with QA and QC requirements of the DOECAP program. By doing this, we have now made DOECAP a HASQARD requirement and linked the two programs.
3. In Section 10.5 (External Audits), add several bullets or sentences that say:
 - Commercial laboratories under contract to Hanford Prime contractors must participate in the DOECAP audit program
 - DOECAP audits are a primary tool for ensuring compliance with HASQARD requirements
 - DOECAP audits will verify laboratory compliance with client requirements as specified in contract statements of work. (Words to this effect could also be placed in Section 12)
4. In Section 8.0, add the following bullets or sentences.
 - Statements of work to commercial laboratories shall specify compliance with DOECAP QA/QC requirements
 - Statements of work to commercial laboratories shall specify applicable HASQARD requirements not specified by the DOECAP QA/QC program
5. Somewhere add the following bullet or sentence:
 - The client shall verify laboratory compliance with applicable statement of work (and hence HASQARD) requirements through verification of data packages.

The Focus Group was in general agreement on this approach. It was stated that if DOECAP is implemented within HASQARD, a gap analysis between the HASQARD requirements and the requirements in the Quality Systems Manual (QSM) which is used as the basis for DOECAP audits will need to be maintained and updated as the QSM is revised. These gaps would be filled by expressing requirements beyond the QSM in SOWs issued to commercial laboratories.

Glen Clark mentioned that there are needs to contract commercial laboratories that are not audited by DOECAP. The other possibility is that DOECAP is somehow discontinued by DOE. Because of these concerns, Glen said the Focus Group will need to ensure HASQARD is up to date and technically sound as the standard for analytical services QA at Hanford. Laboratories that are not audited by DOECAP will still require a HASQARD audit as a basis for approval. Jonathan Sanwald echoed these thoughts stating that AVS has recently been requested to approve a laboratory that is not audited by DOECAP.

The concerns regarding DOECAP experiencing a reduction in funding were discussed. Glen Clark stated that on the last DOECAP conference call the concept of auditing labs on a two-year rotation, rather than annually as is the current practice, was suggested.

Noe'l Smith-Jackson said that if the approach suggested by Chris is implemented in HASQARD, the results of the gap analysis would need to be documented somewhere other than the SOWs to laboratories because Ecology does not see SOWs but has access to HASQARD. It was stated that the HASQARD Focus Group would likely end up as the responsible party for producing/maintaining the gap analysis and the HASQARD Focus Group web site would be a good place to post the documentation of the most recently completed gap analysis. Glen Clark said that in his experience producing a gap analysis, some requirements of HASQARD are met by DOECAP but not using the same words or exact requirement statement. Glen said each contractor may have to make independent decisions on the significance of these requirement statements relative to their intent as they develop SOWs that address the gaps.

Jeff Bramson echoed the need to have something documented and available concerning the gaps and their significance. Wendy said the gap analysis documented will be a critical need for Hanford Contractors that don't have DOECAP auditors. Chris Thompson expressed the concern that HASQARD is relatively stable in relation to the QSM. That is, the QSM is revised as often as annually, meaning any gap analysis would need to be evaluated annually as well. Glen Clark agreed, gap analysis updates would become a constant duty of the HASQARD Focus Group but added that the last revision of the QSM did not have very many changes. Karl Pool stated that most Contractors put commercial laboratories on contract for a term of at least three years. If the QSM is revised in the middle of that term it would result in the gap analysis also being revised and additional gaps may need to be addressed in the laboratory SOW. Jonathan asked what the ideal way to address this issue would be. Glen Clark stated that the SOW would need to say that the laboratory is expected to be in compliance with the latest revision of the QSM in order to perform acceptably in a DOECAP audit. Chris Sutton added that the SOWs should say that when the DOECAP QSM and HASQARD are not equivalent, the HASQARD requirement takes precedent. Sarah Nagel added that the QSM already has a statement that when the QSM and "client documents" are in disagreement, the client documents take precedent.

Jeff Bramson stated that the language in a SOW could say the laboratory shall comply with HASQARD and we will use the DOECAP audits to ensure the laboratory adequately complies with HASQARD.

Noe'l Smith-Jackson added that it makes sense to use the DOECAP program for auditing laboratories in light of an environment where funding seems to be

an issue and from the perspective of allowing valuable Hanford resources to focus on other thing rather than be auditing laboratories all the time. Lynn Albin asked how a laboratory gets added to the list of laboratories that DOECAP will audit. Glen Clark stated that DOECAP collects information on the laboratories used by DOE Contractors and schedules audits accordingly. Glen added that the DOECAP program has recently suffered budget cuts also. Therefore, they are looking at cost cutting initiatives. Sarah Nagel said that those budget cuts have resulted in the DOECAP program cancelling an annual audit at Test America – Knoxville. This is because in the FY 2015 DOECAP audit of that laboratory had no findings and no observations. In FY 2016, the DOECAP audit of Test America – Knoxville resulted in one finding and no observations. Therefore, the decision to skip one year of auditing at Test America was viewed as an acceptable risk by the DOECAP coordinators. Jonathan Sanwald and Glen Clark acknowledged the logic associated with this decision but expressed frustration that the DOECAP had not made this decision more visible prior to the time some sites were expecting a new audit to occur. Better communication regarding laboratories that will not be audited by DOECAP in a given year is required for sites that need laboratory evaluation information during the year that DOECAP is not auditing there.

With the Focus Group in general agreement on the approach for incorporating DOECAP audit expectations into HASQARD, Jeff Bramson suggested that the revised language be inserted in HASQARD and the document sent to the Focus Group for discussion at the next meeting. The Focus Group looked for a volunteer to work with Chris Sutton’s suggestions and incorporate them in the HASQARD document. Both Jonathan Sanwald and Cliff Watkins stated they would make an attempt to get something out for review.

Noe’l Smith-Jackson stated that HASQARD is being mentioned in meetings involving Bechtel/WTP personnel now. Cliff Watkins asked for a contact at Bechtel so they could be invited to the Focus Group meetings. Noe’l stated she would check with the Ecology personnel that attend the WTP meetings to find out who the appropriate contact at Bechtel is.

IV. Jonathan Sanwald asked if there is any new business to discuss.

Taffy Almeida asked about the status of available Revision 4 checklists. Jonathan stated that for Revision 4, Volume 1 and Volume 4 checklists are completed, a checklist for Volume 2 is out for review and a checklist for Volume 3 is on Wendy Thompson’s “to do list.”

Jonathan Sanwald and Glen Clark discussed and agreed that the number of gaps between the DOECAP QSM and HASQARD can be addressed by producing Revision 5 of HASQARD. Glen stated there is a gap analysis for DOECAP QSM and HASQARD Revision 3, there is a need for one for HASQARD Revision 4 and once Revision 5 is issued one for that revision

will be necessary also.

Jonathan Sanwald said he wants to make the DOECAP group aware of the effort we are going through to do these gap analyses, adding that we would likely be updating our gap analysis annually. Glen Clark said he believes that if we send requests for requirements to be added to the QSM to the DOECAP group, they will consider them and very likely incorporate them in the QSM for us in each annual update.

Cliff Watkins asked if other sites have this issue (i.e., a site QA standard for analytical services that has inconsistencies with the DOECAP QSM).

Jonathan Sanwald said he thought he had heard of this situation occurring at least at one other site. Jonathan has been listening in the DOECAP meetings for an indication that this is the case elsewhere. Glen added that no DOE Contractor operated laboratory is audited by the DOECAP group. Therefore, the other sites must have something in place for those laboratories.

Fred Dunhour stated that there was no such QA standard for analytical services in Idaho when he was there. Cliff Watkins echoed this saying that in Idaho specific analytical services QA requirements were specified in master subcontract SOWs that were issued to both DOE Contractor operated and commercial laboratories when he was there.

Glen Clark mentioned that as we are revising HASQARD to Revision 5, we should be sensitive to requirements present in HASQARD that are not equivalent to those in the DOECAP QSM and request DOECAP to add them to the QSM or consider whether they are necessary to be restated in HASQARD.

Jonathan Sanwald requested any additional new business and, hearing none the Focus Group Chair adjourned the meeting at 3:07 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on March 21, 2017 in Conference Room 308 at 2420 Stevens.