

HASQARD Focus Group
Meeting Minutes
October 24, 2017

The meeting was called to order by Jonathan Sanwald, HASQARD Focus Group Chair at 2:07 PM on October 24, 2017 in Conference Room 308 at 2420 Stevens Place.

Those attending were: Jonathan Sanwald, HASQARD Focus Group Chair (Mission Support Alliance (MSA)), Cliff Watkins - Focus Group Secretary (Corporate Allocation Services, DOE-RL Support Contractor), Marcus Aranda (Wastren Advantage Inc. Wastren Hanford Laboratory (WHL)), Jim Douglas (CH2M HILL Plateau Remediation Company (CHPRC)), Robert Elkins (Washington River Protection Solutions (WRPS)), Scot Fitzgerald (CHPRC), Anthony Nagel (CHPRC), Sarah Nagel (CHPRC), Noe'l Smith-Jackson (Washington State Department of Ecology), Chris Sutton (CHPRC), Chris Thompson (PNNL) and Rich Weiss (Tradewind).

- I. The Chair requested review and approval of the meeting minutes from the previous two meetings of the HASQARD Focus Group held on August 22 and September 19, 2017. The draft minutes from these two meetings were distributed and time was allowed for one final review. Hearing no comments on the draft meeting minutes, the minutes from both meetings were approved.

- II. At the September meeting of the Focus Group, a revision to the HASQARD Focus Group Charter was discussed. The HASQARD Focus Group Charter had last been signed by Focus Group members and approved by DOE in 2010. Because the companies involved in the HASQARD Focus Group have changed through that time period, a revision is necessary.

The Secretary had provided the draft revised Charter to the membership prior to the meeting. A version showing changes from the previous revision and a version showing those changes incorporated in the document were provided in hard copy to those in attendance at the meeting. The Secretary summarized the changes and the bases for the changes. A comment to change the order of the signatures on the signature page to match the order the member companies are listed in the body of the Charter was received and incorporated in the draft revision.

After incorporation of the one comment received, the Focus Group members present were satisfied with the draft Charter revision. Because the attendance at the meeting did not include all of the voting members, the revised Charter could not be voted on. The Secretary took an action to distribute the revised Charter to the voting members, determine who the voting member from Bechtel National, Inc. (BNI) and/or the Waste Treatment Completion Contractor (WTCC) will be and obtain a vote on the revised Charter. If an affirmative vote is obtained, the Secretary will get signatures on the Charter,

distribute the signed Charter to the Focus Group members and ensure DOE-RL issues a memo to file to capture the approved Charter in the RL Records.

Post Meeting Note: The Secretary held a discussion with Aruna Arakali of WTCC. Aruna stated that based on the roles and responsibilities of the two companies; there is no reason for BNI to have a membership on the HASQARD Focus Group. Aruna took an action to check with Brian Sheridan regarding who the voting member from WTCC will be and provide that information to the Focus Group Secretary.

- III. During the August 2017 meeting, the DOE-HQ (AU-21) Analytical Services Program Manager (Steve Clark) stated that the DOE Consolidated Audit Program Accreditation Program (DOECAP-AP) would provide considerations for the fact that HASQARD contains requirements that are either different than (e.g., more specific), or in addition to, the requirements in the Quality Systems Manual (QSM) upon which the DOECAP-AP accreditation will be based. To ensure the HASQARD requirements will be assessed by the ABs, Steve requested a list of the specific lines of inquiry the ABs would need to include in their accreditation audits at the laboratories that Hanford contracts. To accommodate this request, a group of HASQARD Focus Group members that are also DOECAP auditors (Glen Clark, Sarah Nagel, Jim Douglas and Scot Fitzgerald) compiled a checklist containing lines of inquiry that represent the HASQARD requirements that would not be assessed during an audit based solely on the QSM. This checklist was distributed to Focus Group members prior to the meeting. The version of the checklist distributed prior to the meeting contained comments from Focus Group members suggesting that some of the lines of inquiry on the initial draft could be dropped because the requirement is covered in the QSM or other QA standards upon which the DOECAP-AP will be based (e.g., the National Environmental Laboratory Accreditation Coalition (NELAC) Institute (TNI) or International Standards Organization (ISO)). The checklist distributed with comments contained 80 lines of inquiry (LOIs). Of those 80 LOIs, eight were highlighted for discussion, either to delete them or combine them with another LOI. The Focus Group members present discussed these eight LOIs and agreed to reduce the draft final checklist from 80 LOIs to 76. Sarah Nagel took the action to edit the checklist to provide a draft final version to the Focus Group Secretary. Because Glen Clark was not present at the meeting, the group agreed his review would be required prior to sending the checklist in final form to Steve Clark.

On October 18, 2017, a preliminary draft of the checklist showing HASQARD requirements that are either different than (e.g., more specific), or in addition to, the requirements in the QSM was provided to Steve Clark to give him an estimate of the number of LOIs that result from this comparison. Steve Clark responded to receipt of the draft checklist with some follow-up

questions and comments related to the checklist provided. The Focus Group discussed these four questions/comments and summarized their response as:

1. Would it be possible to clarify what type of information-instructions you are looking to document in the blank columns of the checklist? (i.e. yes, no, n/a, demonstrated yes/no, examples provided, narrative types, etc).

The checklist was modified from the draft version to add column headers to the checklist that are intended to meet this purpose. The Focus Group members present believe the auditors will be able to use the LOIs on the checklist and their professional judgment to determine what objective evidence is required to satisfy them that the requirement is being met or not.

2. Would it be possible to identify those admin related items that could be verified ahead of the onsite assessment vs. those that require onsite visuals?

The first two sections of the checklist are labeled “Programmatic.” These are items that the auditors may be able to assess ahead of the on-site audit by review of the laboratory’s QAP, procedures, etc. Of course, an auditor may want to follow-up with review of objective evidence at the on-site audit for some of these items to satisfy the auditor that the requirement is being implemented as indicated in the laboratory’s QAP and/or procedures. The Focus Group members present stated a general belief that the auditors will be able to use the LOIs and their professional judgment to determine how much additional objective evidence is required to satisfy them that the requirement is being met or not.

3. We want to maximize the opportunity for you here so keeping it to just those onsite visual items that need to be verified or documented during the onsite visit would be the AB Assessment focus.

The Focus Group members present understand this concern. Again, the response from the Focus Group was that this is a matter of professional judgment that auditors exercise on all audits. The auditors will have the requirements; they will just need to satisfy themselves that the requirements are being met.

4. Did you intend to require the ABs to send to the labs prior to their visits and follow up from there with the onsite? OR are you able to send it to the labs and identify what the AB needs to look at based on this checklist? We just want to maintain consistency with what the 3 ABs are going to be doing as well as similar types of information/data being reported back to your group.

The Focus Group membership was under the impression that the statement from the minutes of the August 22 meeting that Steve Clark attended was how business would be conducted. The final minutes from the August 22

HASQARD Focus Group meeting includes the statement:

“Steve Clark said the process he envisions would have the laboratory receiving a QSM/DOECAP checklist. The laboratory would complete that checklist and return it to the AB before the audit. The AB will use this completed checklist to determine if any issues can be identified prior to going to the audit. Only the AB will have the HASQARD gap checklist. The AB will assess the HASQARD gaps only during the on-site audit. Cliff clarified his question stating that if the ABs all have different checklists, how will they know where the gaps between their checklist and HASQARD are. Steve Clark said the ABs will all have the same DOE QSM checklist. That checklist would be the one sent to the laboratories for completion prior to the audit. The HASQARD-specific checklist would only be used by the AB at the audit.”

The Focus Group members present generally believe that if this is the way the DOECAP-AP envisions the ABs using the HASQARD gap checklist, then the ABs would not be sending the gap checklist ahead of time. However, if Steve would like the ABs to send the HASQARD gap checklist ahead of time to facilitate time efficiency when they are at the laboratory that is certainly an option.

Additional comments made during the discussion of Steve Clark’s four questions and use of the HASQARD gap checklist included:

Rich Weiss stated that when conducting laboratory audits, he commonly walks into the laboratory knowing what laboratory documents are required to serve as objective evidence that a requirements is being met.

Robert Elkins stated that based on Steve Clark’s questions, Steve must be thinking the laboratories will complete the administrative portion of the checklist and that the AB auditors may not have time to look at objective evidence to support all of the responses to this section of the checklist during the on-site portion of the audit. Robert said this is similar to American Industrial Hygiene Association (AIHA) audits he has been subject to.

Jim Douglas stated that an auditor can generally tell what kind of objective evidence is required by the nature of the LOI.

The Focus Group Chair asked if the results from previous audits ever get used during audits conducted by the ABs as part of other certifications.

Sarah Nagel has been audited by the ABs when she was working in a commercial laboratory and stated that the ABs send a set of forms to the laboratories ahead of the audit. Some of the forms indicate past issues noted at the laboratory and request updates on corrective actions taken and whether

the laboratory believes the corrective actions have addressed the issues.

The Focus Group Chair added that the use of past audits allows the laboratory to know the expectations of the auditing organization.

Robert Elkins stated that the Hanford Contractors that are members of the HASQARD Focus Group would like to see the AB's completed checklists (including the HASQARD gap checklists) to see what the ABs did to assess the requirements.

Marcus Aranda stated that if there is a way to identify documents that all auditors are interested in, the laboratory could have enough copies prepared ahead of time to satisfy that need.

Sarah Nagel said that the ABs do that. That is, they request copies of the laboratory's QA Manual, examples of QA reports to management, past audits, etc. to be provided to the lead auditor 30-days ahead of the date the ABs are to be at the laboratory. The expectation would be that the ABs could then review those documents to ensure they cover all of the elements required by HASQARD using the gap checklist.

Rich Weiss asked if there was anything on the HASQARD gap checklist that could only be assessed while on-site.

Anthony Nagel and Marcus Aranda pointed out there are some that would require on-site verification. For example one gap checklist item states, "All balances, and any thermometers, pipettes, and automatic sample dispensers used for quality affecting measurements, shall be uniquely identified." One would have to be on-site to verify this is done. Sarah Nagel added that an auditor could ask for the internal laboratory document that reflects this requirement, but it would have to be verified on-site.

The formatting of the HASQARD gap checklist was discussed. Scot Fitzgerald stated that the DOECAP checklists pose all of the LOIs as questions. The HASQARD gap checklist specifies only requirements and does not express these requirements in question form. The Focus Group Chair stated that the way they are listed in the HASQARD gap checklist is, from his experience at AVS, preferable. This is because it clearly states the requirement and allows the auditor to use his/her judgment to determine if the requirement is being met or not. The general consensus of the Focus Group was to leave the LOIs in the form of a requirements statement.

Rich Weiss asked if any of the Focus Group members was involved in the effort to revise the DOECAP checklists. Sarah Nagel responded that she is a member of the DOECAP QA committee involved in that effort. Rich stated that in the DOECAP radiochemistry Section 8 is a set of generic LOIs related

to quality control (QC). The section is very repetitive by asking the question, “When a QC parameter is not met, was this mentioned in the case narrative?” This question is repeated for each of the QC parameters for which failure requires mention in the case narrative. Rich said he was able to reduce the volume of the checklist significantly by asking one question something like, “When any of the following QC parameters is not met, is it mentioned in the case narrative?” Rich has also added an LOI to the DOECAP radiochemistry checklist regarding how the acceptability of a QC result is determined. The hierarchy of this determination is supposed to be: national consensus method, client requirements and QSM requirements in that order. The LOI asks if the laboratory has a process to ensure the required hierarchy is observed.

One Focus Group member pointed out that one of the LOIs on the HASQARD gap checklist indicated a need for the ABs to be able to review the HASQARD documents when necessary. The specific LOI states:

Are the calculations used for the following common data quality indicators in agreement with those defined in HASQARD Sections 7.1 and 7.2?

- relative standard deviation
- relative percent difference
- percent recovery based on a sample spike
- percent recovery based on a standard

Sarah Nagel pointed out that the HASQARD document is easily found by a simple Google search of the term HASQARD. Acknowledging the AB’s unfamiliarity with the Internet presence of HASQARD, and expressing a desire to make things as easy as possible for the ABs to use the HASQARD gap checklist, the Focus Group Secretary took an action to show the web site where HASQARD can be found on the HASQARD gap checklist provided to Steve Clark.

IV. The path forward for producing Revision 5 of HASQARD was discussed.

Chris Sutton said that a discussion of “should” versus “shall” statements from Volume 4 would not be a useful use of time. The decisions on which statements are “should” and which are “shall” was debated during the production of Revision 4 of HASQARD and the people that argued one way or the other are no longer present.

The HASQARD Chair expressed the opinion that it is not good for a quality standard to be full of guidance.

Chris Sutton has always wondered if the HASQARD is a requirements document or if it is guidance. Chris believes there is a need to completely rewrite HASQARD. This is based on recent audits conducted at CHPRC

where the QA requirements in Volume 1, many written to be applicable to only laboratories, are being invoked on sampling organizations. This has been done by the auditors due to the paragraph in HASQARD Revision 4, Volume 1 that states:

“The HASQARD is made up of four volumes: Volume 1, Administrative Requirements; Volume 2, Sampling Technical Requirements; Volume 3, Field Analytical Technical Requirements; and Volume 4, Laboratory Technical Requirements. Volume 1 describes the administrative requirements applicable to each of the other three volumes and is intended to be used in conjunction with the technical volumes (e.g., Volumes 1 and 2 describe the requirements for sample collection and handling, Volumes 1 and 3 describe the requirements for field analytical activities, and Volumes 1 and 4 describe the requirements for laboratory analytical activities).”

Chris also believes much of Volume 3 could be eliminated because it repeats material from Volume 4 and is not very useful for the field analyses being conducted today. Because of the difficulty following HASQARD verbatim, he has always wondered if HASQARD should be treated as a guidance document or a requirements document.

Anthony Nagel pointed out that HASQARD has the words “quality requirements document” in the title and therefore, it is intended to reflect requirements not guidance.

Chris Thompson concurred that there is confusion on the HASQARD requirements versus guidance and the applicability of both suggesting that a revision should be made that clearly delineates any requirements in the document from guidance. Chris Sutton agreed to this perspective.

The Focus Group Chair stated that the primary drivers, in his mind, for production of Revision 5 or HASQARD is acknowledgment of the role of the DOECAP-AP and to ensure anything that is causing WRPS and WHL to not be able to implement the revision is addressed to ensure all Hanford contractors are using the same revision of HASQARD.

Robert Elkins stated that the only issue causing the 222S laboratory from not being able to comply with HASQARD Revision 4 is the statement found in Volume 4, Section 2.2 that states:

“Daily monitoring of temperatures in refrigerators and freezers used for sample storage shall be performed and documented. For temperature monitoring, “daily” refers to calendar days, not working days. Temperature monitoring data loggers are acceptable provided they have the capability of providing notification of an out of control event to responsible individual(s) during routine and non-routine work periods. Corrective actions shall be

performed in the event of an out of control condition or catastrophic failure of a refrigerator or freezer.”

Robert Elkins stated that the 222S laboratory and DOE-ORP have always interpreted this requirement to mean that an automated call-out system must be used at the laboratory. Meaning the temperature monitoring system would need to be capable of sending an automated text message or telephone call to alert laboratory personnel when a temperature excursion has occurred even if it's in the middle of the night or on the weekend. This has resulted in DOE-ORP never requiring the 222S laboratory (i.e., WRPS or WHL) to implement HASQARD Revision 4 due to the costs that would be associated with installation and use of a temperature monitoring system with call-out capability.

The possibility of modifying the language using a deminimis change to the HASQARD document was discussed. The Focus Group Secretary took the action to discuss this possibility with DOE-ORP personnel.

The Focus Group Secretary noted that the meeting had gone beyond the scheduled end time for the meeting and adjourned the meeting at 4:08 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on November 28, 2017 in Conference Room 308 at 2420 Stevens.