

HASQARD Focus Group
Meeting Minutes
September 19, 2017

The meeting was called to order by Jonathan Sanwald, HASQARD Focus Group Chair at 2:06 PM on September 19, 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)), Steve Chalk (U.S. Department of Energy – Richland Operations Office (DOE-RL)), Glen Clark (Washington River Protection Solutions (WRPS)), Dan Coughlin (WRPS), Jim Douglas (CHPRC), Fred Dunhour (DOE-ORP), Scot Fitzgerald (CHPRC), Anthony Nagel (CHPRC), Sarah Nagel (CHPRC), Matt Perrott (MSA), Noe'l Smith-Jackson (Washington State Department of Ecology), Chris Sutton (CHPRC), Geoff, Schramm (WRPS), Chris Thompson (PNNL) and Rich Weiss (Tradewind).

- I. The Chair stated that because the DOE-HQ personnel that attended the August meeting of the HASQARD Focus Group had requested additional time to submit comments on the minutes from that meeting, the approval of the meeting minutes from the August meeting will be tabled until the October meeting.

- II. On September 13-14, 2017, the DOE-HQ (AU-21) Analytical Services Program hosted a workshop in Las Vegas, NV to provide information, and receive input, on the DOE Consolidated Audit Program Accreditation Program (DOCAP-AP). The meeting was attended by representatives from the DOE sites, commercial laboratories and the accrediting bodies that will evaluate the laboratories for accreditation under the new DOECAP-AP. Three HASQARD Focus Group members (Taffy Almeida, Glen Clark and Sarah Nagel) attended the meetings. Glen Clark provided a briefing of the discussions held at the workshop:

As stated by Steve Clark (AU-21) when he was at the August HASQARD Focus Group meeting, the DOECAP-AP plans to use three third part, commercial Accrediting Bodies (ABs) to audit and ultimately accredit the laboratories used by DOE sites. The ABs are the American Association for Laboratory Accreditation (A2LA), Perry-Johnson Laboratory Accreditation, Inc. (PJLA) and the American National Standards Institute (ANSI) – American Society for Quality (ASQ) National Accreditation Board (ANAB).

The DOECAP-AP would be very similar to the U.S. Department of Defense (DOD) Environmental Laboratory Accreditation Program (ELAP). The DOD ELAP currently accredits approximately 90 laboratories. The DOECAP has

audited approximately 20 laboratories for the DOE sites. There are about seven laboratories that DOECAP has audited that the DOD ELAP has not accredited. One of these seven laboratories, Southwest Research Institute, stated that they would not pay for, or seek, DOECAP-AP or DOD ELAP accreditation. For laboratories that a DOE entity feels they must do business with that will not pay for DOECAP-AP accreditation, the supplier evaluation costs will fall on the DOE entity requiring that laboratory's services.

At the workshop, Steve Clark reiterated that the status quo of DOECAP auditing is too expensive and will not continue. Therefore, the DOECAP-AP is the solution.

Glen Clark characterized the schedule for implementation of the DOECAP-AP as "ambitious." A memo has been issued by the DOE-HQ Associate Acting Undersecretary for Environment, Health, Safety and Security (AU) announcing the DOECAP-AP would be implemented. The memo states that, "As described in the attached schedule, all laboratory participants are expected to transition to third-party accreditation no later than December 31, 2018." The memo also requests "...all procurement departments standardize the terms and conditions of existing and proposed contracts to allow acceptance and participation in the DOECAP, to include the audit accreditation process." The schedule attached to the memo shows the steps that AU intends to take in implementing the DOECAP-AP. **[Post-meeting Note:** A copy of the full memo and attachment are available from the HASQARD Focus Group Secretary.]

Glen Clark said that while at the workshop he had the opportunity to visit with representatives from each of the ABs. Glen said he also got the opportunity to review the audit checklist used by PJLA. Glen stated that the PJLA closely follows The National Environmental Laboratory Accreditation Coalition (NELAC) Institute (TNI) accreditation checklist. Glen said the radiochemistry portion of the PJLA checklist seemed better than the one used by TNI due to the material PJLA was able to glean from the DOD/DOE Quality Systems Manual (QSM). Glen felt like there was room for improvement in the AB's checklists. The DOECAP-AP intends to use the checklists developed by the ABs. Glen said for this to work for Hanford we will need to provide the ABs input for the HASQARD and American Industrial Hygiene Association (AIHA) additions/differences from the QSM.

The ABs will not be auditing/accrediting the radioactive materials management activities at the laboratories as is done during the current DOECAP audits. The ABs that Glen met with understood that this is important to DOE and believe the plan will be for a DOECAP auditor to be present to cover that aspect of the audit at the same time the AB is at the laboratory conducting the accreditation audit.

The laboratories will be allowed to choose which of the ABs will come to conduct the accreditation audit. The ABs will accredit laboratories by analytical method and by analyte within each method (e.g., metals analysis by inductively coupled plasma EPA Method 6010 for iron, copper, antimony, arsenic, etc.).

During the workshop, Steve Clark said that DOE would like to send an observer to each accreditation audit. How much influence that observer will have, and what the observer's specific role at the audit will be, is to be determined. For example, could the observer identify a violation of a requirement and bring it to an auditor's attention or will their role be to simply report back to AU on violations not recognized by the AB? There is a procedure under development by the Analytical Services Program to describe the interfaces with the ABs numbered AB-1. It is anticipated that the AB-1 procedure will contain the role and authority for the DOE observers at the AB audits. The first item to be accomplished on AU's schedule for implementation of the DOECAP-AP is to establish written agreements between DOE and the ABs to define DOE requirements and oversight in accrediting commercial analytical laboratories. This is to be done in October 2017. In November, the plan is to release the audit calendar for both TSDF and laboratory visits, defining the number of auditors needed from DOE Program Secretarial Offices to support each scheduled audit. No TSDFs will ever be audited by the ABs. The requirements of DOE Order 435.1 have been interpreted to include the need for a Federal employee to lead the TSDF audits. By January 2018, the AU schedule for implementation of the DOECAP-AP shows that the audit schedule for calendar year 2018 will begin. There are about seven laboratories that are not part of the DOD ELAP and it is assumed that the transition to the DOECAP-AP may require these facilities to be DOECAP audited until they are accredited. This implies there will be some form of reciprocity if a laboratory is DOD ELAP accredited, has not been accredited under the DOECAP-AP yet, will not be on the DOECAP-AP evaluation schedule for calendar year 2018 and has a DOECAP audit due in calendar year 2018. The schedule for transition to the DOECAP-AP includes that all current DOECAP audited laboratories will have contracts that specify DOECAP-AP accreditation is required and that all these laboratories been assessed to the DOD/DOE QSM, version 5.1 by December 2018.

At the workshop, AU had sign-up sheets for individuals volunteering to be auditors of the RMM portion of the DOECAP-AP and/or TSDF modules for what remains the purview of DOECAP.

At the workshop, Steve Clark stated that for any laboratories under contract to one of the Hanford Site prime contractors, there would be an additional module for the auditors to assess related to differences between HASQARD and the QSM version 5.1. Sarah Nagel added that this statement drew and audible "groan" from the audience.

After transition, the plan for the DOECAP-AP will be to conduct an on-site accreditation audit at the laboratories in the DOECAP-AP every other year and conduct some sort of data validation activity as a “desk evaluation” on the off years. Therefore, the accreditation granted by the ABs will be a two-year accreditation. The DOECAP contractor to AU will conduct the data validation/desk evaluation exercise in the off years. This contractor will be called the DOECAP data quality group. That group could identify issues that lead to an unscheduled audit if necessary. For example, the laboratory will be required to report turnover in staffing as it occurs. If too many significant positions are changed too quickly, it may trigger a concern requiring an on-site evaluation.

Part of the DOECAP-AP evaluation process will be that the commercial laboratories will receive their chosen AB’s checklist 90 days ahead of the on-site visit. The laboratory will be asked to complete the checklist and identify objective evidence to support the responses on the checklist. The laboratories will have 60 days to complete the checklist and return it to the AB. In talking with the ABs, Sarah Nagel discerned that there is a confusion about whose checklist would be used (i.e., the ABs checklist or the DOECAP-AP produced checklist). The ABs believe it will be their checklist. However, it was not clear how this expectation correlates to DOE AU’s expectation that a HASQARD module will be used for laboratories supporting Hanford and for a more technically complete radiochemistry checklist. Currently, the ABs have taken the TNI checklists and added the DOD requirements from the QSM to them. The feeling from the workshop attendees was that the ABs intend to use their current checklists and add the DOE specific requirements from the QSM to them. In evaluating the AB’s checklists against the DOECAP checklists, Glen Clark found that where the DOECAP checklists contain some specific criteria for evaluation (e.g., Quality Control (QC) limits), these criteria are absent from the AB’s checklists implying no evaluation of these criteria would be made during an AB audit.

Rich Weiss recognized some issues with the data validation approach. End-user contractual requirements may influence the protocols under which any particular analysis or data package is completed by the laboratory. Therefore, Rich hopes that when a potential issue is identified by the validation entity, the owner if the data is contacted to determine if the issue is a result of the specific protocol being implemented or a true deviation from a requirement.

Another participant in the ASP workshop commented to one of the Hanford participants that the idea of having the laboratory complete the AB checklists in 60 days prior to the accreditation is ambitious. The individual stated that it could easily take 20-50 hours per checklist to do a good job responding to the lines of inquiry. Therefore, to complete five separate checklists, one each for

inorganic chemistry, radionuclide analyses, organic chemistry, radioactive materials management and quality assurance program could take 100 man hours.

Chris Sutton asked if the AU presenters stated at what point a laboratory is considered to be accredited. That is, some audits don't "close" until corrective actions are in place.

Glen Clark stated that it was his understanding that the laboratory will have to complete the audit, address any findings in a corrective action response sent to the AB, and the AB will provide a recommendation on whether they believe the response is adequate. The audit report, corrective actions proposed and the AB recommendation will be presented to a committee to review all relevant documentation and vote on accreditation or no accreditation. This ensures a review by someone other than those that conducted the audit will be required prior to accreditation being granted.

Rich Weiss mentioned he heard it said that DOECAP auditors could end up working for the ABs if they are so inclined. Glen Clark agreed saying that they will certainly be looking for technically qualified individuals to cover the RMM module of the audits.

Chris Sutton asked how the ABs accredit laboratories to a method and analyte within a method. That is, is it done on the basis of performance evaluation sample results? Glen Clark said that's how he believes it is done.

Rich Weiss added that the transition year will be interesting. There are still open findings at some of the laboratories related to their most recent DOECAP audits that require the corrective actions taken to be assessed at the next DOECAP audit before the finding can be closed. The plan, as Rich understands it, will be for one of the DOE observers on the AB audit to evaluate the effectiveness of corrective actions taken to resolve those residual DOECAP findings.

Chris Thompson added that Taffy Almeida also attended the ASP workshop and had left Chris a voice message with a couple comments (since she knew she could not be present at this HASQARD Focus Group meeting). Taffy's comments included that fact that Debbie Rosano sounded helpful and interested in ensuring the needs of all DOE sites are met by this program (including HASQARD considerations). He also mentioned that Mike Gamon from Southwest Research Institute (SWRI) has already stated that their laboratory will not seek DOECAP-AP accreditation. Sarah Nagel echoed that she had also heard that and assumes sites that need services from SWRI would need to audit them directly.

Sarah Nagel stated that all the ABs provided information on how they qualify

auditors. The qualification requires them to have a four year degree, bench experience in a laboratory conducting the analyses they will be auditing and auditing experience. All of the ABs have a documented training program and most employ full-time auditors.

Anthony Nagel asked who would issue the audit report produced following an accreditation audit. Glen Clark stated the report will be a DOECAP-AP report. Glen also stated he was more impressed with the first impression he received of the AB personnel than he thought he would be.

Sarah Nagel added that the schedule for the DOECAP-AP includes an expectation that DOECAP-AP audits will begin by February 2018. Rich Weiss noted that this will put a strain on the ABs as the schedule starts to get compressed.

Glen Clark noted that the ABs are all non-profit companies. That said, it is also true they need to pay their staff. Therefore, the need to collect a fee from the laboratory to conduct the accreditation assessment. The fee for conducting the accreditation will vary from laboratory to laboratory and AB to AB depending on the scope of the assessment and could be >\$25K per year for some laboratories depending on the number of methods and analytes for which accreditations is sought, etc.

Jonathan Sanwald asked how the program would be administered for some of the other administrative work that would need to be done (e.g., coordinating audits, notifying the DOE sites regarding accreditation results, maintaining an accredited supplier listing, etc.). Glen Clark stated that he believes this will be done by the current DOE-HQ AU support contractor Project Enhancement Corporation (PEC).

Rich Weiss added that his understanding is that the current contractor personnel at Oak Ridge that were doing the administrative work for DOECAP are available to help but are not taking the lead on the DOECAP-AP administration. The administrative function will move to Washington, DC under PEC. Rich also noted that he has been attending the annual ASP workshop annually using Webex for 4-5 years and has noted a marked decrease in the number of people online attending using this service. He is not sure what to make of this decrease in interest.

- III. The HASQARD Focus Group Secretary stated that with all we have heard today regarding the DOECAP-AP and AU's willingness to include a HASQARD module for auditing the laboratories during the DOECAP-AP accreditation audit, the Focus Group has some actions. He inquired on whether the Focus Group was clear on what those actions are and if individuals are assigned to take the lead for each of them.

Chris Sutton said he has volunteered time from Scot Fitzgerald, Sarah Nagel and Jim Douglas for working on the checklists required to ensure HASQARD differences from the QSM are adequately assessed by the ABs. Chris asked if Glen Clark could lead the effort for the organic analysis checklist. Glen agreed to do this.

The DOECAP-AP anticipates the checklists being updated to QSM version 5.1 prior to use in the DOECAP-AP audits. Therefore, differences between QSM version 5.1 and HASQARD revision 4 will be provided in the checklists. Sarah Nagel recalled hearing one of the ABs say that they have already developed a checklist to assess compliance with QSM version 5.1. Rich Weiss added that the TNI standards are being updated. Therefore, revisions to the checklists the ABs use for TNI assessments will also be required. Glen Clark added that the TNI revisions are being driven by updates to ISO 17025.

The plan for the Focus Group will be to add the HASQARD specific material to the DOECAP checklists and highlight those additions. This will allow the ABs to be able to quickly find the HASQARD-specific material.

Jonathan Sanwald asked if this could be completed by the December 15 meeting of the Focus Group to conform to the DOECAP-AP schedule. An affirmative response was received.

Chris Sutton said the goal should be to eliminate redundant lines of inquiry currently in the DOECAP checklists and add the HASQARD-specific additional material.

Glen Clark mentioned that the ASP was soliciting volunteers to revise the current DOECAP audit checklists to minimize redundancy; correct erroneous references found in the current checklists and address new QSM version 5.1 requirements.

Glen Clark stated that the 222S Laboratory had never developed a HASQARD Revision 4 checklist, nor passed down HASQARD Revision 4 to their subcontractors because the WRPS contract has never been revised and they are still working to HASQARD Revision 3. Fred Dunhour stated this has been the topic of recent discussion at ORP and he believes there will be an alternative to standardization statement issued requesting WRPS to implement HASQARD Revision 4 for subcontracted analytical services while using HASQARD Revision 3 at the 222S Laboratory. All Focus Group members in attendance agreed with the desire to eliminate requirements that caused this inconsistent implementation of HASQARD Revision 4 to occur when producing HASQARD Revision 5.

Rich Weiss stated that it was his understanding that the on-site DOE

laboratories would not be accredited by the DOECAP-AP and asked if others understood that to be the case. Glen Clark affirmed that this was the same thing he understood from the ASP workshop discussions.

The Focus Group Secretary stated that he assumed that once the revised checklists showing the differences between the QSM and HASQARD are produced that the Focus Group would want a review and comment period. This comment was received with a general affirmative response. Therefore, the Secretary asked if the checklists could be completed prior to Thanksgiving to allow review and comment at the November 28 HASQARD Focus Group meeting and finalization of the checklists in early December. The Focus Group members agreed this schedule was required to meet the AU-21 schedule expectations.

- IV. The HASQARD Focus Group Charter has not been updated for many years. With the MSA Waste Sampling and Characterization Facility (WSCF) closure and the end of the Washington Closure Hanford (WCH) contract there is a need to update it. The Focus Group Secretary had provided a proposed revision to the Charter to the Focus Group before the meeting and asked for comments. The following comments in addition to the revisions provided were received:

In regards to the composition of the HASQARD Focus Group, the term “Hanford contractors” should be replaced with “Hanford prime contractors” to ensure that it is clear that not all companies possessing a contract to work at Hanford are included in the membership.

The expectation that minutes be produced within seven working days of a Focus Group meeting should be clarified as to not being applicable to Working Group meetings.

The Area of Focus for MSA should be changes from “Provides supplier evaluation services to DOE” to “Contractor responsible for the maintenance of HASQARD.”

The Secretary took the action to incorporate these comments and provide the Focus Group a revised Charter that will be voted on at the next Focus Group meeting.

[Post-meeting Note: Following the meeting, representatives from ORP and RL discussed one additional proposed change that will be reflected in the revised Charter that will be issued for vote. This change involves the status of the Battelle Memorial Institute (Battelle) in the Focus Group. Battelle is not a Hanford prime contractor to either RL or ORP. It is acknowledged that Battelle had a major role in development of the HASQARD. In the past, Battelle also had responsibilities for off-site environmental monitoring and, in

that capacity, required analytical services to meet regulatory requirements. The role of Battelle today is the same as any other laboratory that works to the HASQARD document. Because no other contracted laboratories are voting members in the HASQARD Focus Group, the Federal personnel present felt that they should be invited to participate to provide historical perspective to passages in the document and as interested members providing technical support but should not have a voting membership.]

- V. The Focus Group used the rest of the meeting time to address requests for interpretations of passages in Revision 4 of HASQARD as part of the process of the on-going effort to generate Revision 5 of HASQARD.
- a. A question had been submitted by a HASQARD user concerning whether alternative language could be used in the 3rd paragraph of Section 4.2.2 of Volume 2 where it now says, “Any attachments taped into the logbook must be taped completely around the attachment.” Because the individual that requested the revision was not present to state the issue behind the current verbiage, the Focus Group members present proposed revising the wording to say, “Any attachments taped into the logbook should be taped completely around the attachment.”
 - b. A question had been submitted by a HASQARD user concerning whether alternative language could be used in Section 3.4 of Volume 4 where it now says, “A system shall be in place to allow tracking of samples and holding times. The system shall allow the laboratory to assess if holding times shall be met or exceeded, and to assess the number of samples available for analysis.” Rich Weiss had tracked this statement back to Revision 1 of HASQARD Volume 4 and stated that he believed this was an attempt to state requirements aimed at ensuring the laboratory had a system in place to prevent missing holding times. Because the individual that requested the revision was not present to state the issue behind the current verbiage, the Focus Group members present proposed revising the wording to say, “A system shall be in place to allow tracking of samples and holding times. The system shall allow the laboratory to assess if holding times shall be met or exceeded.”
 - c. The Focus Group revisited the subject of “should” versus “shall” statements in Volume 1. Any additional shall statements to replace should statements were added and recorded by the Focus Group Secretary in the working Revision 5 file.

During this discussion, Anthony Nagle noted several inconsistencies that require the Assessments sections in HASQARD to be revised. This was tabled to be reconsidered in a future meeting.

The term “specification” is used in HASQARD and the need to find a

standard definition for this term was identified.

Chris Sutton asked if Volume 3 of HASQARD could be eliminated by adding specific requirements for field analyses as an appendix to HASQARD Volume 4. None of the Focus Group members present felt prepared to provide a “final” opinion on this, but all were open to review the idea in upcoming meetings.

The Secretary asked if we now have enough clarity on the DOECAP-AP to revisit the language the Focus Group has proposed for Revision 5 of HASQARD that incorporated the DOECAP audits as part of the HASQARD assessments process. The HASQARD Focus Group members present acknowledged the need to do that before Revision 5 is published.

Glen Clark mentioned that some in WRPS management are questioning the applicability of HASQARD to some analyses the Focus Group has typically interpreted HASQARD as being applicable to (e.g., air analyses). This was mentioned as a heads up to be ready for additional questions that may be raised to the HASQARD Focus Group Secretary as WRPS management clarifies their position.

The Focus Group Secretary noted that the meeting had gone beyond the scheduled end time for the meeting and adjourned the meeting at 4:10 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on October 24, 2017 in Conference Room 308 at 2420 Stevens.