

HASQARD Focus Group
Meeting Minutes
September 25, 2018

The meeting was called to order by Jonathan Sanwald, HASQARD Focus Group Chair at 2:10 PM on September 25, 2018 in Conference Room 223 at 2430 Stevens Center Place.

Those attending were: Jonathan Sanwald, HASQARD Focus Group Chair (Mission Support Alliance (MSA)), Cliff Watkins - Focus Group Secretary (Corporate Allocation Services, U.S. Department of Energy – Richland Operations Office (DOE-RL) Support Contractor), Glen Clark (Washington River Protection Solutions (WRPS)), Jim Douglas (CH2MHILL Plateau Remediation Company (CHPRC)), Fred Dunhour (U.S. Department of Energy – Office of River Protection (DOE-ORP)), Markus McGrath (WRPS), Heather Medley (CHPRC), Karl Pool (Battelle – Pacific Northwest National Laboratory (PNNL)), Paula Sellers (Waste Treatment Completion Contractor (WTCC)), Geoff Schramm (WRPS), Noe'l Smith-Jackson (Washington State Department of Ecology), Rich Weiss (MSA), Tricia Wood (Wastren Advantage Inc. Wastren Hanford Laboratory (WHL)).

- I. The Secretary requested review and approval of the meeting minutes from the HASQARD Focus Group held on August 21, 2018. The draft minutes from the meeting were distributed and time was allowed for one final review. One editorial comment was provided to the Secretary. Hearing no additional comments on the draft meeting minutes, the minutes from the August 21, 2018 meeting were approved.

- II. The HASQARD Focus Group has a standing agenda item to discuss the status of activities associated with the DOE Consolidated Audit Program – Accreditation Program (DOECAP-AP) at all HASQARD Focus Group meetings. This month, the following updates were discussed:

Heather Medley stated that the DOECAP-AP assessment at Test America – Richland (TARL) started today. Heather indicated that the communication from the Accrediting Body (AB) ahead of this assessment and behavior toward the radiochemistry technical specialist seemed quite inconsistent with other reports from assessments held previously. The AB for this assessment is ANSI-ASQ National Accreditation Board (ANAB). Glen Clark stated that Robert Elkins, the WRPS observer for the TARL assessment, was impressed with ANAB's organization of the assessment and their assessment plan. Heather Medley stated that the technical assessor for radiochemistry was scheduled to be Scot Fitzgerald. When Scot arrived at the laboratory, he was informed he would be observing while the lead auditor assessed the radiochemistry portion of the laboratory. The materials Scot needed to conduct the audit were not available to him on the ANAB web site and Scot reported that ANAB did not understand the HASQARD checklist.

Glen Clark stated that on September 17-19 he was he was in Salt Lake City, Utah to observe the Perry Johnson Laboratory Accreditation (PJLA) DOECAP-AP assessment at the ALS Environmental Laboratory (ALSU). Glen was there because WRPS uses ALSU for Industrial Hygiene (IH) analyses. The DOECAP-AP was there because, in the past, the Department of Defense (DOD) had not audited ALSU for IH analyses whereas the DOECAP had audited ALSU to the QSM and prior to that the Quality System for Analytical Services (QSAS) which included IH analyses. When the QSAS and the DOD/DOE Quality System Manual (QSM) were merged, not all requirements were merged and the QSM does not specify what to do when there are conflicting requirements. The assessors provided by PJLA had no experience assessing IH laboratories to the DoD/DOE QSM and accepted Glen's input very professionally. Glen was able to provide appropriate input on IH analyses to alleviate some of the frustration expressed by the laboratory personnel. Glen stated that PJLA did a fine job assessing the scope they were requested to assess (i.e., the non-IH analyses). Glen also served as the HASQARD SME for completion of the HASQARD checklist and follow-up related to that aspect of the ALSU assessment. The first day of the assessment, nobody knew how to apply The QSM to the IH scope of the assessment. This resulted in Glen expressing a desire to have the QSM clarified with respect to the QA/QC requirements that are applicable to IH analyses. Glen stated that he would volunteer to revise the QSM and provide the DOECAP-AP with a checklist for the laboratory assessments applicable to IH analyses. If the DOECAP-AP does not want to accommodate IH analyses, WRPS will continue to conduct supplier evaluations at laboratories that perform these services.

Heather Medley stated that CHPRC requires a laboratory conducting IH analyses to be AIHA accredited and does not perform a separate supplier evaluation based on that requirement. Fred Dunhour added that when he was in Idaho, requiring AIHA accreditation was how the Idaho Site contractors avoided duplicative supplier evaluations at IH laboratories. Glen stated that AIHA is more lenient in the accreditation process than the DOECAP-AP is. The DOECAP-AP looks at methods in more depth than AIHA does. Tricia Wood agreed with Glen's view adding that AIHA allows a laboratory to become accredited by field of testing. A laboratory may have many methods for testing constituents in a field of testing. The AIHA accreditation can be achieved using proficiency test results that were produced using any method from within that field of testing. That gives the AIHA (and users of AIHA accredited laboratories) no information on the laboratory's proficiency using the other methods in that field of testing. Also, the latest updates in the AIHA policies are allowing greater flexibility to accommodate the small business laboratories. For example, it is now acceptable for the laboratory manager to also be the QA manager for the laboratory. Another example is that AIHA will no longer require a laboratory to have a quality program

manual if they can show they are meeting the AIHA requirements in other documents. Glen Clark added that for DOECAP-AP assessments of IH analyses, the AB should look in greater detail at each method utilized by the laboratory than an AIHA assessor would. Glen stated that with the greater public sensitivity to having exceptional IH analyses performed for WRPS, he would prefer the laboratories used by WRPS for IH analyses to be both AIHA accredited, DOECAP-AP accredited and QSM compliant for the methods used. Glen stated that he anticipates no change from the current WRPS SOW requirements that include these requirements. Noe'l Smith-Jackson asked if the DOECAP-AP accreditation would be by laboratory or by method within a laboratory. Glen stated that the DOECAP-AP is accrediting by method, matrix and analyte. There are some problems with this however for IH analyses. For example, IH proficiency testing material is not available for every analyte of interest in every possible matrix of interest. This may be one reason why AIHA accredits multiple methods in a single field of testing using proficiency testing samples for only one method in that field of testing. Even though the ABs will probably not be able to accredit IH analyses to a matrix-method-analyte, accrediting by technique and field of testing (e.g., “metals by Inductively Coupled Plasma – Atomic Emission Spectroscopy”) would be better than simply “metals”.

Since the last HASQARD Focus Group meeting the DOECAP-AP held their annual workshop in Las Vegas August 29 - 30. The HASQARD Focus Group Secretary asked if anyone had attended. Glen Clark stated that he attended and had presented the HASQARD gap checklist slides to the meeting attendees. Glen stated that the presentation went well. Glen also thought the ABs did a good job in presenting the DOECAP-AP and talking about the program. There were a lot of questions and discussion about the approach being taken to accredit laboratories by matrix, method, and analyte. The DOE-Idaho personnel from the Radiological Environmental Systems Laboratory (RESL) that administer the DOE Mixed Analyte Performance Evaluation Program (MAPEP) used the example that many laboratories failed the proficiency testing analyses for total isotopic uranium. This is because most commercial laboratories do not conduct a total dissolution of solid matrices when preparing samples for analysis. Instead, the solid samples are leached with strong acid and the acidic digestant is analyzed. The MAPEP determines acceptable test results based on total dissolution of the solid matrix prior to analysis. The MAPEP personnel present stated they have no proficiency testing material available for which they have determined the acceptance criteria for demonstration of laboratory proficiency in testing for “leachable uranium.” The RESL personnel present stated they would look into the possibility of providing proficiency testing acceptance criteria for their solid matrix material for both total and leachable uranium.

At the workshop, the new requirements in the 2017 revision of the International Standards Organization (ISO)/International Electrotechnical

Commission (IEC) standard 17025, *General Requirements for the Competence of Testing and Calibration Laboratories* were discussed. For the DOECAP-AP ABs to remain compliant with ISO 17025, they are expected to adopt the ISO/IEC 17025:2017 version of the standard within three years. It was stated that the National Environmental Laboratory Accreditation Conference (NELAC) Institute (TNI) has announced that they will not be adopting the ISO/IEC 17025:2017 requirements. However, the DOE Data Quality Workgroup will be adding the new requirements to the QSM.

At the workshop, it was stated that the DOECAP-AP AD-1 procedure (the administrative procedure that the DOECAP-AP operates to) will be issued by the end of calendar year 2018. It is expected that Revision 5.2 of the QSM will be issued first and the AD-1 procedure will follow. The Revision 5.2 of the QSM will have the HASQARD gap checklist included as Appendix E. It was also stated at the workshop that the Hazardous and Radioactive Materials Management (HRMM) and radiochemistry audit modules will be updated. Finally, the workshop presentations from the DOECAP-AP ABs mentioned that they are recruiting auditors to support their efforts.

Heather Medley asked if Glen had heard from other sites whether they shared some of the same concerns Hanford is having as the DOECAP-AP is being initiated. Paula Sellers stated that she has heard other sites raising issues on the number and role of the observers on the DOECAP-AP assessments, the limited number of observers allowed to go to the assessment to observe, the preparation time being allowed, and the ABs expressing concerns that there are too many observers present. Heather Medley stated that at the TARL assessment this week there are only 2 or 3 observers.

Glen Clark stated that one of the things he presumed would be asked by the Focus Group, based on his experiences with the DOECAP-AP and at the workshop, is would the DOECAP-AP and QSM be able to replace DOECAP audits augmented with HASQARD gap assessments conducted by Hanford assessors. Glen stated that ultimately, he believes the DOECAP-AP and QSM will eventually meet our needs for specifying how Hanford assures acquisition of environmental analysis data that meet all applicable requirements. Glen stated that the Hanford observers need to continue to assess the ABs performance at DOECAP-AP assessments. The Hanford contractors need to know that all of the ABs are doing a comparable job in performing their assessments.

Jonathan Sanwald asked Glen Clark if the DOECAP-AP was only going to allow DOE Contractors to send observers to DOECAP-AP assessments through the first year of the program. Glen stated that Steve Clark told him that the DOECAP-AP would allow at least two observers to be present at each assessment and in the second year at least one and perhaps two would be allowed to attend. Glen added that as long as there is a HASQARD gap

checklist to be used in the assessments, the Hanford contractors cannot rely on the ABs to understand it and fully assess to it. Jonathan Sanwald concluded that we need to keep this fact in front of Steve Clark as it seems that Hanford contractors have a greater need to be present at the applicable DOECAP-AP assessments. Glen stated that this fact is appreciated by Steve Clark. Jonathan Sanwald asked if this need to be present at all applicable DOECAP-AP assessments would ever end. Glen Clark stated that his plan is to include all of the requirements from the HASQARD gap checklist (Appendix E of Revision 5.2 of the QSM) into the body of the QSM in Revision 6.0 of the QSM. Glen is currently conducting an exercise to try to identify a technical requirement for each of the items in the current HASQARD gap checklist. Those for which he can find a technical driver, he will petition the QSM Data Quality Workgroup (DQW) to include the requirement in Revision 6.0 of the QSM. The goal of this exercise is to eliminate the need for a HASQARD gap checklist. When the HASQARD gap checklist is eliminated, there will be less need (if any) for a Hanford observer to be at applicable DOECAP-AP assessments. The current situation is that even including the HASQARD gap checklist in an Appendix does not motivate the DOECAP-AP ABs to generate a finding based on a HASQARD gap checklist deficiency. Cliff Watkins asked Glen if he was trying to identify technical requirements associated with all HASQARD requirements or just those represented in the HASQARD gap checklist. Glen said he is looking into only those associated with the HASQARD gap checklist. There are 55 differences identified in the HASQARD gap checklist and Glen stated that he has identified a technical requirement for most of the 55 gaps.

Cliff Watkins asked if the schedule for production of Revision 6.0 of the QSM was known. It was stated that Revision 6.0 is scheduled to be ready by January 2020. **[Post Meeting Note:** A conference call was held on September 26 where QSM personnel stated that Revision 6 of the QSM likely won't be issued until January 2021] Revision 5.2 of the QSM is due out before the end of the calendar year 2018. At the workshop, Diane Lawver, a consultant who is chairing the QSM DQW, stated that she reviewed the HASQARD gap checklist and was impressed with the requirements contained in it. She stated that some good thought went into stating those requirements.

Heather Medley asked about whom at Hanford is on the QSM DQW. Glen Clark stated that Robert Elkins is involved representing WRPS but if anybody else wants to be included, they should contact Steve Clark and make the request.

Jonathan Sanwald asked what laboratories used by Hanford contractors were coming up on the DOECAP-AP schedule. Heather Medley stated that Test America – Denver will be assessed October 11-12 and CHPRC is sending an observer. Also, Columbia Basin Analytical Laboratory will be assessed October 29-31 and WRPS is sending two observers to this assessment.

Jonathan Sanwald asked if January 2020 becomes the target date for phasing out Volumes 1 and 4 of HASQARD. Rich Weiss stated that Volume 1 will still be necessary in some capacity to tie to Volumes 2 and 3 and the old Volume 4 requirements to the QSM. Glen Clark agreed but believes it can be a much smaller Volume 1. The Focus Group agreed there is a need to continue production of Revision 5 of HASQARD to address known deficiencies (e.g., places where references are outdated).

In regard to the discussion on elimination of Volume 4 of HASQARD, Noe'l Smith-Jackson stated that she would caution against that because she has recently seen references to HASQARD Volume 4 in the draft of Revision 9 of the Hanford site-wide RCRA permit. Glen Clark stated that to address the possibility that HASQARD Volume 4 gets referenced in documents, Volume 4 would never go away entirely. Rather Revision 6 of HASQARD Volume 4 can be produced with simply a statement on the historical purpose of this document and that now all requirements formerly implemented using HASQARD Volume 4 are implemented by conformance to the DOD/DOE QSM. Cliff Watkins inquired on whether the site-wide permit was in final reviews. It was stated that the permit is still being drafted so there is time to make comments regarding references to HASQARD that are too specific. Noe'l Smith-Jackson added that she attended a meeting about the draft permit modification the week of September 17 in which many analytical chemistry issues were discussed. Noe'l recommended that the companies send a chemist to these discussions.

Glancing through the minutes from the August meeting, Glen Clark recalled he had the action to inquire about accreditation of laboratories for analysis of the 40CFR Part 264 Appendix IX list of groundwater contaminants of interest. Glen stated that he visited with a program specialist from A2LA who told him they accredit laboratories by analyte for the Appendix IX constituents. The A2LA program specialist agreed this can be a problem if a laboratory user adds an analyte to the list for which the laboratory has not been accredited.

Rich Weiss stated that he has received a meeting invitation for the three-hour webinar to be offered to discuss Revision 5.2 of the QSM. Those that are interested and have not received the invitation should contact Steve Clark. This webinar is being presented mainly as a chance to understand the changes as opposed to making comments that can be incorporated since Revision 5.2 is due to be released at the end of December. Glen Clark stated that the webinar will likely focus on the revisions made to ISO/IEC 17025:2017 and how they have been incorporated into the QSM.

III. The Chair asked if there was any new business to be heard.

The Secretary stated that with the HASQARD Revision 5 subcommittees reinitiating their efforts, perhaps October 16 (three weeks from this meeting) would be too soon to expect a meaningful update. The Secretary also noted that the December meeting of the HASQARD Focus Group is often canceled. With that in mind, the Secretary suggested that the Focus Group meet only twice more in 2018. The Focus Group members present agreed and the dates of October 30 and December 4 were selected for the last two meetings of the Focus Group in 2018. The Focus group members present agreed to shoot for a goal of January to begin reviewing the drafts of Revision 5 of HASQARD.

Hearing no additional new business, Jonathan Sanwald adjourned the meeting at 3:05 PM.

After the meeting it was determined that a conference room was not available for October 30. Therefore, the Secretary sent an email to announce that the next meeting of the HASQARD Focus Group will be at 2:00 PM on November 6, 2018 in Conference Room 308 at 2420 Stevens Center Place.