

HASQARD Focus Group
Meeting Minutes
August 22, 2017

The meeting was called to order by Cliff Watkins, HASQARD Focus Group Secretary at 2:00 PM on August 22, 2017 in Conference Room 308 at 2420 Stevens Place. The Secretary explained that the HASQARD Chair could not be present due to a personal matter he needed to attend to.

Those attending were: Cliff Watkins - Focus Group Secretary (Corporate Allocation Services, DOE-RL Support Contractor), Taffy Almeida (Battelle - Pacific Northwest National Laboratory (PNNL)), Marcus Aranda (Wastren Advantage Inc. Wastren Hanford Laboratory (WHL)), Jeff Bramson (CH2M HILL Plateau Remediation Company (CHPRC)), Steve Chalk (U.S. Department of Energy – Richland Operations Office (DOE-RL)) Jeff Cheadle (U.S. Department of Energy – Office of River Protection (DOE-ORP)), Cliff Clark (DOE-RL), Glen Clark (Washington River Protection Solutions (WRPS)), Steve Clark (U.S. Department of Energy – Headquarters (DOE-HQ), AU-21), Deborah Coffey (PNNL), Dan Coughlin (WRPS), Jim Douglas (CHPRC), Fred Dunhour (DOE-ORP), , Judy McCluskey (WRPS), Anthony Nagel (CHPRC), Sarah Nagel (CHPRC), Karl Pool (PNNL), Debbie Rosano (DOE-HQ, AU-21), Paul Schroder (DOE-ORP), Noe'l Smith-Jackson (Washington State Department of Ecology), Joe Sondag (DOE-RL), Chris Sutton (CHPRC), Chris Thompson (PNNL) and Rich Weiss (Tradewind).

- I. Because this meeting of the HASQARD Focus Group was attended by visitors from DOE-HQ (AU-21), the Secretary asked the personnel present to introduce themselves, indicate their employer, title/position or applicable affiliation with the HASQARD Focus Group.
- II. The Secretary requested review and approval of the meeting minutes from the previous meeting of the HASQARD Focus Group held on May 23, 2017. The draft minutes from the May 23 meeting were distributed and time was allowed for one final review. Hearing no comments on the draft meeting minutes, the minutes were approved.

The meeting was attended by two visitors from DOE-HQ (AU-21), Steve Clark and his manager Debbie Rosano. Steve is the DOE-HQ Analytical Services Program (ASP) Manager. The ASP is proposing to reduce the costs associated with the current DOE Consolidated Audit Program (DOECAP) by initiating a DOE Laboratory Accreditation Program. Because Hanford submitted the most comments and expressed the most number of concerns regarding implementation of this new program, Steve and Debbie felt it was important to come to Hanford and discuss their vision of ensuring the program meets the needs of all of DOE. They wanted to hear the concerns from the HASQARD Focus Group to ensure Hanford's situation is addressed

as the program is being designed. Steve Clark had prepared presentation slides. The slides presented are attached to these minutes. The following minutes in this section highlight key statements made by Steve Clark during the presentation and document the questions, comments and discussions that occurred during the presentation:

Steve Clark said that the accreditation program will not apply to the waste treatment, storage and disposal (TSD) facilities currently audited by the DOECAP. The DOECAP will continue to audit those facilities for DOE.

Noe'l Smith-Jackson asked if the auditors that evaluate the laboratories for the accrediting bodies (ABs) are certified in any way. Steve Clark and Debbie Rosano responded that while the auditors are not "certified" auditors, they are qualified by each of the ABs in accordance with each AB's training and qualification program. This training includes on the job evaluation to ensure the auditors possess the necessary temperament, interviewing skills and technical knowledge to serve in the role.

The criteria for a laboratory to be included on the schedule for DOECAP audits is that they must do \$50K worth of work for at least two different DOE sites.

As Steve Clark was presenting the costs of the DOECAP at its current level of effort, he stated that the total cost to DOE is approximately \$1.8M annually. Chris Sutton asked if this \$1.8M had been compared to the total cost of analytical services conducted by EM annually to determine the percentage of the costs of analytical services that are represented by the laboratory evaluation process. Steve Clark said that these data could be discerned by examining the figures on other slides yet to be presented.

Steve and Debbie explained that the ABs will be required to send the laboratory seeking DOE accreditation a copy of the DOECAP checklist that is required to be completed prior to the AB assessment. The ABs will do this several weeks ahead of the AB's audit team arriving. The laboratory will be requested to complete the checklist and return it to the AB prior to the assessment date and copies will be made available on the DOECAP Sharepoint site for ease of access and review. The AB will then use this information to assist in their planning for areas of focus during the on-site audit and as a basis to request objective evidence to validate the content of the completed checklist when they arrive. Later in the meeting, Sarah Nagel spoke from her experience as both a QA Manager at a commercial laboratory and as a DOECAP auditor. She stated that when ABs sent her the checklist in the past that it was difficult to complete in any reasonable amount of time. She added that with the details requested in the DOECAP audit checklists that it could take one QA Manager a year to get the checklist complete with supporting references. Debbie Rosano noted this as a potential issue and

agreed to follow-up to determine a path forward. Steve Clark added that the current DOECAP checklists may be pared down for use by the laboratories during this pre-audit preparation activity to ensure it is not too onerous while ensuring it can be used to collect the most pertinent/useful information. Steve added that these are the kinds of details he expects to hear in discussions at the ASP Workshop that is scheduled for September. Glen Clark stated that he liked the idea of the laboratories completing the checklist ahead of time, but agreed that they will need to be pared down from their current detail for the laboratories to have a chance at completing them in any reasonable amount of time.

Steve Clark discussed his initial vision for how DOE will oversee the ABs. He stated that there will be lots of opportunities for oversight by stakeholders and mandatory routine oversight built in to the program. For example, the DOE ASP Manager will hold quarterly meetings to discuss AB performance, issues identified, corrective actions taken, etc. The oversight of the ABs during their assessments at the laboratories themselves will include two DOE Observers on every evaluation conducted by the ABs. This level of oversight during the on-site evaluations is not intended to decrease after the first year, but will depend on evaluation of the first year's performance.

Steve Clark stated that DOECAP will continue to audit the laboratories that are currently used by DOE and are not currently in the DOD Environmental Laboratory Accreditation Program (ELAP) until these laboratories are accredited to the DOE program.

Responding to the concern that by DOE adding an accreditation program it puts an additional burden on laboratories that are also in the DOD ELAP, Steve Clark stated that adding DOE accreditation to those DOD ELAP laboratories is actually a reduced burden. Steve stated that the ABs operate in a manner to reduce redundancy. For example, Steve recently observed an AB evaluation of a laboratory that was being assessed for the DOD ELAP, the State of Louisiana's accreditation and a The National Environmental Laboratory Accreditation Coalition (NELAC) Institute (TNI) assessment all done by the same AB during the same on-site visit. Using this model, Steve would envision the ABs doing DOE laboratory accreditation as part of the same visit to the laboratory as the visit done to renew their other accreditations, as applicable, resulting in a shared visit..

In discussing the pre-audit completion of checklists by the laboratory, Glen Clark asked if a laboratory was requesting both DOD ELAP and DOE accreditation, would they be complete two checklists ahead of the audit, one for each accreditation. Steve Clark stated that this may be the case, but he is not aware of a DOD pre-audit checklist. However, during any given audit there may be one checklist for DOD's accreditation and one (or more) for DOE's accreditation, the number of checklists being based on what areas of

scope the laboratory was seeking accreditation (e.g., organic analysis, inorganic analysis, radionuclide analysis). If a DOE site requires new scope from a laboratory for which they are currently not accredited, the laboratory would contact the ABs directly letting them know of the additional evaluation needs.

Noel Smith-Jackson asked if there would be a hierarchy between DOE and DOD regarding the “influence” or “priority” one agency or the other would have over the ABs. Steve Clark said the ABs would be in a separate arrangement with DOE for accrediting laboratories. The only thing the DOD and DOE share in common in their respective accreditation programs is the Quality Systems Manual (QSM) on which DOECAP audits and the DOD ELAP are based. Even then, the QSM contains a significant amount of material that is specific to DOE. The DOE has a QSM working group that is separate from the DOD working group. When the document needs revision, the two working groups get together to make those changes at the same time. The ABs will need to demonstrate competence with the differences between DOD only and DOE only requirements including HASQARD requirements at laboratories used by Hanford contractors. If a laboratory is DOD ELAP accredited, and wants to do business with DOE, they will not be “approved” by reciprocity due to their DOD ELAP accreditation. The programs are completely separate and the laboratory will need DOE accreditation to do work for DOE.

Steve Clark said the DOE accreditation program will include reporting requirements the laboratory must meet that are not currently included in the DOECAP audits. For example, if a laboratory changes their QA manager, they will need to report this to the AB which, in turn, gets reported to the ASP Manager. The ASP Manager would then distribute this information to the field.

The ABs acknowledge that their level of expertise in radionuclide analysis and hazardous and radioactive materials management (HRMM) is not as sophisticated as that present in the DOECAP cadre of auditors. Therefore, Steve Clark stated DOE will provide the auditing personnel for these two modules of the accreditation until DOE feels the ABs have employed qualified personnel to fill this role. These areas may never get turned over completely to the ABs. Steve acknowledged that the DOE and DOECAP cadre of auditors for radionuclide analysis and HRMM is few in numbers, aging and some are nearing retirement. Steve anticipates that an opportunity for some exists to either moonlight if there is no perceived conflict of interest, or to work after retirement with the ABs being the employers.

Cliff Clark asked if the vision is to coordinate the accreditation program through DOE-HQ. Steve responded that yes, the ASP Manager will be the focal point for the program within DOE. Cliff Clark clarified that the purpose

of his question was to ask how the potential “moonlighting” or ex-DOECAP auditors would be contracted. Steve Clark stated that it would be incumbent upon these individuals to contact the ABs with their resume and interest in being employed for this purpose. The ABs will be responsible for qualifying their personnel. DOE will not be involved in this process.

Noe’l Smith-Jackson asked how much approval authority DOE will retain for the personnel utilized by the ABs to conduct the audits. Steve Clark stated that the ABs are to submit the resumes of all personnel that will staff an upcoming audit to the ASP Manager and the laboratory being assessed. Debbie Rosano added that DOE’s agreement/contract with the ABs will allow DOE to exclude any auditor for any reason. Steve reiterated that DOE would provide two DOECAP auditors as observers to each AB audit at least for every audit done at a laboratory used by DOE for the first year or two of the program. The DOE observers would not be auditing but acting only as observers of the AB’s performance. The DOE observers would be funded for their participation the same way DOECAP auditors are funded to participate now. Glen Clark asked if DOD sends an observer to every DOD ELAP audit. Steve Clark said he did not know the answer to that question but he doubts it since DOD has a longer history with the ABs and is more comfortable with them.

Deborah Coffey asked what the carrot is for the ABs. That is, what motivates them to do this work for DOD and DOE? Steve Clark stated that they are in this as a business. They will charge the laboratories a fee for accreditation that recovers their costs and allows for profit. One of the Focus Group members asked is the fee was the same from every AB. The response was that the fee is slightly different depending on the AB. Cliff Clark asked what prevents a laboratory from “AB shopping.” That is, trying to find the cheapest (or most favorable) AB to work with. Debbie Rosano said that this does happen, but rarely. But, if DOE’s oversight of the ABs is adequate, there should be no “easy way” to accreditation because the ABs will be doing an equally acceptable job. Glen Clark added that the three ABs are certified by ISO ISO/IEC 17011:2004, *Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformance Assessment Bodies*. This standard specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs).

Debbie Rosano said that one method the ABs use to ensure consistency and prevent against “bias” is to never send the same auditor to the same laboratory two audits in a row. Sarah Nagel asked when they started doing that. Sarah clarified her question by saying that when she was working in a commercial laboratory, she saw the same auditor from one of the ABs five years in a row. Debbie Rosano took note of this and said she would look into it. Steve Clark stated that this has been noted and it won’t be allowed for the DOE accreditation program.

Deborah Coffey asked a question regarding consideration of the scope of the laboratory's accreditation to provide calibration services and calibration standards which need to be tested and that is the reason some labs perform analytical services. If DOE could link the certification process to the full scope of what the laboratories do, there would be added benefit to DOE in meeting NQA-1 requirements (to qualify suppliers of calibration services and calibration standards which are primary activities for labs under ISO17025). There was a general response that DOECAP audits in the past were only focused on analytical services.

Noe'l Smith-Jackson asked how DOE will ensure HASQARD requirements are assessed at laboratories used by Hanford contractors. Steve Clark stated that if Hanford can provide a checklist that indicates the differences between the QSM and HASQARD, he will make it a requirement of the ABs to utilize that checklist when assessing laboratories used by Hanford for accreditation.

Glen Clark mentioned one complication is that at Hanford, different contractors are implementing different revisions of HASQARD based on contract direction from their respective DOE offices. This may make the "gaps" between the QSM and HASQARD different for different contractors and they both may be using the same commercial laboratory. The HASQARD Focus Group Secretary clarified that there is an effort underway to produce Revision 5 of HASQARD and hopefully unify the revision being used by all contractors. Steve Clark said he would just need Hanford's help to specify which gaps needed to be assessed by the ABs and at which laboratories. Debbie Rosano added that these issues highlight why it will be critical for the ASP Manager to have points of contact at each site to ensure the site's needs are addressed with the accreditation program. It was determined that Steve Clark's primary points of contact at Hanford will be Cliff Clark, Steve Chalk, Paul Schroder, Jeff Cheadle and the HASQARD Secretary.

Karl Pool asked if DOE-HQ will treat this like an evaluated suppliers list. That is, would a listing of all accredited laboratories and what they have been accredited for be available. Steve Clark said that was the plan he had in mind. Anyone with access to the Sharepoint he uses to post this information would be able to look at it at any time. Debbie Rosano added that the goal is for the DOE laboratory accreditation program and status be transparent and visible to all stakeholders including the Regulators at each site upon request.

Anthony Nagel asked if the DOECAP auditor for HRMM would be preparing a DOECAP report or if the AB would be preparing the report. Steve Clark clarified that it would be a DOECAP report.

Steve Clark displayed a slide indicating what the costs of maintaining the DOECAP as it is now would be. Steve said the concept of the accreditation program was supported by all offices within DOE-HQ except EM which raised the issues identified mostly at Hanford. When one Federal DOE-HQ EM employee advanced idea of EM funding DOECAP and retaining the status quo, a manager at a higher level in the EM organization said that was absolutely not an option. Paul Schroder mentioned that requiring the sites to provide observers for AB audits from that site's DOE contractors results in similar costs to DOE for travel and time as the DOECAP status quo. Steve Clark acknowledged that the accreditation program will still require sites to provide funding to contractors for participation. However, the need for participation will be less than is required for DOECAP. Debbie Rosano added that it has been difficult to get enough auditors to staff DOECAP audits in its current format. Therefore, this reduction in need may line up nicely with the qualified personnel available and willing to support the effort.

Rich Weiss addressed the issue associated with the amount of time it will take a laboratory to complete a checklist ahead of an audit. Rich said that as the program matures, DOE will have examples of checklists that have been completed well. These examples could be sent to laboratories to show them the level of effort required and expected. Cliff Watkins asked about how the additional HASQARD criteria would be worked into the pre-audit checklist completion. 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. Sarah Nagel stated that at the commercial laboratory she worked in, she was asked to complete both a program specific and AB specific checklist prior to an upcoming audit. Debbie Rosano took note of this as a potential issue to resolve.

Because organic and inorganic analyses are very common and comparable between DOD and DOE, Debbie Rosano asked how comfortable the HASQARD Focus Group would be if all the DOE accreditation program did was accredit radionuclide analyses and HRMM. Noe'l Smith-Jackson said Ecology would not be at all comfortable with that.

Chris Sutton asked to switch subjects slightly. One vision of the accreditation

program is that an audit will only be required once every other year at laboratories that are performing acceptably. However, data validation will be done for some of the data from a given laboratory on the years they are not audited. Chris asked what the vision for this would be, how it would be done, what implications it had, etc. Debbie Rosano said she thinks this would be accomplished similarly to the way the Environmental Data Quality Work Group (EDQW) has done this in the past. That is, she will use volunteers from the sites to provide data validation services as part for the program. Chris said he did not know who would do that at Hanford. In Chris's organization, data validation is done by an independent third party. It is not done to find problems. In fact, Chris says his organization knows by screening the data as they are delivered where problems exist. Data validation is only done to provide an independent evaluation of the data to add to the confidence the Regulators can have in making a decision using those data. Noe'l Smith-Jackson added that the Sampling and Analysis Plans prepared by the contractors require the data validation, not the Regulators or any specific regulation. Chris added that the percentage of data receiving third party validation ranges from 5% to 100% depending on importance of the data for decision making. However, the packages provided to the data validators won't have problems because the problems are discovered in-house before a package is sent for validation. Debbie Rosano asked that if problems are recognized in-house, are those problems shared with anyone. Chris said they may call the other contractors on-site that are using the same laboratory to see if they have seen similar problems or to give them the heads up to be looking for them. Debbie Rosano was appreciative of this discussion and committed to have a similar discussion of the data validation process across the sites and see if/how data validation could be incorporated into the accreditation program. Debbie said her initial vision would be that she would not be requesting packages from the sites. Rather, she would request packages directly from the laboratories through the contract holders in order to represent data for a couple different DOE sites. Any issues noted during data validation would be forwarded to the sites to determine if similar issues have been noted by internal processes. One of the actions that may result from this effort is revision to the QSM where criteria are too tight relative to what can be achieved at a laboratory.

Steve Clark discussed the schedule for implementation of the DOE accreditation program. The first step will be to get an agreement in place with the ABs. This agreement could include language that requires incorporation of HASQARD as applicable. The HASQARD Secretary asked if a draft of the language could be reviewed and commented on by the HASQARD Focus Group. Steve Clark agreed to provide the draft language.

Anthony Nagel also suggested that the agreement with the ABs specify expectations for the report format and that it get technical editing before

distribution. Anthony said that he has read reports from ABs that are almost unreadable they are so bad.

Noe'l Smith-Jackson thanked the AU-21 personnel for making the effort to come and present the plans for the DOECAP accreditation program to the HASQARD Focus Group. Noe'l said that if implemented as described here (i.e., ensuring HASQARD-specific requirements are included in the accreditation process as applicable) the program sounds good. Noe'l said she would report this back to Ecology management and continue to monitor the implementation of the program.

The Focus Group Secretary noted that the meeting had gone beyond the scheduled end time for the meeting and adjourned the meeting at 4:39 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on September 19, 2017 in Conference Room 308 at 2420 Stevens.