

**HASQARD Focus Group**  
Meeting Minutes  
May 23, 2017

The meeting was called to order by Jonathan Sanwald, HASQARD Focus Group Chair at 2:23 PM on May 23, 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), 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)), Jeff Cheadle (U.S. Department of Energy – Office of River Protection (DOE-ORP)), Glen Clark (Washington River Protection Solutions (WRPS)), Dan Coughlin (WRPS), Fred Dunhour (DOE-ORP), Scot Fitzgerald (CHPRC), Sarah Nagel (CHPRC), Matt Perrott (MSA), Paula Sellers (Bechtel National, Inc.), Noe'l Smith-Jackson (Washington State Department of Ecology), Chris Sutton (CHPRC), Chris Thompson (PNNL), Wendy Thompson (MSA) and Rich Weiss (Tradewind).

- I. Jonathan Sanwald (Focus Group Chair) requested review and approval of the meeting minutes from the previous meeting of the HASQARD Focus Group held on April 25, 2017. The draft minutes from the April 25 meeting were distributed and time was allowed for one final review. Minor editorial comments were provided to the Secretary as the review progressed. Hearing no additional comments on the draft meeting minutes, the minutes were approved.
  
- II. Approximately two days prior to the May 23 meeting, the HASQARD Focus Group Secretary was made aware of a change to the DOE Consolidated Audit Program (DOECAP) being driven by the DOE-HQ (AU-21) Analytical Services Program (ASP) Manager, Steve Clark. Specifically, the DOE-HQ ASP has decided that the DOECAP will no longer be continued in its current format for environmental analytical laboratory supplier evaluations. This imminent change was added as a topic for the agenda for the meeting and displaced all other agenda items related to revising HASQARD to incorporate expectations related to DOECAP participation. The topic was introduced by the first HASQARD Focus Group member to hear of this change, Scot Fitzgerald.

The week of May 8, 2017, a DOECAP audit team was in Fort Collins, CO to audit the ALS Laboratory Group. Scot Fitzgerald and Robert Elkins were representing Hanford on the DOECAP audit team for this audit. At one point in the audit, Steve Clark called the team together to announce that the DOECAP would not be continued in its current format beginning in fiscal year (FY) 2018. Scot stated that Mr. Clark said the program had to change

because there is not enough funding in upcoming budgets to afford the current costs. Mr. Clark said that there were two options, in his mind, for the direction the program will take starting in FY 2018. The two possibilities being that either laboratories are audited biennially, or the DOE adopt an environmental analytical laboratory accreditation program similar to the one currently used by the Department of Defense (DOD). The DOD accreditation program goes by the title, Environmental Laboratory Accreditation Program (ELAP). The DOD ELAP is conducted using four independent accrediting bodies (ABs). The laboratories desiring to do business with DOD are required to pay one of these ABs to come assess their capabilities and, if found satisfactory, accredit the laboratory. Scot stated that the “tone” of Mr. Clark’s remarks indicated that he clearly favored the DOD ELAP model as a solution to the DOECAP funding issues as opposed to biennial audits conducted by DOE personnel. During the audit, there was not a great deal of discussion on this announcement. Scot said he believes this is because everybody present was surprised and had not prepared their thoughts carefully enough to discuss them.

On May 18, the monthly conference call of the DOECAP laboratory auditors was held. During this call, Steve Clark provided a slide presentation to discuss the ASP’s need to revise the DOECAP to reduce costs. The slides from Steve Clark’s May 18 presentation were displayed and the HASQARD Focus Group members that were present on the DOECAP auditors’ conference call led the discussion of the slides as they were presented. The remainder of the meeting was spent reviewing and commenting on these slides.

Taffy Almeida stated that the DOECAP participants were told they have until May 30 to provide comments and that DOE-HQ plans to make a final decision by June 30. At that time, DOE-HQ will issue a memo that introduces this change and directs the field offices to comply with the new program.

Chris Sutton stated that during the DOECAP conference call he asked for clarification on what the memo would say. The response received was that it would likely say that the DOECAP is being revised and that the sites are not to use this as a justification to begin individually auditing their laboratories.

Glen Clark asked if DOE-HQ can mandate the Field Offices to implement the new laboratory accreditation program. The response received was that they can definitely send out such direction.

Chris Thompson asked who would fund the new program and why does DOE-HQ think it would be at less cost. The response was that details were yet to be presented in the slides, but that the laboratories will pay to become accredited which is opposite of what happens now. To this point, Chris Sutton added that 15 of the 22 laboratories in the FY 2017 DOECAP audit schedule are

already accredited by the DOD ELAP. Therefore, if the DOD ELAP is adopted and shared by DOE and DOD, these 15 laboratories would incur no new costs. The other seven laboratories would have to be approached regarding the expectation that they pay to be accredited by DOE.

Glen Clark stated that ELAP is not comprehensive for the types of analyses that DOE requires and for which the DOECAP currently assesses laboratory capability.

Noel Smith-Jackson asked if DOD audits these laboratories. The response was no, they rely on the third party ABs to audit and accredit the DOD laboratories. Once accredited, all assessments of the laboratories are done reactively (i.e., by review of data packages received).

Sarah Nagel mentioned that DD uses three ABs, American Association of Laboratory Accreditation (A2LA), Perry Johnson Laboratory Accreditation, Inc., and the ANSI-ASQ National Accreditation Board. Each of these ABs have unique audit checklists they use to support their accreditation process. Therefore, there is likely inconsistency between the audits done by the different ABs.

Chris Thompson asked whether the ABs use the DOD/DOE Quality Systems Manual (QSM) as the basis for their audits. Glen Clark stated that they do, but the QSM has a significant amount of material highlighted as applicable to DOE only. At this time, the ABs are not considering the additional DOE requirements as applicable to a laboratory's accreditation status.

The DOD has accredited 90 laboratories using the ELAP.

Under the proposal for revising the DOECAP, the DOECAP audits done to evaluate treatment, storage and disposal facilities (TSDFs) would continue as they are done today.

It was mentioned that as Steve Clark spoke to the DOECAP conference call, he mentioned a frustration about how some DOECAP audits are overstaffed while at other times the DOECAP has trouble fielding enough auditors to cover a scheduled audit. Sometimes, auditors will cancel their commitment to support a scheduled audit at very inconvenient times. One perceived benefit of going to an accreditation program would be to put the burden of staffing audits on the ABs that are doing them as a routine function of their business.

Rich Weiss mentioned that the current DOECAP includes an audit when a laboratory closes to ensure no legacy waste management issues will impact DOE. The DOD ELAP does not include a laboratory close-out audit as part of its scope. During the DOECAP conference call, Steve Clark acknowledged that DOE needs to keep this variety of audit covered.

The slide presentation included a slide that showed an estimate of costs to DOE for the DOECAP program. Of the \$1.8M annual cost, approximately \$550K comes from DOE-HQ to support the DOECAP coordination contractor. The other \$1.25M comes from the operating budgets at the various Field Offices as they provide auditors for the program.

All of the ABs used by the DOD ELAP are certified by the International Laboratory Accrediting Coalition (ILAC) using the ILAC Mutual Recognition Agreement (MRA).

During the conference call Steve Clark mentioned his belief that data validation is important and can be used by the sites to fill in any information not gleaned by sending auditors to a laboratory and meet QA program requirements to assess suppliers' performance. Glen Clark stated that his experience is that when an issue is identified during data validation, the ability to follow-up on that issue in person during a DOECAP audit has been very effective.

It was asked whether the ABs have technically qualified personnel to assess a laboratories radiochemistry capability. The response was that the ABs do very little auditing related to radiological analyses in support of DOD and no auditing of a laboratory's radioactive waste management system. Rich Weiss added that DOD's focus for radiological measurements is much less than DOE's as far as specific requirements/expectations for adequate service. For some aspects of radiological measurements, the DOD relies on the National Environmental Laboratory Accreditation Coalition (NELAC) to assess laboratories.

Glen Clark mentioned that some DOD auditors have participated in DOECAP audits to enhance their understanding of DOE requirements and radiological analyses.

In response to questions regarding how thorough the DOD AB audits are for the price paid by the laboratories, Scot Fitzgerald stated the a representative from the GEL laboratory in Charleston, SC stated that their laboratory pays approximately \$25,000 annually to two auditors to come to their facility for a four day audit.

It was stated that Steve Clark is amenable to the possibility of DOECAP auditor personnel from the sites serving as observers during the first year of audits being conducted by ABs as the DOE accreditation program is introduced. Jonathan Sanwald stated that he has experienced situations where he was an observer at an audit and observed an auditor conducting themselves in an unethical way. However, as an observer he had no recourse to correct

the situation. Chris Sutton added that the purpose of the observers for the first year of the DOE accreditation program will be to see if the AB auditors are covering DOE's concerns adequately. Jonathan Sanwald stated that considering the detail in DOECAP checklists and the numbers of auditors the ABs typically assign to DOD accreditation audits, it is likely the ABs will not be able to cover half of the items a DOECAP audit covers in the time the ABs spend at a laboratory. Glen Clark stated that the DOECAP auditors should be involved with the development of the audit checklists that the future DOE ABs use. Chris Sutton concurred and believes the plans are for DOECAP auditors to support development of the checklists used by the DOE ABs.

Noel Smith-Jackson added that if the DOECAP is gone, we will need a gap analysis between whatever the DOE accreditation program assesses and requires and HASQARD.

Rich Weiss stated that he is not aware of how the DOD ELAP is structured or how its requirements are stated. If DOE is going to have a laboratory accreditation program, it needs to have detailed technical requirements defined. These programmatic requirements need to be transmitted to the ABs as a contractual relationship between DOE and the ABs. That is, DOE will need to specify requirements in more detail than simply stating "audit the DOE laboratories to the DOE/DOD Quality Systems Manual using the DOE specific requirements." Chris Sutton stated that at the DOECAP conference call, a reference was provided for the DOD ELAP manual. Chris took an action item to find this manual and get it distributed to the Focus Group.

The driver for making this change was stated as a need to reduce costs. Scot Fitzgerald stated that at the ASL audit where this change was announced, the comment was made that the DOE Mixed Analyte Performance Evaluation Program (MAPEP) was also having its funding reduced and speculation is that costs saved from elimination of DOECAP audits will be funneled into MAPEP.

Jonathan Sanwald asked about the possibility of one or more of the seven laboratories that are not currently part of the DOD ELAP accreditation process refusing to pay to be accredited by DOE. That is, has a risk analysis of losing one or more of these laboratories been completed?

It was stated the the DOE-HQ Analytical Services Program (ASP) Steering Committee will make the final decision on whether a DOE accreditation program will be implemented.

Scot Fitzgerald mentioned that Steve Clark is quite aware of HASQARD and that no other site has a program as mature as the multi-contractor HASQARD process. In fact, during the ASL audit, a question being asked by a DOECAP auditor was answered using the method detailed in HASQARD on how to

address the auditor concern. Steve asked if the QSM could be rolled into HASQARD and was informed of the Focus Group's efforts to make the two documents as compatible as possible without losing Hanford-specific criteria that we have found useful.

At the end of the DOECAP conference call, it was stated that comments on the elimination of DOECAP audits in favor of a DOE accreditation program could be submitted to DOE-HQ personnel no later than May 30. Jonathan Sanwald inquired on how the Focus Group comments should be compiled and transmitted. The Focus Group Secretary agreed to compile comments and ensure the appropriate DOE Field Office representative received them for transmittal to DOE-HQ.

Chris Sutton stated that, aside for some of the issues and concerns that have been expressed at this meeting, some aspects of having a DOE laboratory accreditation program could be beneficial. That is, if it is done well and the DOE sites believe it meets their needs, the MSA Acquisition Verification Services (AVS) organization would have a reduced work load in adding laboratories to their Evaluated Suppliers List (ESL). Jonathan Sanwald stated that this would be similar to other testing laboratories currently on the MSA AVS ESL that are there based on being certified to ISO-17025. Chris Sutton said that a DOE accreditation could correlate to the Washington Department of Ecology accreditation program already in use.

The Focus Group Secretary stated that the proposal seems to move DOE away from the requirements that it imposes upon its contractors to implement a QA program consistent with EM-QA-001, NQA-1, etc. Specifically, QA program requirements for procurement, control of items and services and independent assessments would be difficult to document for analytical laboratories accredited by a third party. The similarity to commercial grade dedication was made. With no source evaluation or commercial grade survey being conducted by the buyer, the ability to be assured laboratory data meet a contractor's requirements for its critical characteristics (i.e., that HASQARD is being invoked) is not being addressed by the contractor's QA program. The Secretary added that is the DOECAP audits are discontinued, the DOE contractors are further removed from their ability to assess their suppliers. They would need to do it using only data validation and the fact that the laboratory is accredited. The only means of ensuring the laboratories being accredited are aware of HASQARD, would be to attached it to contract SOWs which at the current time is not being allowed by MSA AVS.

Marcus Aranda asked if WRPS could request additional funding to start auditing (or at least visiting) contracted laboratories to discuss HASQARD and its implementation at the laboratory. It was stated that this would not be an easy thing to do.

While discussing laboratory SOWs the fact that there is an Inter-Contractor Procurement Team (ICPT) SOW and Basic Ordering Agreement (BOA). Chris Sutton mentioned that the DOE negotiates prices for the ICPT BOA SOW. A site may request a laboratory to provide services under the ICPT BOA but if requirements are added to the SOW, the laboratory has the right to renegotiate pricing to support the additional requirements.

Rich Weiss mentioned that WCH used the ICPT BOA with HASQARD invoked as additional requirements. This resulted in the laboratories responding with revised pricing. Rich added that if a DOE accreditation program is invoked, it is possible that a laboratory won't be able to "opt out" of becoming accredited if they still want business from a DOE client. If the Hanford contractors use the ICPT BOA and invoke HASQARD, the question becomes, how does the Hanford contractor assess whether HASQARD is being accurately and completely implemented with no on-site audit/assessment capability?

Jeff Bramson also expressed a concern relative to implementation of the company's QA program stating that the proposal to do away with assessments that contractors participate in and to not allow contractors to determine the QA requirements to be implemented at a laboratory are unacceptable.

Noel Smith-Jackson stated that Ecology's issue with accepting DOECAP as the laboratory auditing entity representing Hanford and HASQARD was that Hanford seemed to have little ability to influence DOECAP to assure HASQARD is being implemented. The fact that Hanford personnel are DOECAP auditors alleviated some of Ecology's concerns such that acceptance of DOECAP was growing amongst Ecology personnel. However, a transition to a DOE laboratory accreditation program where Hanford personnel will not be involved in assessing the laboratories at all will likely be perceived by Ecology personnel as a move further away from assurance that HASQARD is being implemented at the laboratories.

Rich Weiss stated that DOE will need to show that their accreditation program provides consistent application of DOE accepted criteria in their oversights of the ABs.

Sarah Nagel added that commercial laboratory personnel have told her that the DOD accreditation audit involved the AB sending the audit checklist to the laboratory with a request for the laboratory to audit itself and complete the checklist. The AB auditors then arrive to "verify" the checklist was completed accurately.

Jonathan Sanwald asked if anybody has polled the seven laboratories that are used by DOE and are not in the DOD ELAP to see if they would balk at the price for participating in a DOE accreditation program. None of the Focus

Group members present knew if this had been done or not.

Scot Fitzgerald said that while talking with GEL about this possibility, the GEL personnel liked the idea of a joint DOD/DOE accreditation program where they only have to deal with one audit annually instead of two. The GEL personnel stated that the DOD AB audit is “more laid back” than the DOECAP audit.

Glen Clark mentioned the fact that there are no IH laboratories being audited by the DOD ELAP and WRPS has need for IH laboratories. To this point, Chris Sutton stated that the CHPRC IH organization does not want DOECAP in the IH laboratories that they contract with. The CHPRC IH organization is satisfied with a laboratory as long as they have been certified by the American Industrial Hygiene Association (AIHA).

With a short-term path forward determined (i.e., accumulation and transmittal of Hanford comments regarding the revisions to DOECAP to DOE-HQ), the Chair asked if there was any value in the HASQARD Focus Group meeting again until DOE-HQ has determined the future direction of DOECAP and/or a laboratory accreditation program. Rich Weiss stated that the monthly DOECAP conference call for June has already been cancelled. The consensus amongst Focus Group members was that there was no need for a June 20 meeting. Because DOE-HQ has stated intent to issue a memo describing the future direction of DOECAP by June 30, the HASQARD Focus Group members present determined that a meeting in July to discuss the ramifications was warranted. Once the future of DOECAP and/or a DOE laboratory accreditation program is known, then work to revise HASQARD to provide appropriate reference to this program can commence.

The Focus Group Chair requested any additional new business and, hearing none the Secretary adjourned the meeting at 3:43 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on July 25, 2017 in Conference Room 223 at 2430 Stevens.