

HASQARD Focus Group
Meeting Minutes
January 22, 2019

The meeting was called to order by Jonathan Sanwald, HASQARD Focus Group Chair at 2:03 PM on January 22, 2019 in Conference Room 308 at 2420 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 (RL) Support Contractor), Glen Clark (Washington River Protection Solutions (WRPS)), Jim Douglas (CH2MHILL Plateau Remediation Company (CHPRC)), Sheila Hahn (RL), Karl Pool, (Battelle – Pacific Northwest National Laboratory (PNNL)), Paula Sellers (Waste Treatment Completion Contractor (WTCC)), Noe'l Smith-Jackson (Washington State Department of Ecology), Chris Thompson (PNNL), Rich Weiss (MSA), Tricia Wood (Wastren Advantage Inc. Wastren Hanford Laboratory (WHL)).

- I. The Chair requested review and approval of the meeting minutes from the HASQARD Focus Group held on December 4, 2018. The draft minutes from the meeting were distributed and time was allowed for one final review. Hearing no comments on the draft meeting minutes, the minutes from the December 4, 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:

Jim Douglas began by commenting about the assessment at Test America – St. Louis that he attended in December. Jim stated that he was impressed by the knowledgeable staff present from the American National Standards Institute (ANSI) National Accreditation Board (ANAB) accrediting body (AB) that conducted the assessment. There were only two personnel from ANAB present at this assessment due to the scope of the assessment. The Hazardous and Radioactive Materials Management (HRMM) portion of the assessment was conducted by Joe Pardue from Oak Ridge. Another individual from Oak Ridge filled the technical specialist assessor role for the radiological analysis portion of the assessment. Jim stated that all of the assessors did a good job. This contrasted greatly with the less than admirable impression left by the other DOECAP-AP AB that Jim has observed, Perry Johnson Laboratory Accreditation (PJLA). Glen Clark asked if this was a gap assessment to address only DOE specific items in the DOE/DoD Quality System Manual (QSM) or a full accreditation assessment. Jim responded that it was a full assessment that lasted three and a half days. Jonathan Sanwald inquired about how well the HASQARD gap checklist was completed since

that has been a common issue from observers in the past. Jim stated that he assisted the AB assessor assigned to the HASQARD gap checklist with interpretations but that the assessor completed the checklist well. Jim stated that he felt he was definitely able to remain in the role of observer rather than feel compelled to act as an assessor while observing the ANAB led team.

Jonathan Sanwald asked if this was Hanford's first experience observing an ANAB led assessment. Glen Clark responded that Robert Elkins and Scot Fitzgerald had observed ANAB at Test America – Richland.

Glen Clark stated that he is still concerned with the level of documentation being provided in the completed checklists that are available to the DOECAP auditors observing the DOECAP-AP assessments. Glen qualified this statement by saying that most of the assessments observed so far have been gap assessments and, because of this, the documentation is perhaps not as thorough as it would be for a full accreditation assessment. Glen demonstrated this using a checklist he obtained from another assessment. Some lines of inquiry on the checklist Glen had obtained showed only a "yes" or "no" response, or no response at all, with no reference to the objective evidence reviewed to make the associated determination of compliance. This is not adequate documentation especially as compared to the documentation produced during DOECAP audits. Glen qualified his concern by saying if the objective evidence is listed in the final report, then the issue with that evidence not being listed on the checklists is minimized. Glen said his bottom line is that the question on whether the level of documentation being produced is adequate is still to be determined. Glen is interested in seeing the level of documentation produced when an AB completes a full accreditation assessment (as opposed to a gap assessment) before passing final judgment on the documentation being produced. Glen acknowledged that even amongst the DOECAP auditors some were better at documenting objective evidence than others. Jonathan Sanwald asked what the thoughts were about how best to raise this concern with Steve Clark at DOE-HQ (EM), asking if an email could be sent to him. Glen stated that he could send an email. Cliff Watkins asked about the upcoming DOECAP auditors conference call and whether it could be brought up then. Glen agreed to bring it up in that call.

Paula Sellers requested clarification on who actually accredits the laboratories, the AB or DOE. That is, if it is the AB, how does it become a DOE accreditation especially if the certificate says it is an accreditation by the AB? Glen Clark clarified that the documentation of accreditation will clearly indicate that the accreditation is to the DoD/DOE QSM requirements.

Returning to the subject of the checklists completed during the assessments, Glen Clark stated that the checklists are a "tool" used by the assessors to stay on track. Some individuals or organizations consider the checklists a higher level of documentation than others. Paula Sellers acknowledged that point

and added that everything in the scope of the assessment should be supported by documented evidence that it was satisfactorily met or not. This can be documented on a checklist or in the final report. But, if the checklist is what is being used during the audit to capture that information, it should be complete. Jonathan Sanwald agreed and stated that in his observations, Hanford has a greater expectation for completeness of the checklists than other sites. Glen stated that he is not sure that this is peculiar to Hanford or not. Jonathan Sanwald stated that perhaps Hanford's expectations come from our involvement with the Multi-Site Approved Supplier List (MASL). Jonathan stated that the MASL expectations for completeness of the checklist are significant but only six DOE sites actively participate in the MASL. Glen Clark added that perhaps our higher expectations derive from the fact that most Hanford contractors manage nuclear facilities, adopt NQA-1 as a consensus standard and NQA-1 has high expectations for documentation. Jim Douglas concurred stating that Hanford contractors are used to complying with NQA-1 Requirement 18 for objective evidence expectations. Glen Clark said that the DOE contractors' expectations are high due to our experience working with DOECAP audits. Glen added that we (the Hanford contractors) need to look at the final assessment reports and if adequate objective evidence is being provided in these reports. If the reports are inadequate, we can bring up these concerns to the DOE-HQ EM Analytical Services Program Manager. Karl Pool asked if we have heard the same concern from other sites. Glen Clark said he would ask the question at the next DOECAP auditors conference call and see if other sites echo the concern.

Paula Sellers asked if the objective evidence issue was only applicable to the HASQARD gap checklist not being present in the QSM. Glen Clark clarified that this is a separate issue related to all lines of inquiry used and documented by the ABs on the assessment checklists. Glen stated that the HASQARD checklist won't be fully incorporated into the QSM checklists until Revision 6.0 of the QSM is issued. The DOECAP-AP is using QSM Revision 5.2 which contains the HASQARD gap checklist as an appendix. This emphasizes the needs for Hanford contractors to be present on applicable DOECAP-AP assessments. Jim Douglas concurred adding that it seems that the DOECAP-AP AB assessors are in need of interpretation of the HASQARD gap checklist.

Glen Clark reiterated the desire to get all of the HASQARD requirements in the QSM. Glen has researched this matter and found that several of the requirements in the HASQARD gap checklist were present in the document to which DOECAP used to audit (the Quality Systems for Analytical Services (QSAS)). When the QSAS was revised to become the DoD/DOE QSM, some of the requirements were dropped. Glen has reviewed all of the gap requirements and has provided the HASQARD Focus Group with a version of the gap checklist indicating the source of the QA requirement or guidance document from which the best practice originates. In Glen's work, some of

the HASQARD gap checklist requirements are recommended to be deleted since they have little or no value added in the commercial laboratory sector. Jim Douglas acknowledged and appreciated Glen's effort in doing the research on the requirements basis for the HASQARD criteria adding that he recalled that the WRPS management has been interested in this. Glen agreed adding that his management has wanted this for a long time. The WRPS management position has been to eliminate duplicative requirements by removing them from HASQARD and retaining them only on the company QA documents. Glen added that this was stated by Chris Sutton before he retired (i.e., that there are duplicative requirements resulting in audits being performed against both sets of requirements to ensure adequate coverage of assessments).

Paula Sellers cautioned against stating that the USEPA SW-846 document is a source of requirements. Paula indicated that if SW-846 is referenced in a program as a standard (as opposed to a reference or guidance document) it must be followed exactly. Glen concurred saying the WRPS QA documents simply say they follow HASQARD.

Noe'l Smith-Jackson stated that she thought the goal was to get all of the HASQARD requirements into the QSM. Glen Clark agreed that this was the goal and indicated that the effort to list the basis for HASQARD gap checklist lines of inquiry were to provide a basis to the QSM committee to encourage them to include these requirements in the QSM. Glen has discussed this idea with Diane Lawver of the QSM working group in the past and she has been supportive of including these requirements in the body of the QSM. Cliff Watkins stated that the ultimate goal was to get all requirements present in the HASQARD into the QSM and remove all requirements related to commercial laboratories from HASQARD. The HASQARD would point to the QSM as the source of all standard laboratory QA requirements. The HASQARD would only need to provide "exceptions" or "relief" from QSM requirements for the on-site laboratories that work with samples possessing higher radioactivity than the samples that can be managed in the commercial laboratories, for example. Jonathan Sanwald agreed adding that the QSM may have additional requirements that the HASQARD never had that will impact the on-site laboratories. Glen Clark agreed, stating that the QSM does have additional requirements. Glen believes this can be easily managed by the on-site laboratories by stating an exception to the requirement(s) that cause an issue because the QSM is not a contract-required document. Tricia Wood added that the 222S Laboratory personnel are taking a look at the DOECAP checklists now to identify requirements that are not in HASQARD to determine if there are any that cannot be supported.

Rich Weiss asked if the 222S Laboratory is using the DOECAP checklists to make this determination because the AB's checklists may be different. Glen Clark added that he has provided copies of the checklists being used by the

DOECAP-AP ABs for the 222S laboratory to use in this comparison. Glen stated that the DOECAP-AP ABs' checklists are comprehensive with the QSM requirements and in the order of the QSM sections and that the DOECAP checklists were not necessarily ordered by Section of the QSM. Glen Clark said that he isn't sharing the DOECAP-AP checklists with anyone because the checklists are based on ISO 17025 which requires a subscription to obtain. Jim Douglas stated that he had heard that the DOECAP-AP AB's checklists are not available because they are considered proprietary. Glen Clark stated that the completed DOECAP-AP AB checklists are considered proprietary, but if you have a legal copy of ISO 17025, the ABs will send you the blank checklists. Both WRPS and the 222S laboratory carry a subscription to ISO 17025. Glen added that the ABs are auditing to both ISO 17025-2017 and 17025-2005. The QSM is based on ISO 17025-2005, but the accrediting authority that accredits the ABs requires them to audit to ISO 17025-2017. Jim Douglas stated that CHPRC has an ISO 17025 subscription, but they have not looked at 17025-2017 yet since the QSM isn't using it yet. Glen added that this subject is one more reason he is a real proponent of moving Hanford away from HASQARD and toward the QSM. That is, the QSM is constantly working to keep it up to date (e.g., method QC acceptance limits). By comparison, the HASQARD takes a great deal of time to update. The QSM is used by all of DOE and covers the HRMM aspects of analytical services that the HASQARD never has. Karl Pool stated that HRMM has never been a component of HASQARD because the on-site laboratories have the HRMM aspects covered elsewhere in their company programs. Glen Clark agreed and stated that the HRMM portions of the QSM would not be audited in a QSM audit of an on-site laboratory.

III. The status of production of Revision 5 of HASQARD was discussed.

The status of Volume 1 was briefly discussed. The Volume had been discussed extensively in the December meeting. Therefore, with no new comments emerging from the Focus Group members present, the Secretary requested a path forward be discussed. The Focus Group members present agreed that Volume 1 is ready for a final review and vote. The Secretary will send out the latest red-lined version of the document and request the voting members to attend the next Focus Group meeting to either vote or request a basis to table the vote.

The Volume 2 subcommittee chair was absent from the meeting. Therefore, additional discussion on Volume 2 was deferred until the next meeting. However, it was mentioned that email correspondence received by the Secretary and Geoff Schramm from Fred Dunhour indicating that Volume 2 should be removed was retracted. Volume 2 provides a basis of common sampling expectations upon which the contractors' specific procedures for sampling will be based.

The Volume 3& 4 subcommittee Chair, Jim Douglas stated that he would like to get Glen Clark's input on how best to meld the revisions to Volume 4 with the revisions made to Volume 1. Jim stated that it is likely that Volume 4 will mostly point to the QSM as the document where analytical services QA/QC requirements are specified. Jim stated that the larger effort will be in Volume 3 because the QSM is not applicable to field analyses. Therefore, Volume 3 will need to specify requirements that are unique to HASQARD.

- IV. In the way of new business, Cliff Watkins asked when the next DOECAP-AP assessment would be that is applicable to Hanford. Glen Clark stated that it was supposed to be the assessment scheduled for GEL Laboratories in February. However, that assessment has been postponed until April. Jim Douglas stated that he is scheduled to go to Test America in Denver, but the date is still listed as TBD on the DOECAP-AP schedule. Glen stated that most of the upcoming assessments applicable to Hanford are later in the year.

The fact that there was a DOECAP auditors conference call scheduled for Thursday January 24 was discussed and noted by those interested in listening in.

Hearing no additional new business, Jonathan Sanwald adjourned the meeting at 3:07 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on February 26, 2019 in Conference Room 308 at 2420 Stevens Center Place.