

**HASQARD Focus Group**  
Meeting Minutes  
March 19, 2019

The meeting was called to order by Jonathan Sanwald the HASQARD Focus Group Chair at 2:05 PM on March 19, 2019 in Conference Room 308 at 2420 Stevens Center Place.

Those attending were: Jonathan Sanwald – 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), Linda Carr (Battelle Memorial Institute – Pacific Northwest National Laboratory (PNNL)), Glen Clark (Washington River Protection Solutions (WRPS)), Scot Fitzgerald (CH2MHILL Plateau Remediation Company (CHPRC)), Heather Medley (CHPRC), Anthony Nagel (CHPRC), Matt Perrott (MSA), Karl Pool (PNNL), Paula Sellers (Waste Treatment Completion Contractor (WTCC)), Noe'l Smith-Jackson (Washington State Department of Ecology), Chris Thompson (PNNL), 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 February 26, 2019. 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 February 26, 2019 meeting were approved.
  
- II. Prior to the February 26 meeting, the Secretary received a suggestion to include a discussion topic on the agenda regarding the fact that the DOE/DoD Quality System Manual (QSM), Revision 5.2 has eliminated all requirements related to participation in the DOE Mixed Analyte Performance Evaluation Program (MAPEP). The results of this discussion indicated a need for DOE to determine if a 1994 DOE-HQ Environmental Management (EM) memorandum expressing requirements for laboratories to participate in MAPEP could be rescinded. The status of this action item was discussed.

The HASQARD Focus Group Secretary reported that a conference call was held on March 7 between the RL QA team lead, The HASQARD Focus Group Secretary, Bob Murray (EM-3.113) and Yevonne Deaton (EM-3.113). During the conversation, Mr. Murray and the Secretary recalled the history behind the issuance of the 1994 memorandum. In 1994, both the Analytical Services Program (ASP) and the Radiological Environmental Sciences Laboratory (RESL) were funded and managed through EM. Today, RESL is funded and managed through DOE-HQ Nuclear Energy (NE) and the ASP is funded and managed through the DOE-HQ Associate Under Secretary for Environment, Health, Safety and Security (AU) organization. Because of this, the EM personnel on the conference call stated that nobody from EM would

attempt to “enforce” or “write a letter to somebody” if they found out that a 25-year old policy memorandum was not being adhered to. The Secretary stated that for this reason, and the technical reasons detailed in the HASQARD Focus Group meeting minutes for the February 26 meeting, there is no impact on deletion of MAPEP from the QSM Revision 5.2. The Secretary further stated that there would be no issue if the Hanford Contractors did not require MAPEP participation at their laboratories.

Glen Clark asked if participation in MAPEP was required in the contractors’ SOWs to the analytical laboratories they are currently using. Heather Medley responded that MAPEP participation is required in the CHPRC SOWs to analytical laboratories.

The Focus Group representatives requested something written be provided from DOE EM to ensure that deletion of the MAPEP requirement could be done based on documented revision of EM policy. The Secretary stated that a full recension of the policy would likely not be forthcoming as EM has no interest in the program at this time. However, the Secretary committed to attempting to obtain an email from EM personnel showing concurrence for the statements made in the March 7 conference call. If obtained, the email will be attached to a memo to file to ensure it is captured in the RL records and posted on the HASQARD Focus Group web site to allow the Hanford contractors to access the written statements.

Tricia Wood added that there is some benefits to analyzing the MAPEP samples. The primary benefit at the 222S laboratory is that technicium-99 (<sup>99</sup>Tc) is a radionuclide of interest at the Hanford Site and the only performance testing (PT) program she is familiar with that offers a sample with <sup>99</sup>Tc in it is the MAPEP. Because of that, the 222S laboratory will continue to participate in MAPEP regardless of whether there is EM policy or a QSM requirement driving the participation.

- III. 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:

No assessments have been conducted by the DOECAP-AP ABs at laboratories used by Hanford Contractors since the last HASQARD Focus Group meeting in February. Therefore, no new observations from HASQARD Focus Group members assigned to observe the DOECAP-AP ABs were available.

An assessment is scheduled for GEL Laboratories in April, but no final dates for this assessment have been announced. Jonathan Sanwald commented that this seems to be a minor issue with the program (i.e., late notification for final schedules). Glen Clark concurred with the comment adding that Judy

McCluskey is scheduled to represent WRPS as an observer at the assessment of GEL. Heather Medley stated there will be no CHPRC representative at that assessment because the list indicated no more spots for observers were available. Heather stated that CHPRC will have observers at Test America – Denver and Test America – St. Louis but those assessments are scheduled for fall 2019.

Glen Clark asked if all Focus Group members had seen the announcement for the ASP Workshop coming up in Denver in July, 2019. Not all had seen this notice and Glen offered to forward the notice to those interested. Glen noted that it was interesting that someone from the Occupational Safety and Health Administration (OSHA) would be speaking at the ASP Workshop. Glen added that OSHA does not audit analytical laboratories, mainly because they do not have a large enough staff to conduct audits, and wondered what their interest in the ASP would be.

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

The status of Volume 1 was discussed. The thinking of the Volume 1 working group is that it is completed and ready except for some edits that may be discovered as being necessary as Volumes 2, 3 and 4 are finalized.

Paula Sellers asked for Focus Group input on whether a Glossary of terms should be included in each Volume of HASQARD or just in Volume 1. Paula expressed the opinion that having the Glossary in only Volume 1 would be best. Matt Perrott agreed with this opinion stating that having a Glossary in each Volume opens a greater possibility that multiple “versions” of the Glossary could exist leading to a potential for inconsistency. Chris Thompson echoed Matt’s view saying that having the Glossary in one place means that if revised, the revision only needs to occur in one place in the document. Glen Clark agreed and said he believed the logical place for the Glossary would be at the end of Volume 1 and the Focus Group members present concurred with that view.

Jonathan Sanwald asked about the progress on Volume 4 saying he had seen a draft of the revised Volume sent from Glen for comment. Glen said that he had done some work on Volume 4 but has not touched Volume 3 because WRPS does not use Volume 3.

The Secretary displayed the version of Volume 4 that is being proposed as closest to “final.” The Focus Group members present reviewed the section on Data Quality Requirements (DQRs) (precision, accuracy, representativeness, comparability and completeness) and agreed the definitions of the terms found in this section should be moved to the Glossary rather than having a section dedicated to DQRs.

Noe'l Smith-Jackson commented on the lack of detail found in Volume 4 with this revision. The Focus Group discussed the material in the revised Section 2 that sends the users of HASQARD to the QSM to find all of the technical requirements expected for analytical services that used to be found in Volume 4 of HASQARD.

The Focus Group discussed situations where the QSM requirements may not be implemented at the 222S Laboratory and PNNL laboratories. This will require HASQARD to include language allowing exceptions from the QSM if adequately justified in the laboratories' QA programs and/or implementing procedures.

Glen has looked at the DOECAP Module 2 (Quality Systems General Requirements) checklists and noted many requirements that are not in HASQARD that the QSM imposes upon a laboratory. The 222S laboratory is complying with most of these additional requirements already even without a HASQARD driver for the requirement. Tricia Wood agreed and added that she is currently looking at DOECAP Module 4 (Quality Systems for Chemical Testing) and Module 6 (Quality Systems for Radiochemical Testing) to determine any requirements that are currently not covered by the laboratory's plans and/or procedures.

Glen Clark stated that an example of QSM requirements from the QSM Revision 5.2 that might not be fully implemented was that this revision of the QSM, although based on ISO 17025:2005, has incorporated by reference the unique requirements of ISO 17025:2017 because the third party accrediting bodies are required to start assessing to the ISO 17025:2017 requirements. Glen recommended that rather than giving the onsite laboratories an exemption to the ISO 2017:2017 requirements because they are not assessed by the third-party accrediting bodies, that it might be best for onsite laboratories to start implementing the ISO 17025:2017 requirements as part of the QSM. That is, for the requirements that can be implemented, the laboratory will implement them all regardless of the cost to do that. Anthony Nagel added that the Tank Farms contractor may have to implement all of the 2017 requirements anyway if they are going to be compliant with ISO 14001. Glen concurred adding that for example, in ISO 17025:2017 there is no requirement for the laboratory to have a QA Program document as long as all requirements are addressed in other documents (e.g., procedures). Glen said that many of the ISO requirements that the laboratory doesn't currently implement will be relatively easy to implement. Most of the requirements to be implemented are on the administrative side such as a formalized customer complaints system. Tricia Wood added that because the laboratory is implementing requirements for AIHA-LAP accreditation, many of the ISO 17025:2017 requirements are met at 222S Laboratory already.

Glen Clark stated that we need to write HASQARD Volume 4 to indicate

where exceptions to the QSM are allowed and explain the basis for those exceptions. For example, the Multi-Agency Radiological Laboratory Analysis Protocols Manual (MARLAP) was discussed. Glen stated that MARLAP is a guidance document and is not a requirements document, and that DOECAP adopted MARLAP equations for quality control (QC) samples in 2007 or 2008. (Glen later found out that the MARLAP equations were really adopted by DOECAP when they merged their Quality Systems for Analytical Services Manual with the Department of Defense's Quality Systems Manual in 2013.) The MARLAP equations are still used in the QSM. The commercial laboratories being accredited by the DOECAP-AP have no issues using these equations. The 222S laboratory may have issues with these equations due to analysis of samples with high activity. Scot Fitzgerald added that the sample can be diluted to allow use of the MARLAP equations when assessing QC samples. Glen Clark agreed but diluting the sample raises the detection limits and this is often a problem with the customer. Scot Fitzgerald agreed adding that when there is a positive result for a radionuclide of interest, diluting the sample to assess QC samples is not an issue except for the non-detected analytes. Scot gave an example of a sample containing  $^{99}\text{Tc}$  at a high activity level but strontium-90 ( $^{90}\text{Sr}$ ) at low activity. A separation technique would need to be employed to separate the  $^{99}\text{Tc}$  allowing the QC associated with the  $^{90}\text{Sr}$  to be evaluated. Glen understood and said it's an example of the kinds of technical issues that HASQARD Volume 4 should address. Paula Sellers asked if these sorts of exceptions are built into a laboratory's processes and procedures already. Glen responded that while the laboratory may have methods to address them, acceptance of QC data is based on MARLAP equations which won't work in highly radioactive samples. Scot Fitzgerald added that the QSM also discusses limitations related to radiochemistry analyses (e.g., an analyst cannot allow pile-up of counts on a gamma detector). The QSM requires dilution of the sample to address the count pile-up issues. The biggest issue is handling and storage of a sample with that much activity. The counting is taken care of by the specified QA/QC requirements. Scot concluded by saying he thinks the MARLAP equations are OK for use. Glen Clark asked whether requiring use of the MARLAP equations would increase costs of analysis at the 222S laboratory and/or PNNL. Karl Pool stated that sometimes the PNNL laboratory accepts and wants samples with high activity. But, for the most part, they want the count rates in samples to be within the capability of their detectors without dilution. If required, PNNL will dilute the sample or analyze the sample at a greater distance from the detector. Setting up the calibration of the instrument to analyze a sample at a greater distance from the detector would cost extra time and therefore money for the analyses requested. Scot Fitzgerald added that high activity samples may also result in more frequent maintenance of the instruments. Glen Clark asked if reprogramming of the instrument and/or data reduction software is required in these instances. Scot Fitzgerald responded that this is not usually an issue.

Scot Fitzgerald stated that meeting holding times for samples collected for analysis of non-radiological constituents is more likely an issue with highly radioactive samples than the counting issues they present for radionuclide determinations. Glen Clark suggested that the radiochemists who observe the DOECAP-AP assessments should be looking at the general exceptions and exemptions taken by commercial laboratories to address known issues with the QSM.

The Focus Group reviewed Table 3-0 in the draft of Volume 4. This Table defines physical testing quality control requirements. Glen Clark stated that the QSM does not address physical properties testing and asked if this testing is something that any of the contractors would request in order to meet analytical services needs required by the TPA. Several members of the Focus Group stated that these tests will be needed. Therefore, it was initially agreed that the table should be retained in Revision 5 of HASQARD Volume 4. One Focus Group member suggested that perhaps the Table could be deleted by adding a statement that QC for physical testing must be addressed in laboratory specific procedures. Representatives from PNNL and the 222S laboratory agreed.

As the review of the draft of Revision 5 of Volume 4 continued, Glen Clark stated that he has retained the section on data usability and data assessment. Glen asked if the Focus Group thought this section was still needed. Noel Smith-Jackson stated that data review and validation are required so it should be left in. Glen Clark agreed and added that he would like to update the information presented in it. Paula Sellers volunteered to provide updated language for this section of the document.

Chris Thompson asked if HASQARD should reference a specific revision of the QSM as being the place where analytical QA/QC requirements are found or should it say "most recent revision." The Focus Group discussed this and agreed that because the commercial laboratories used by the Hanford contractors will be accredited to the most recent revision of the QSM, the most recent revision should be the one referenced in HASQARD. During this discussion, one Focus Group member inquired about changes made to the QSM that one of the laboratories cannot implement due to costs or other factors. The answer to this issue is, as with existing QSM requirements that are unimplementable, the laboratory will need to write an exemption to the requirement and the basis for the exemption. Glen Clark stated that Revision 5 of HASQARD Volume 4 should include a link to the website that allows HASQARD users access to the latest revision of the QSM. The text of Volume 4 should also state that when a revision is made, the laboratory is allowed 12 months to fully implement the revision.

In discussing the data usability and data assessment section of HASQARD, Anthony Nagel suggested that the current language on handling samples to

meet the client's DQOs should be deleted. The expectation should be that the contractors manage special sample handling using communications with the laboratory (e.g., SOW, task order SOW, telephone conversation).

V. Jonathan Sanwald asked if there was any new business to be discussed.

Glen Clark stated that Revision 5.2 of the QSM contains the HASQARD gap checklist as Appendix E. Glen continues to work on the goal of getting all requirements specified in the gap checklist moved into the body of the QSM so there will be no need for Appendix E when Revision 6.0 of the QSM is released. With Appendix E being added to the QSM, the ABs are supposed to be assessing laboratories to this appendix in addition to the requirements found in the main body of the document. Glen is concerned that the ABs are so pressed for time during the assessments that the Appendix E material is not being evaluated very well during the assessments. This emphasizes the need to have an observer from Hanford at the DOECAP-AP assessments to ensure the material in Appendix E is being assessed.

Glen has gone to the Appendix E of the QSM and attempted to find a technical or regulatory driver for the requirements specified. Glen would like to request help in determining if there is a driver for those he cannot find anything for. Ultimately, Glen wants to present the requirements in Appendix E that we propose be inserted in the QSM body, but would like to make that proposal with technical or regulatory drivers backing the requirements. If there is nothing but HASQARD driving a requirement, then Appendix E will need to stay in the QSM or, if the Focus Group agrees that Appendix E of the QSM should not be necessary, the HASQARD Focus Group would need to agree that the requirements in Appendix E that have no driver are not needed and can be deleted from Appendix E. Glen asked if HASQARD is the only driver for a requirement, do we need the requirement in Appendix E or should we handle the need for that requirement another way (e.g., laboratory SOWs).

Glen said he does not want to wait until the last minute to present the proposal to include the Appendix E requirements in QSM Revision 6.0. Ideally, he would like to discuss this with the data quality workgroup (DQW) at the ASP workshop in Denver in July. Glen is requesting input from other HASQARD Focus Group members on this. Glen volunteered to send his work to date to anyone that can help him with this effort.

Noe'l Smith-Jackson asked about the case where the QSM is revised in future and that revision results in deletion of a requirement that has always been in HASQARD. Cliff Watkins responded to that by saying that the Focus Group needs to stay cognizant of the work being done by the DQW on proposed revisions to the QSM. If a requirement is being removed for which there is a technical or regulatory basis, the HASQARD representatives should point this out to the DQW and attempt to retain the requirement. Cliff stated that with the HASQARD document deferring to the QSM, the Focus Group becomes an

oversight organization overseeing the DOECAP-AP and DQW activities.

Scot Fitzgerald agreed with Glen's plan adding that the laboratories and ABs will pay more attention to requirements found in the main text of the QSM than in an Appendix.

Karl Pool asked what level of "tracked changes" is given to reviewers of the QSM when a proposed revision is provided for review. Glen Clark stated he did not know the answer to that question but agreed we will need it and committed to addressing that question with the DQW.

Anthony Nagel asked whether requirements in Appendix E, for which we can find no driver, should have Focus Group agreement prior to their elimination. The Focus Group members present concurred that this would be necessary.

It was stated that some requirements found in HASQARD are "over protective" (e.g., specifying that the results from blank sample analyses not to be subtracted from concentrations of the same constituent reported in field sample results). These kinds of requirements can be eliminated because no laboratories are complying with them anyway.

It was mentioned that Module 1 of the QSM includes a requirement to participate in PT programs but MAPEP participation is not required. It was asked if this would be a problem for the on-site laboratories. Tricia Wood had already stated that the 222S laboratory will continue to participate in MAPEP anyway to ensure <sup>99</sup>Tc analyses can be evaluated. Karl Pool said that in PNNL's case, he would need to look at the QSM to see what kinds of PT programs are required and where they would obtain them, etc. Glen Clark said that the on-site laboratories likely won't be accredited by the DOECAP-AP. Therefore, to meet the QSM requirements some kind of Analyte-Method-Matrix (AMM) PT sample will need to be obtained.

Hearing no additional new business, Jonathan Sanwald adjourned the meeting at 3:47 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on Wednesday April 17, 2019 in Conference Room 199 at 2430 Stevens Center Place.