

HASQARD Focus Group

Meeting Minutes

November 19, 2013

The meeting was called to order by Huei Meznarich, HASQARD Focus Group Chair at 2:05 PM on November 19, 2013 in Conference Room 308 at 2420 Stevens.

Those attending were: Huei Meznarich (Focus Group Chair), Cliff Watkins (Focus Group Secretary), Taffy Almeida, Joe Archuleta, Mike Barnes, Jeff Cheadle, Glen Clark, Robert Elkins, Scot Fitzgerald, Joan Kessner, Mary McCormick-Barger, Noe'l Smith-Jackson, Chris Sutton, Amanda Tuttle, Rich Weiss and Eric Wyse.

- I. Huei Meznarich asked if there were any comments on the minutes from the October 15, 2013 meeting. No Focus Group members stated they had comments on the August meeting minutes and, after hearing a motion and second for approval, the minutes were approved.
- II. A discussion of the latest efforts to complete Revision 4 of HASQARD was held:
 - a. The first agenda item was to have a dialogue with Washington Department of Ecology personnel concerning questions the Focus Group has had on when a method can be modified, what constitutes a modification and when reporting this modification to Ecology is required. Mike Barnes of Ecology was present and he stated that the analytes and methods for characterizing tank residuals and for the Waste Treatment Plant are defined in the Ecology-approved document, "Regulatory Data Objectives Supporting the Tank Waste Remediation System Privatization Project" (PNNL-12040). Mike stated that for tank residuals he has not received any requests to approve a method modification since he joined Ecology to oversee tank waste characterization. The waste characterization activities of the tank residuals program are not a permit driven activity. He also acknowledged that the cyanide determination for tank residuals includes an additional EDTA treatment for the tank waste samples. The EDTA is needed due to the sample matrix. A laboratory or the program/project would need to notify Ecology if the methods specified in the PNNL-12040 document would be modified or not used in favor of an alternative method. Mike stated that alternative methods (e.g., microdistillation and additional of EDTA) have been approved for use on residuals with proper notification and technical basis. Mike also stated that if an analytical method is specified in a permit, the program/project would need to inform the permit writer within Ecology and gain approval from the permitting group prior to using a modified or alternative method. It was not clear at the meeting whether the notification process is described in the Sampling and Analysis Plan (SAP) used for tank residue sampling and analysis activities. Mike

does not get personally involved in the permit process within Ecology and is not familiar with the requirements associated with method modification in that program. To ensure complete understanding, Eric Wyse asked if a method specified in a permit was modified, would Ecology approval be required. Mike stated that yes, approval would be required. Several members also stated that modification of methods specified in a permit is not commonly done. Almost all of time, the project/program or data management group will use the laboratory that has the capability to meet the permit requirement. Chis Sutton provided his experience with sample analyses required by permit stating that if a permit specifies a method and the laboratory they are working with cannot offer that method, they send the samples off site to a Washington accredited laboratory to obtain the analyses. Huei Meznarich provided an example where EPA method 625 was identified in one of the permits. The laboratory does not perform method 625 (although it is very similar to SW-846 method 8270 which the laboratory does perform). Also, the laboratory does not modify method 8270 to meet method 625. Therefore, the data management group sends samples requiring analysis by EPA method 625 to a laboratory with method 625 capability. Mike stated that a decision was made a while ago to stick with select methods to ensure the most comparable data possible. Mike also stated that the local Ecology chemists rely on the Laboratory Accreditation personnel within Ecology for determining when a laboratory's modification to a method is acceptable and approved for use. When a laboratory modifies a method for which the laboratory holds an accreditation, it is expected that they inform Ecology and the accreditation section. The accreditation personnel will discuss the modification and inform the laboratory if this modification impacts their accreditation or not. Eric Wyse stated that from the laboratory's perspective, it is their customer that holds the permit. Therefore, the question becomes whether it is the customer's responsibility to know if/when a method is modified and whether that modification is acceptable. Mike Barnes sought clarification asking if Eric was referring to the sample management organization as the laboratory's customer. Eric said in most cases, yes it would be a sample management organization that would be the direct customer.

Eric Wyse provided some additional context to the discussion to help Ecology personnel understand why this topic has been a sticking point for completing Revision 4 of the HASQARD. Eric explained that the section under discussion uses the term "deviation." It is not clear if that is a supposed to refer to "on the fly" deviations from a procedure or deviations from a published analytical method. Also, the language in this section of HASQARD uses the term "modification" and the Focus Group was interested in whether this term had significance with Ecology. That is, the intent was to try to make a distinction between deviations and modifications. That is, the term modification would be a change that would require an acceptance from Ecology. Mike Barnes provided the

opinion that because Ecology accredits laboratories on a method and analyte specific basis, if the modification was enough that it would trigger the laboratory to inform the Ecology accreditation personnel of the change and request assessment of the change's impact to the laboratory's accreditation, then the permit people or tank farm chemists at Ecology would want to be informed also. Eric Wyse stated, that while it is true that the Ecology accreditation is specific to method and analyte, the laboratories are not accredited to the sample preparation method used and this is often where a modification to the published method is made. Huei Meznarich stated that initial accreditation or annual accreditation renewal for a method/analytes requires acceptable performance evaluation results or acceptable quality control standards. Huei directed the group members present to the proposed HASQARD Volume 1, Revision 4 Procedure Section that describes a process from selection of the method, development of a laboratory procedure to execute the method selected, the type of changes from the selected method allowed, "one-time" changes from the procedure when executing the procedure during analysis etc. The section also describes client notification or approval for changes in the procedure and, if required, the modification of methods used to determine method-defined parameters. HASQARD identifies when the regulator's formal approval is required (described in Section 4.7 of Volume 1) for the modification of methods used for determination of method-defined parameters. Modification of methods used for anything other than the method-defined parameters will require "notification" to the affected client(s) and/or their sample management group (if such organization is used) and the regulators.

Mike Barnes stated that most of the Ecology personnel in the permitting group expect exact compliance with the analytical methods specified. They rely on the fact that the laboratories are accredited for specific methods and therefore compliance with them is required to maintain that accreditation. Glen Clark asked what programs the Ecology laboratory accreditation applies to. For example, are methods used to satisfy a RCRA waste characterization requirement (other than the method defined parameters) applicable to the accreditation? Mike Barnes reiterated that laboratories are accredited by method and analyte. Therefore, anytime a laboratory analyzes a specific analyte by the method for which they are accredited to analyze that analyte, the accreditation applies. However, accreditation may not be required by Ecology for some applications. For example, there are several methods used for analyzing tank residuals for toxic metals and some of them not on the laboratories accreditation list. This is because while the published method for which the laboratory is accredited states that it is applicable for an analyte, it does not work well for determining that analyte in the tank residuals waste matrix.

Mike Barnes summed up the discussion saying that of a method is

modified, his part of Ecology would not be the group that determines if the modification is appropriate or acceptable. Acceptance of the modification would be the purview of the accreditation section of Ecology. However, the section of Ecology that oversees tank farm remediation and/or any permitting organization within Ecology would want to be informed.

Rich Weiss provided a proposed revision to the current order of the language in the revision to Section 4.5 being evaluated by the Focus Group. The Focus Group members present reviewed this revised section and initially felt that one of the paragraphs in Section 4.5 captures the need to seek approval for method modifications as applicable. The proposed paragraph says, "If not specifically defined in contractual or other requirement documents, or if the client specified method is inappropriate for the requested analysis, the client shall be informed as to the laboratory's proposed method prior to use. Any procedure may require formal acceptance (including acceptance by DOE or regulating body) prior to initiation of analysis." The group discussed this further and wondered if the text as written would adequately capture instances where the specified method would be used but in a modified manner. That is, there was a concern whether the client would be notified in time to gain acceptance when required. Rich Weiss stated he would look at this concern and propose a revision if required. One of the Focus Group members present thought that HASQARD should provide a descriptive process for method modification. But several members expressed the difficulty trying to ensure consistency and clarity if HASQARD were to provide the descriptive conditions for method modification and that the method modification process should be included in the laboratory QA document. The Focus Group members present felt that decisions concerning method modification should be made between the laboratory and its clients (e.g., the program/project) due to the widely varying nature of samples analyzed and the programs they support (i.e., waste characterization, groundwater monitoring, permits etc.). The Focus Group members present agreed that the current proposed wording for the procedures may be not quite clear on when notification and/or approval of method modification is required and Rich Weiss agreed to add a few sentences for clarification.

Rich Weiss discussed the basis for his reformatting the material in Section 4.5. Rich stated that he was trying to ensure the section primarily addresses modifications to methods that would affect the method performance in a negative way (e.g., poorer accuracy and/or precision). The proposed text is to address this concern while allowing flexibility for revisions or modifications that have no impact on accuracy or precision. For example micro-distillation is a technique that would represent a modification to a published SW-846 method but would have no impact on accuracy and precision.

Robert Elkins asked for clarification on what is required by Ecology when a modification is proposed and approval is required. Mike Barnes stated that the Ecology laboratory accreditation personnel would determine the requirements for submittals or approval would occur during the triennial accreditation review. This review could occur more frequently than triennially if the proposed revision results in the accreditation personnel wanting to conduct a non-routine review.

Mike Barnes acknowledged that this subject (i.e., method modifications, what constitutes them, what triggers the need for approval and how approval should be granted) is confusing within Ecology also. Mike stated that for example some permits are very specific about the exact analytical method to be used and others allow leeway for professional judgment by the laboratory and/or project chemists.

- b. The proposed revision to the Software QA section of HASQARD was discussed. Chris Sutton announced that Steve Smith has retired from CHPRC and will no longer be leading this effort. Steve had provided Chris with the latest draft of the software QA sections and some background to provide the group concerning the development of the draft. Chris has seen two previous proposals for the software QA section and didn't like either of them. So, Chris reviewed the software QA language found in the CHPRC QA Program (PRC-MP-QA-599) and extracted the language he felt may be applicable to HASQARD. Chris also reviewed the QSAS and the joint DOE/DOD document that will replace the QSAS for language applicable to software QA. Chris combined the language as best he could and sent the draft it to Steve Smith. Steve did not revise the draft but rather sent the draft to the Focus Group Secretary to be distributed for comment. Joe Archuleta introduced himself as one of two CHPRC QA personnel that will interface with the HASQARD Focus Group in the future. Joe stated that it is likely that it will either be him or Jan McCallum that will replace Steve as HAQARD Focus Group participants. Joe suggested that the current draft be reviewed with an eye toward a graded approach in implementing software QA within HASQARD. Joe stated it is likely that not all of the language in the current draft is applicable to HASQARD applications. Huei Meznarich stated that some of the material in the draft is very valuable but asked why the language used by NQA-1 for design requirements was retained when NQA-1 is not applicable to laboratories implementing HASQARD. Chris Sutton acknowledged Huei's concern and said the material distributed needs editing. Joe Archuleta accepted the action to lead the effort to revise the software QA section to include only language applicable to analytical laboratories. Chris Sutton added that there is more attention to software QA needed than twenty years ago when HASQARD was originally issued. The life-cycle management associated with software QA is much more important today also. Chris expressed the opinion that

nothing previously written on this subject for inclusion in HASQARD has been rigorous enough for today's information-focused world. There was general concurrence for these remarks from the Focus Group members present. Joe said his intent will be to do a gap analysis and ensure the language proposed makes sense for commercial laboratories as well as on-site facilities. The Focus Group agreed that while NQA-1 design control requirements need not be included, best practices such as those found in Institute of Electrical and Electronics Engineers (IEEE) standards should be included. Joe Archuleta received this feedback and committed to providing a new draft to the Focus Group for review.

- c. The group discussed the need to review the glossary and references section in HASQARD. In Revision 3 of HASQARD, the Glossary is only present as Appendix A to Volume 1. The Focus Group agreed that this is adequate but each definition in the Glossary will need to be evaluated against the revisions proposed in the draft Revision 4 to HASQARD. It was agreed that during final review the references will be checked to ensure they represent the most current versions of the documents cited and that they are actually called out in HASQARD. If not called out, and deemed a valuable source of relevant information, a bibliography section should be added to HASQARD in addition to the references section.
- d. Taffy Almeida had completed a review of Volume 4 and had provided comments to the Focus Group Secretary. A discussion of her comments was held with all Focus Group members agreeing to the comments Taffy provided. As they were discussed and accepted, Taffy's comments were incorporated in the working version of Volume 4 that will be used to produce the final review copy of Volume 4, Revision 4.

The Focus Group Chair asked if there was any new business to discuss. The members present discussed revising the language associated with chain-of-custody and agreed the language proposed was better at addressing the logistical issues associated with sample shipments and transfers from the perspective of both a field and laboratory custodian(s). The Secretary took the action to incorporate the revised language in Volume 2 before transmitting the file to Chris Sutton. The Chair suggested that the meeting be adjourned. Hearing no objections, the Chair adjourned the meeting at 3:58 PM.

The next meeting is scheduled for December 17, 2013 at 2:00 PM in 2420 Stevens, Room 308.