

HASQARD Focus Group
Meeting Minutes
June 18, 2013

The meeting was called to order by Huei Meznarich, HASQARD Focus Group Chair at 2:05 PM on June 18, 2013 in Conference Room 308 at 2420 Stevens.

Those attending were: Huei Meznarich (Focus Group Chair), Cliff Watkins (Focus Group Secretary), Glen Clark, Scot Fitzgerald, Joan Kessner, Larry Markel, Karl Pool, Chris Sutton, Amanda Tuttle, Rich Weiss and Eric Wyse.

- I. Huei Meznarich requested comments on the minutes from the May 21, 2013 meeting. No HASQARD Focus Group members present stated they had any comments on the May meeting minutes and, after hearing no objections, the minutes were approved.

- II. A discussion of the latest efforts to complete Revision 4 of HASQARD was held:
 - a. The status of the activities to produce Revision 4 of HASQARD Volume 1 was discussed:
 - i. At the May meeting a long discussion was held on a variety of issues associated with the material in Section 4 of Revision 3 of HASQARD. Due to sequestration, and the mandatory furloughs that resulted, Steve Smith was not at the May meeting. This made addressing the Focus Group's comments very difficult. Also due to sequestration-related mandatory furlough, Steve could not attend the June meeting. As a result, he asked Chris Sutton to open the discussion on the status of the Volume 1 efforts. Chris reported to the group that Steve would like the Focus Group to provide specific details on what they want to see in Section 4 in Revision 4 of HASQARD and reach consensus on this material before an additional effort is expended trying to guess at what this might be. Chris stated that he knew Rich Weiss was preparing a proposal for revising Section 4 and, if the Focus Group concurs, that direction will satisfy Steve Smith's request.

 - ii. Prior to the meeting, Rich Weiss obtained a copy of the working file for Volume 1 from the Focus Group Secretary. Rich used the electronic file to prepare a proposed revision which was projected for the Focus Group to review. Rich began his presentation by stating that he does not believe the language in Revision 3 works nor is it necessary anymore. The purpose of the Revision 3 language on modifications to procedures and methods is not

necessary any longer due to the better understanding that laboratories, regulators and data users have on the difference between requirements and guidance in specifying an analytical method. It is much better understood and accepted that a laboratory “meet the intent” of a method rather than adhere to “wrote compliance.” Rich stated that the proposed language provided to the Focus Group came from input received at the May meeting and the Quality System for Analytical Services (QSAS) document used by the Department of Energy Consolidated Audit Program (DOECAP) and the document being proposed to replace it the Quality Assurance System (QAS). Rich stated that he also drew from the USEPA SW-846 document and laboratory procedures in developing his proposal. Rich went back through the revisions of HASQARD to try to follow the development of the language that is found in Section 4 of Revision 3. He found that most of what is present in Revision 3 of this section was not in Revision 1. The proposal Rich presented used some of the text found in Revision 3 but largely replaced all of the Section with new material. The Focus Group members present reviewed the material presented. The comments made during Rich’s presentation included:

- a. In discussing the proposed Section 4.1, a paragraph from Revision 3 that was suggested for complete deletion in Rich’s proposal was discussed. This paragraph said, “HASQARD recognizes that if a consensus standard or standard method is written in a way that it can be used as published by the operating staff in a laboratory, it does not need to be rewritten as an internal procedure. However, it requires the same procedural approval process as normally implemented in the laboratory.” Huei Meznarich stated that according to language found in the International Standards Organization (ISO) 17025 standard, “*General Requirements for the Competence of Testing and Calibration Laboratories*” a laboratory need not prepare a laboratory-specific procedure if a published method will be followed exactly. That language is found in a note n Section 5.4.1 of ISO 17025 and says, “International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or

additional details.” Rich Weiss stated that it is difficult to control the documentation of the method execution if it is not made into a laboratory procedure. Huei stated that there have been cases when clients make a one-time only request for a unique method (i.e., not a routine analyses). The paragraph from HASQARD being discussed provides a policy on laboratory procedure that allows the flexibility required for the laboratory to accommodate these very infrequent requests. Karl Pool added that at PNNL they have no written laboratory-specific procedure for running the Toxicity Characteristic Leaching Procedure (TCLP) but there is a TCLP procedure that has a procedure number with a cover sheet showing the proper reviewers and reviewers’ signatures. After discussing this, the Focus Group felt that the proposed language is flexible enough to allow use of a method as published as long as a process exists in the laboratory to allow this practice.

- b. In discussing the proposed language for the new Section 4.4, “Field Sampling Activities,” Chris Sutton proposed that a cross-walk evaluation be conducted and if this material is already present in the proposed Revision 4 to Volume 2 of HASQARD, then it should be removed from this section. Eric Wyse stated that Volume 1 defines QA guidance relative to Volumes 2, 3 and 4 and no Volume is meant to stand alone. Chris acknowledged this is the case but stated that he would like sampling personnel to be intimately familiar with Volume 2 and not necessarily be experts on Volume 1. Chris stated that the currently proposed Revision 4 to Volume 2 was written to mimic the USEPA Contract Laboratory Program (CLP) Sampler’s Guide. That EPA document stands alone and Chris’ goal for Volume 2 is that it can also be used alone for the sampling crew in the field. Chris stated that the proposed Revision 4 for Volume 2 refers to Volume 1 for general QA requirements. Larry Markel also stated that he believe Volumes 1 and 2 should be used together just as Volume 1 and 4 are used together. Chris stated that is the language proposed by Rich Weiss was accepted by the Focus group, the language in the proposed Revision 4 to Volume 2 will need to be changed to ensure consistency with the proposed content for Section 4.4.
- c. In the proposed language for the new Section 4.5, “Field and Laboratory Analyses,” the content of the sixth paragraph was discussed. The paragraph starts with

sentences that say, “One time departures or changes to procedure steps are allowed if deemed necessary by the professional judgment of technical supervision to accommodate variation in sample matrix, radioactivity, chemistry, sample size or other parameters. The departures or changes shall require approval by supervision prior to implementation.” The Focus Group had some questions about the definition of “one-time.” The Focus Group proposed that this language specify that changes are applied on a batch basis (e.g., applied to all method QC samples analyzed) but this may be subject to change if a better proposal is provided to Rich. Other than this comment, the Focus Group felt that Section 4.5 was an improvement over what is in HASQARD Revision 3 and addressed most of the issues raised with this section at the May HASQARD Focus Group meeting. Eric Wyse suggested that language concerning permanent incorporation of procedural changes that are consistent with the language in the 222S laboratory’s QAP might be beneficial in this section. Eric took the action to provide Rich with that language for his consideration.

- d. In discussing the proposed Section 4.7, “Modification of Required Regulatory Methods,” a comment was made regarding the reference to the Federal Resource Conservation and Recovery Act (RCRA) citations. Because Washington State has authority to administer their own hazardous waste program, the question was raised whether it was more appropriate to use the Washington Administrative Code (WAC) references to the regulations that require use of a specific waste testing method.
- e. Also in discussing Section 4.7, identification of the need to define the term “modification of methods” arose. There has been some discussion in the past regarding whether this is required because the section indicates that permission must be sought from clients and/or regulators to modify the methods specifically cited in regulations and the laboratory needs to know when a change from the published method “crosses the threshold” and becomes a modification. Chris Sutton added that modifications to regulatory methods are negotiated between the laboratory’s client and the regulators and never between the laboratory and regulators directly. Rich Weiss agreed and stated he has ideas for language that would address this concern. Rich stated that he believes this issue can be covered subtly in

other subsections of Section 4 rather than addressing it in Section 4.7 which applies to the methods specifically called out and required by regulation (i.e., for the method-defined-parameters). Huei Meznarich expressed concern about whether HASQARD should be too prescriptive about deviations being called modifications. Rich said the language he has in mind should satisfy the need for both a definition of modification and flexibility in laboratory operations.

- f. In wrapping up the discussion on the proposed revision to Section 4, Chris Sutton said he will need to ensure anything proposed is consistent with the language in Volume 2 because field sampling methods are also applicable to Volume 1, Section 4. Eric Wyse suggested that the language in the introduction to Volume 1 be reviewed also to see how it says that Volume 1 interrelates with the other Volumes of HASQARD. Eric's intention was that if Chris needs Volume 2 to stand alone, the language in Volume 1 may be too strong. Chris Sutton stated that he never intended Volume 2 to be separated from Volume 1. Amanda Tuttle read the paragraph from HASQARD Revision 3, Section 1.0 that was applicable to this discussion, "The HASQARD is made up of four volumes: Volume 1, *Administrative Requirements*; Volume 2, *Sampling Technical Requirements*; Volume 3, *Field Analytical Technical Requirements*; and Volume 4, *Laboratory Technical Requirements*. Volume 1 describes the administrative requirements applicable to each of the other three volumes, and is intended to be used in conjunction with the technical volumes (e.g., Volumes 1 and 2 describe the requirements for sample collection and handling, Volumes 1 and 3 describe the requirements for field analytical methods, and Volumes 1 and 4 describe the requirements for laboratory analytical methods."
- iii. With Rich's presentation on the proposal for Section 4 completed, the Focus Group members present began reviewing the remaining sections of the proposed Revision 4 to Volume 1. The members present started to debate the material in Section 5.1, "Initiation of Corrective Action." Of specific concern was the new introductory language to the section which was proposed as, "Conditions adverse to quality, including failures, malfunctions, deficiencies, defective items, out-of-control processes, and nonconformances shall be identified. Examples of conditions where investigation and corrective action determinations may be conducted include the

following:” The introductory language to this section in Revision 3 of HASQARD says, “Examples of conditions where investigation and corrective action determinations are required include the following:” This introductory material is followed by a list. The Focus Group members present inquired as to why the Revision 3 language requires the list of items to involve initiation of corrective actions and the proposed language says corrective action “may be conducted.” Larry Markel said that the QA subcommittee had held the same debate and decided to present it to the Focus Group in this fashion to seek concurrence and/or rejection from the group. The Focus Group members present felt that some of the items in the list may not require formal corrective actions each time they occur. However, there was a need to specify the corrective action activities are required when warranted. No resolution to this issue was obtained before the membership present had to start leaving the meeting to meet other commitments. This issue was tabled to be addressed at the next meeting of the Focus Group.

The Focus Group Chair recognized that the meeting attendance was dwindling to a low level of participation as a significant number of those initially present began to depart. Focus Group members started leaving the meeting at 4:00 and continued to do so from that time through adjournment. Therefore, the discussion turned briefly to a series of e-mail notes that had been exchanged between Rich Weiss and Eric Wyse concerning expired standards and calibration check solutions for radiological analyses. The conclusion of the discussion was that both Rich and Eric agreed that there will be no need to add language to the proposed Revision 4 of Volume 4 to address the issues discussed. After this discussion the Chair adjourned the meeting at 4:25 PM.

Due to conflicts related to availability of key personnel, the next meeting has been moved from the third Tuesday of the month to the fourth Tuesday of the month in July and is scheduled for July 23, 2013 at 2:00 PM in 2420 Stevens, Room 308.