HASQARD Focus Group
Meeting Minutes
January 17, 2012

The meeting was called to order by Huei Meznarich, HASQARD Focus Group Chair at 2:04 PM on January 17, 2012 in Conference Room 308 at 2420 Stevens.

Those attending were: Huei Meznarich (Chair), Cliff Watkins (Secretary), Mike Barnes, Jeff Cheadle, Glen Clark, Scot Fitzgerald, Shannan Johnson, Joan Kessner, Larry Markel, Cindy Taylor, Chris Thompson, Amanda Tuttle, Sam Vega, Rich Weiss and Eric Wyse.

I. Huei Meznarich requested comments on the minutes from the December 13, 2011 meeting. No HASQARD Focus Group members present stated any comments on the December meeting minutes and, after hearing no objections, the minutes were approved.

II. The Status of the preparations of Revision 4 for Volumes 1, 2 and 3 were discussed.

a. The Status of the review for Volume 2 was discussed. The Chair recalled that the due date for comments was the date of the meeting (January 17, 2012). The Secretary summarized the people that had submitted comments and requested whether anyone needed more time to review the document and submit comments. The Secretary noted that due to the large number of comments received, another review and comment cycle would likely occur. None of the Focus Group members present indicated a need to extend the deadline for submitting comments.

b. Larry Markel and Cindy Taylor reported that the QA Group continues to meet and expects that the revisions to Volume 1 will be ready for Focus Group review when the Volume 4 reviews conducted at Focus Group meetings are complete.

III. HASQARD Volume 4, Revision 4 Proposals

Continuing with the process begun at the November Focus Group meeting, the Secretary projected the Word file containing the combined set of proposed revisions to Volume 4 of HASQARD as provided by the organic analysis, inorganic analysis, radiochemistry and quality assurance (QA) subcommittees on a screen for all to view. The Secretary used the software to revise as necessary as the Focus Group started discussing proposed revisions from the point they left off at the December meeting, the beginning of Section 4.0.

After discussion, the language in the second paragraph of Section 4.0 was revised to say:

"Analytical measurements are made using systems that include sample handling, sample preparation and measurement processes. Data generated for clients shall be acquired using calibrated equipment. Documentation of calibration must be maintained such that it is traceable to the measurement system and results generated from that system. Equipment not calibrated by the user (e.g., an analytical balance) that is out of calibration must be clearly identified to prevent use. Ancillary data (e.g., temperature, pressure, humidity, particle size, volumetric capacity, mass, and flow rate) may also be needed, requiring accurately calibrated instrumentation for their measurement. Accordingly, any of the instruments, standards, and methods used to generate information essential to generation of final results shall be calibrated to assure that their accuracy is within acceptable limits. Analysis shall not be initiated until a valid calibration is achieved."

However, the Focus Group did not reach consensus on how to more clearly state the sentence, "Equipment not calibrated by the user (e.g., an analytical balance) that is out of calibration must be clearly identified to prevent use." An action was taken to see if the concept discussed in this sentence is covered elsewhere in HASQARD. A comment box was added to the file from which the Focus Group is working to ensure this issue is not lost as the process continues.

All other revisions proposed for Section 4.0 were acceptable to the Focus Group members present.

After discussing the last paragraph in Section 4.2, the Focus Group decided that paragraph should read:

"It is considered good laboratory practice that mechanical volumetric dispensing devices used for quantitative measurements be verified daily or prior to use to ensure acceptable performance. Daily, before use, single-delivery volume checks shall be performed and documented. Unless practical concerns preclude this practice (e.g., radiological work environments), volume checks shall be performed by delivery weight. Alternate volume check methodology shall be defined by procedure. Glass microliter syringes do not require daily or quarterly verification, but must come with a certificate attesting to established accuracy or the accuracy must be initially demonstrated and documented by the laboratory. Volumetric dispensing devices used for quantitative measurements (except Class A glassware), such as burettes or volumetric transfer pipettes, shall be checked for accuracy by delivery weight on a quarterly basis."

In discussing Section 4.3, the Focus Group members present spent a great deal of time determining what the requirements should be for standards, especially when no nationally or internationally recognized reference material is present. The content of this section was greatly revised from Revision 3, and the current proposed language for the section is:

"The following standard specifications shall be used unless otherwise specified in Section 4.4.

Standards used for calibration of measurement systems or preparation of other QC standards (e.g., LCS, surrogate spiking solutions, matrix spiking solutions) shall be traceable to a nationally or internationally recognized standard agency (e.g., NIST) source or measurement system, if reasonably available. When a nationally or internationally recognized standard material is unavailable or its purchase is impractical, the laboratory shall;

- purchase standard material from a reliable source, or
- establish or define an alternate calibration protocol (e.g., use of surrogate radioisotope for the unavailable material)

The laboratory shall have procedures in place to determine the acceptability of such non-routine materials. Purchased standards shall be accompanied by a Certificate of Analysis or record that includes the vendor, lot number, purity, date of preparation and/or expiration, and concentration or activity of the standard material. The accuracy and traceability of all working standards to appropriate primary grade standards or the highest quality standards available shall be documented.

The laboratory shall retain records for all standards, reagents, reference materials or other media potentially impacting the quality of reported results. These records shall allow for unambiguous traceability to all appropriate calibration and sample analysis activities. Traceability to purchased stock reagents or materials used directly need only identify manufacturer and lot number.

The laboratory shall address recommended storage conditions, and document an expiration date after which the material shall not be used unless its reliability is re-verified. The laboratory shall have in place procedures and protocols to ensure that materials are not used for quantitative purposes past their defined expiration dates. Standards shall be stored in a manner to prevent cross-contamination with samples.

A program for verifying and documenting the accuracy of all standards shall be routinely followed. The criteria used to verify or re-verify standards, reagents, reference materials or other media potentially impacting the quality of reported results shall be documented and shall be defined to assure that acceptable accuracy is maintained when used.

Laboratory prepared standards shall be traceable to the primary standard documentation. At a minimum, the following information shall be maintained regarding laboratory prepared standards, reagents, reference materials or other media potentially impacting the quality of reported results:

- Name of preparer
- Date prepared
- Standard identification
- Traceability to purchased stocks or neat compounds
- Relevant information on the stock standard(s) (e.g., identification numbers, matrix, etc.)
- Dilution documentation, including volume/weight of standards, final volume, etc.
- Traceability to any critical equipment used (e.g., balance IDs, pipette IDs)
- Final concentration or activity
- Reference to the method of preparation (e.g., procedure ID)
- Expiration date or shelf life (if applicable).

Containers for standards, reagents, reference materials or other media potentially impacting the quality of reported results shall be labeled in a way to ensure traceability to preparation/certification documentation. The minimum amount of information required to be on each standard label includes:

- Expiration date or shelf life (if applicable)
- A unique identifier that allows traceability to the applicable standards preparation documentation.

The expiration date of a laboratory prepared standard shall not exceed the expiration date of the primary standard. Expired standards shall not be used unless their reliability is verified by the laboratory. If expired standards are not recertified, the laboratory shall remove the standard or clearly designated as acceptable for qualitative purposes only. A standard is considered as valid for quantitative purposes up to the date listed as the expiration date (including the date listed). When expiration date is expressed as a month/year, the last valid date for use is the last day of the month listed."

The Focus Group requested that the Secretary determine the origin of the statement, "A program for verifying and documenting the accuracy of all standards shall be routinely followed." After reviewing the inputs received, it was determined that this sentence came from the Radiochemistry group. The Focus Group did not seem entirely satisfied with that sentence remaining in the document, but agreed to move on.

In Section 4.4 (and several other Sections in Volume 4), the Inorganic Analysis group proposed to add language regarding how to address situations where HASQARD and a required regulatory methods specifications deviate.

The language proposed for addition to Volume 4 is the exact language present in Volume 1. The inorganic group felt it should be repeated in Volume 4 to emphasize the point and ensure HASQARD users that may not read Volume 1 frequently have a greater chance of encountering this requirement. The Focus Group decided that now would be the time to revise this language and took note that any revisions made also need to get incorporated in Volume 1. The language agreed to at the January meeting is:

"The minimum requirements of calibration, frequency, and acceptance criteria for laboratory measurement systems are presented in Table 4-1 through Table 4-9. Where a Hanford Site activity requires using a specific regulatory method (e.g., permits, National Pollutant Discharge Elimination System), and the regulatory method is in conflict with HASQARD, the regulatory method shall take precedence. Where no conflict exists or no requirements are specified in the regulatory method, all other sections of HASQARD would apply."

After discussing Section 4.4, the Secretary noted the size of Section 4.4.1 and the large number of proposed revisions present in that section. Therefore, the Chair stated that rather than start into Section 4.4.1 the meeting should be adjourned. The Chair requested that the Secretary send the current version of the proposed revisions to all Focus Group members so they can study what has been accepted in Sections 1.0 - 4.4 and be prepared to discuss the remaining proposals at the next meeting.

Hearing no additional new business, and no objections to the proposal to adjourn, the meeting was adjourned at 3:54 PM. The next meeting is scheduled for February 21, 2012 at 2:00 PM in 2420 Stevens, Room 308.