HASQARD Focus Group
Meeting Minutes
November 16, 2010

The meeting was called to order by Dave Crawford, Focus Group Chairman at 2:03 PM on November 16, 2010 in Conference Room 208 at 2425 Stevens.

Those attending were: Dave Crawford (Chair), Cliff Watkins (Secretary), Lynn Albin, Heather Anastos, Paula Ciszak, Glen Clark, Doug Duvon, Kathi Dunbar, Robert Elkins, Scot Fitzgerald, Joan Kessner, Larry Markel, Huei Meznarich, Steve Smith, Chris Sutton, Noe'l Smith-Jackson, Chris Thompson, Eric Wyse.

New members to the Focus Group were introduced. Scot Fitzgerald will now represent CHPRC on analytical chemistry technical subjects since Heather Anastos has moved to a new position. Doug Duvon announced he has accepted a new position at the WTP and introduced Paula Ciszak who will represent WCH QA on the HASQARD Focus Group.

I. Dave Crawford requested approval of the minutes from the October 19 meeting. The Secretary highlighted the revisions to the minutes that were made as a result of comments received. A motion for approval of the minutes was made by Steve Smith and seconded by Joan Kessner. The minutes were approved.

II. The Action Tracking matrix was discussed. The following updates were provided:

a. From the August 24 meeting, Chris Sutton accepted an action to determine if language pertaining to storage of sample containers in a "contaminant-free" environment has been revised in the Volume 2 revision being prepared by the sampling subcommittee. Chris stated that he had no news on the contaminant free environment question. The sampling Supervisors have been dealing with 82 corrective actions and this has taken priority to HASQARD Volume 2 revision efforts. Dave Crawford set the due date for this action item to TBD to allow for the sampling subcommittee to manage priorities and address this item when time can be found to do so.

b. At the September 21 meeting, Dave Crawford and Cliff Watkins accepted the action to produce an annual report of the HASQARD Focus Group's activities. Dave and Cliff will meet immediately following the Focus Group meeting to determine a time to meet to discuss the outline and content for the report.

c. At the September 21 meeting, Dave Crawford accepted the action to revise the DOECAP/HASQARD gap analysis and HASQARD revision schedule into something closer to what the activity looks like at this time. Huei Meznarich presented two options for how the schedule might look at this

time. She collected input from all subcommittees and will use one of the draft schedules presented to finalize the schedule based on the input received. The new schedule will be distributed and updated at upcoming Focus Group meetings.

d. In response to concerns initially raised at the September 21 meeting of the Focus Group, the concerns related to the current language in HASQARD Volume 1, Section 10.4, "Quality Systems" were discussed at the October 19 meeting. In the October meeting, the Focus Group decided a subcommittee should meet to explore options to rectify the issues identified. Cliff Watkins presented the outcome of the subcommittee's efforts. The subcommittee recommended that the entire Section 10.4 be deleted because the issues causing the concerns in the "Quality Systems" section (specifically the frequency independent assessments are required and what constitutes an acceptable assessment of the quality system) seemed to be addressed in Section 10.0. Further, it should not be inherent upon the laboratory to determine how frequent an independent assessment is conducted at the laboratory; rather, that frequency policy is driven by the QA policy/requirements of the users of the laboratory. There was initial agreement on deletion of the Section until Paula Ciszak, Chris Sutton and Larry Markel pointed out that deleting the section would leave one area of assessments mentioned in the bullets in section 10.0 (i.e.,quality systems assessments) completely unsupported with a standalone section. The resolution to this matter was to send the subcommittee back to work to propose acceptable alternative language for the "Quality Systems Assessments" section of the HASQARD.

e. At the October 19 meeting, Huei Meznarich took the action to determine a location for the December 13 meeting. That meeting will be held at 2430 Stevens, Room 199 from 2:00-4:00. Glen Clark asked if that room was equipped with the projector system required to project proposed changes to the HASQARD on the wall as is 2425 Stevens, Room 208. The answer to that question was not known within the group, but Dave Crawford took the **Action Item** to find out if it is, and if not, to ensure a projector is available for the meeting. The action to schedule a room will be closed and removed from the action tracking matrix.

III. New Business

a. Eric Wyse initiated a discussion on expiration dates and holding times, or anything where a due date is involved. The question Eric posed to the group was, "Is the item still valid on the expiration date, or only invalid *after* the expiration date." For the ATL laboratory, the item is still valid on the expiration date. Eric also asked, in the cases where a vendor provides only month and year, "Is the item valid throughout the entire month, or

does it expire on the first day of that month?" To be consistent with the date question, one might argue that if the item is still valid on the expiration date, then if only a month is provided, it goes to follow that the item is valid the entire expiration month. Unfortunately, when this question was first raised a few years ago, Eric opted for the more conservative stance, to ensure he would not be challenged in the future for being too lax. Because of this, the ATL QAPP specifically states that if only a month and year are assigned, the lab will take this to mean that the expiration date is the first of that month. Eric polled the group and seemed to gain agreement that if an expiration date was a month and year, the product was good throughout the month listed as the expiration date.

The discussion was then expanded to holding times. For holding times that specify 24 hours, there seemed to be disagreement on whether that meant analysis must be completed anytime before the end of the next calendar day or an absolute 24-hour period. For example, if a sample was listed as collected at 14:37 on 11/16, is the analysis good if the laboratory reports it as being analyzed any time before 23:59:59 on 11/17 or does it need to be analyzed prior to 14:36:59 to be considered analyzed within the 24-hour holding time? The group also discussed the concept of determining compliance with a holding time based on the units with which the holding time is expressed. That is, if a holding time is expressed in hours, then compliance is measured to the nearest hour. If it is expressed in days, then the holding time would be deemed as met if the sample was extracted or analyzed within the correct number of calendar days. No final conclusion on that point seemed to be made, but the final option seemed to be favored by the majority.

This discussion included a discussion of what "time analyzed" means. Most agreed it was the time the sample was "stabilized" or, in the case of some organic analyses, the time an extraction into a solvent had begun or the sample was injected into an instrument. Most agreed that for the purpose of assessing holding time compliance, the date/time extracted or analyzed is the date and time reported by the laboratory regardless of what action the laboratory uses to determine that date/time. For example, a laboratory reports an extraction date/time, but the data user does not know how an individual laboratory determines that date/time of analysis unless they asked what that particular laboratory's practices are. That is, the data user "knows" the date and time, but specifically how that date/time (time more so than date) is determined is not necessarily known.

There was no action requested regarding inclusion of any of these thoughts/requirements in the HASQARD at this time. Eric was mainly looking for input on this topic as he considers revisions to the ATL QAP, however he suggested it may be worth keeping these concepts in mind as

we address proposals for Revision 4 of the document.

b. Chris Sutton requested that the Focus Group revisit the deminimis language currently posted regarding the use of custody seals. The current language is not specific enough concerning what must be done if a custody seal is not applied directly to a bottle. That is, it is not clear that when one chooses not to apply a custody seal directly to a bottle whether a sample container must be bagged with a seal placed on the bag or if simply sealing the shipping container is adequate. After discussion the consensus of the group seemed to favor requiring a secondary container (e.g., bag) that has a custody seal in addition to the shipping container having the seal. Cliff Watkins took that **Action Item** to revise the language in the deminimis guidance to remove this ambiguity and share it with Chris Sutton to ensure the sampling NCOs all agree to the new language before presenting it at the next HASQARD Focus Group meeting.

IV. HASQARD Revision 4 Proposals

a. The organic analysis subcommittee started their presentation of revisions they suggest should and should not be made to the HASQARD as a result of the DOECAP/QSAS/HASQARD gap analysis.

This presentation was initiated with a summary of revisions the subcommittee suggested <u>not</u> be made based on their review. The material for which <u>no revision</u> was suggested included:

Method detection limits shall be updated or verified on an annual basis

The LOD must be verified annually for each quality system matrix, method, and analyte according to the procedure specified in Appendix C, Section 3.

These requirements come from the QSAS, Gray Box 5.9 DOE-3 and Section D.1.2.1.d respectively. The discussion amongst the Focus Group seemed to agree that there is no regulatory or method-based requirement driving a frequency of MDL determinations and/or verification. Eric Wyse felt that a frequency for MDL verifications should be specified, he just did not know what would be appropriate or what a basis for a requirement on this would be. Glen Clark agreed to an Action Item research the frequency requirements for determining MDLs and LODs and report back to the Focus Group on his findings.

The requirements to spike the number of target analytes in the LCS and matrix spike, based on the total number of target analytes to be analyzed.

These requirements come from the QSAS, Sections D.1.1.2.1 and D.1.1.3.1.c . The discussion was mixed on this matter and no consensus on whether this should not be included was reached. Heather Anastos made statements in favor of including this language. Her points focused on data comparability. The commercial laboratories are performing this practice to adhere to QSAS. Heather also stated that it is easier to draw conclusion on analyte performance in a set of analyses if an analyte is present in an LCS and/or MS/MSD sample rather than draw conclusions using "chemically similar" analytes. Steve Smith asked about where the number of analytes spiked is specified. The response was that this is included in laboratory SOWs. Stave asked if you do not have a basis for the number of analytes spiked in your requirements documents, how do you have a basis for the requirements in your statement of work? Joan Kessner added that it would not be appropriate to add all elements of a SOW to HASQARD. The analytical methods requested typically list recommended or required matrix spike compounds. Eric Wyse pointed out that SW-846 method 8270D contains language stating that "*some projects may require the spiking of the specific compounds of interest, since the spiking compounds listed in Method 3500 would not be representative of the compounds of interest required for the project*." This language implies a project-by-project specification for the matrix spike analytes to be used is more appropriate in some instances and the SOW is the logical place to make these specifications rather than in HASQARD. Because this QSAS requirement applies to more than just organic analytes, it will be revisited in coming presentations. Therefore, the group agreed to ponder this matter and discuss it again at a later date.

The concept of Marginal Exceedance (ME) limits and the number of allowable marginal results exceeding the criteria

These requirements come from the QSAS, Section D.1.1.2.1.e, and Gray Box D.1 DOE-4. Heather Anastos stated she likes the concept and thinks it is helpful for not requiring an excessive number of reanalyses in the laboratory. The concept of MEs is closely related to the discussion above on the number of analytes used to spike LCS samples. If less than eleven analytes are in an LCS sample, the MEs do not apply. For example, if the method 3500 recommended analytes are used to spike the LCS, there will be eleven analytes and the use of MEs in HASQARD would allow one analyte to exhibit a ME with no corrective action required. The group agreed the concept of MEs should not be added to HASQARD.

Joan Kessner asked if there was a basis for the recommendations of why something that is present in the QSAS would not be added to HASQARD. Robert Elkins responded that it was a perception of value added. That is, the organic subcommittee felt that if these four items were not included in HASQARD, most everybody's needs would still be met by the

HASQARD. Robert reminded the group that the purpose of these presentations is to present one subcommittee's opinion and the Focus Group may overturn any opinion on whether to include or not include something.

The organic subcommittee next presented a tracked changes version of HASQARD showing the revisions they feel should be made based on the HASQARD/DOECAP/QSAS gap analysis:

The QSAS, Section 5.4.1.2.b, and Gray Box 5.4 DOE-1 include two specific procedures that the list of required procedures in HASQARD Section 4.1.4 did not contain. Specifically, the QSAS requires procedures for "Instrument/equipment maintenance" and "Data reduction, internal verification/validation and reporting." The organic group recommended adding these procedures to the list. Huei Meznarich opposed this addition of procedures since there are sections in HASQARD that already address these requirements. Several members of the group pointed out that there are many other procedures on the list where requirements are specified elsewhere in HASQARD (e.g. sample custody and handling, laboratory sample chain of custody, etc.). Some stated that the HASQARD should be the document that specifies the requirements, and laboratory procedures are written to implement these requirements. Glen Clark stated that the Laboratory QA Plan document can be used as the laboratories' procedure, when applicable, and there is not a need to require additional procedures. A clear agreement on this proposed addition to the HASQARD was not reached. It was agreed to table the proposed revisions until final roll-up of all subcommittee's revisions and a vote on this added material would come in the discussion of the final Revision 4 of the document.

The DOECAP Checklist #2, line of inquiry item 2.2 contains a list of information required for technical and test procedures. The HASQARD has a similar list in Volume 1, Section 4.3. The DOECAP checklist contained required information that is not included in HASQARD. The information proposed for addition to the HASQARD list were: "Determining appropriate dilution for preparation and/or analysis," "Method Detection Limit," "Data reduction, internal verification/validation and reporting" and "Forms, tables, diagrams and/or charts used in context of the procedure." The Focus Group approved adding these items to HASQARD is not an issue since HASQARD already qualifies this list by saying: "The following information is required for technical and test procedures as appropriate to the scope and complexity of the procedure or work requested:" The words "as appropriate" allow for inclusion or exclusion as deemed appropriate by the procedure author.

The organic subcommittee added a paragraph to Volume 1, Section 6.3 in

HASQARD to address specific language called out in the QSAS, Section 4.12, and Gray Box 4.12 DOE-6. This language dealt with specific practices required when using hard copy logbooks. Joan Kessner felt this material was already covered in HASQARD and prior to adding language here it should be determined if it is covered already. The members of the subcommittee said that if they had found these details, they would not have recommended this addition. After discussing this matter, it was agreed to revisit this specific language in the context of the QA subcommittee's revision to the document.

The organic subcommittee added a paragraph to Volume 1, Section 9.1 in HASQARD to address specific language called out in the QSAS, Sections 5.5.3, 5.5.5, and Gray Box 5.5 DOE-9. This language dealt with specific practices required in maintaining hard copy records or electronic records for equipment maintenance. After discussing this matter, it was agreed to revisit this specific language in the context of the QA subcommittee's revision to the document.

The organic subcommittee added a paragraph to Volume 1, Section 10.3 in HASQARD to address specific language called out in the QSAS, Gray Box 5.9 DOE-1. This proposed language was: "Participation in the DOE Mixed Analyte Performance Evaluation Program (MAPEP) is required for all laboratories that possess a radiological materials license and perform Inorganic, Semivolatile Organic, or radiochemical analyses. Laboratories that provide volatile organic and wet chemistry analyses shall participate in a nationally recognized PE program for all matrices." Because no "enforced" or "current" requirement for laboratories to participate in MAPEP exists and because this language would inappropriately impact some laboratories used for Hanford projects, the Focus Group rejected this language preferring to maintain the current language. The current HASQARD language states that participation in a program that consists of analysis of externally provided blind samples is the minimum requirement.

The organic subcommittee completed presenting their proposed revisions to Volume 1 of HASQARD and the meeting end time was reached.

Hearing neither additional new business nor objections to the proposal to adjourn, Dave Crawford adjourned the meeting at 4:05 PM.