

HASQARD Focus Group
Meeting Minutes
August 16, 2011

The meeting was called to order by Dave Crawford, HASQARD Focus Group Chairman at 2:07 PM on August 16, 2011 in Conference Room 208 at 2425 Stevens.

Those attending were: (Chair), Cliff Watkins (Secretary), Lynn Albin, Heather Anastos, Jeff Cheadle, Kathi Dunbar, Robert Elkins, Scot Fitzgerald, Jim Jewett, Kris Kuhl-Klinger, Joan Kessner, Larry Markel, Huei Meznarich, Noe'l Smith-Jackson, Cindy Taylor, Amanda Tuttle, Rich Weiss and Eric Wyse.

- I. Dave Crawford requested comments on the minutes from the June 21, 2011 meeting. No HASQARD Focus Group members present stated any comments on the June meeting minutes and, after hearing no objections, the minutes were approved.

- II. The Action Tracking matrix was discussed:
 - a. The issue of the posted deminimis language for use of custody seals was discussed. Jim Conca and Huei Meznarich have agreed that the language proposed by CHPRC personnel on November 29, 2010, is acceptable but suggested that a temperature specification for cooled samples be stated as $<6^{\circ}\text{C}$ rather than $4^{\circ}\pm 2^{\circ}\text{C}$. They also requested CHPRC to provide specific language concerning the term "shipping container" to ensure it reflects current practices. At the April meeting, Chris Sutton took the **Action Item** to check the language with CHPRC sampling personnel and provide the final language to the Focus Group for concurrence vote at the May meeting. If approved, the Secretary would have posted the deminimis change on the HASQARD web site after the June meeting. However, Chris Sutton was not present at the June meeting. The action remained open and deferred to the August meeting for completion. Chris Sutton was again not present at the August meeting. Completion of this action was deferred to the September 20 meeting.

 - b. The schedule for presentation of the subcommittee recommendations for revision to the HASQARD document was discussed. The schedule will be updated based on input at this meeting (see item III below) and provided in hard copy form at the September meeting. Huei Meznarich pointed out that the latest completeness results (i.e., items stated as completed at or since the last meeting) are now being shown in yellow highlighted text on the hard copies she is providing at the monthly meetings.

- III. Dave Crawford did not request a status update from the subcommittees established to compare the QSAS and HASQARD requirements and propose revisions to the HASQARD. The only remaining group to present results is

the radiochemistry group and Joan Kessner stated they should be prepared to do this at the September meeting.

IV. New Business

The published agenda for the August HASQARD Focus Group meeting included a new business discussion on the definition of a de minimis change and the process used for approving these changes. Prior to the meeting, the Secretary was contacted by the individual that requested this agenda item to say he could not be present at the meeting. Therefore, Dave Crawford requested input from the HASQARD Focus Group members present on the urgency to discuss this matter immediately versus tabling it to the September meeting to allow the requesting HASQARD Focus Group member to be present for the discussion. Hearing no urgent need to discuss this matter, the issue was tabled to the September meeting.

V. Presentation Proposed Revisions to the HASQARD Requirements Concerning Determination of Low Limits of Detection or Quantification

Eric Wyse presented a discussion on some independent research he has been doing over the last few years regarding the requirements associated with method detection limit studies. This presentation was provided as PowerPoint slides that are available from Eric upon request. The highlights of the discussions that occurred during the presentation are captured below.

The subject of method detection limits cannot be discussed without also involving the other terms commonly used in low-limit reporting for analytical data such as, practical quantitation limit (PQL), estimated quantitation limit (EQL), reporting limit (RL), instrument detection limit (IDL), etc. Rather than get into an exhaustive discussion of what the definitions of these terms are, Eric's presentation focused on the technical approaches that have been published for determining these limits.

The most often cited method for determining method detection limits (MDLs) is found in 40CFR Part 136 Appendix B. This method uses statistics to determine a limit, above which one can say within a specified level of certainty whether or not an analyte of interest is present. While the result of such a determination is a concentration or quantity, measurements at (and just above) the detection limits determined in this fashion are not considered quantitative due to the relatively high uncertainty at such low concentrations. That is, even though the determined detection limit is a concentration value, there is no confidence in being able to detect an analyte if it is truly present in a sample at the MDL concentration. Also, it is believed to be unlikely that a statistically-derived MDL could be reproducibly verified. . The MDLs

determined in this fashion are not believed to be reproducible because they represent specific conditions at the time of determination, and analytical conditions continually change. If an analyte fails the MDL determination criteria, the entire process must be repeated robbing a production laboratory valuable time for an effort with questionable benefits.

Communications received from the EPA Office of Solid Waste and Emergency Response (OSWER) Methods Information Communication Exchange (MICE) indicate that for SW-846 applications, the EPA is discouraging use of the 40CFR Part 136 MDL determination technique. One of the notes Eric received from MICE personnel stated, “The SW-846 Methods Team is discouraging the use and application of the MDL determination, regardless of the sample matrix type, as defined in 40CFR Pt 136 Appendix B, for the simple reason that it is not a true indication of the method sensitivity.” Recent communications from EPA-OSWER MICE reinforce this position saying, “The USEPA Office of Resource Conservation and Recovery (ORCR) still uses the lower limit of quantitation (LLOQ) rather than method detection limit to assess method sensitivity.”

HASQARD requires the use of the MDL which requires that MDL studies in some form be completed in order to be compliant with HASQARD.

Rich Weiss emphasized that the concept of MDL or lowest limit of detection needs to be retained in some form. This is because from a data user’s perspective, it is unacceptable for a laboratory to report a concentration that is measured by an instrument between the QL or RL and the MDL as undetected. That is, if the QL is 10 and the MDL is 1 and the instrument measures a result at 5, Rich cannot tolerate the result being reported as 10U or <10. There was no dissent amongst the HASQARD Focus Group on this view.

Huei Meznarich stated that while the limitations and inconveniences of the 40CFR Part 136 MDL determinations are understood, there is some good information that comes out of doing those studies. She stated that the traditional method is good for determining sensitivity of new instruments and after you have experience with a method and instrument, the MDL method provides information on how well the instrument continues to perform with age.

Eric's presentation included a proposed method for determining an MDL that he believes is a more accurate and defensible method than the 40 CFR Part 136 determinations being done by most labs. Eric stated that he was not suggesting that this new approach be stated as a preferred approach or that it be published in HASQARD. Rather, he would like to see the language of HASQARD revised to allow a laboratory to determine MDLs in what they believe is the most technically-sound way using written laboratory-specific methods/procedures.

The HASQARD Focus Group discussed whether the laboratory's desire to do the most technically-sound approach would align with the customer's expectations for MDL determinations and frequency and the customer's data reporting expectations. Eric suggested that this should be done through the customer negotiations on detection and reporting limit needs that are already called for throughout HASQARD.

The HASQARD Focus Group discussed the impact on historical data and statistical analyses that would be conducted using historical and more recent data if the "less-thans" reported all of a sudden went from <MDL to <QL values (which may be as much as a factor of 10 different). Noe'l Smith-Jackson stated that the impacts would be felt in risk assessments where typically censored data (data reported as "less-thans") are used at a value of one half the reported value. Therefore, moving to reporting "less-thans" as <QL would result in a more conservative risk assessment scenario. That is, more clean-up may be required due to agreed upon data quality assessment criteria where the mean concentration of an analyte with some detected results and some non-detects is raised due to the "less-thans" being used with a higher assigned concentration.

Eric's presentation included citing EPA Method 6020A, "Instrument detection limits (IDLs) are a useful tool to evaluate the instrument noise level and response changes over time for each analyte from a series of reagent blank analyses to obtain a calculated concentration. They are not to be confused with the lower limits of quantitation, nor should they be used in establishing this limit."

Rich Weiss pointed out that while EPA says, "They are not to be confused with the lower limits of quantitation, nor should they be used in establishing this limit," EPA does not provide guidance or reference in the method for how lower limits of quantitation should be determined.

Following Eric's PowerPoint presentation, he displayed a proposed red-line/strike-out revision of Section 7.5.1 of HASQARD, Volume 4. By applying the revisions Eric suggests, he believes the laboratories would have the flexibility to determine MDLs as appropriately determined by that laboratory. The laboratory could also report results for analytes measured at less than the QL as <QL rather than as <MDL whether the constituent is detected at a concentration <QL or not unless clients require reporting results at the measured concentration with some kind of qualification.,

The conclusion of the presentation was that the HASQARD Focus Group members will review the proposed revision for acceptability and if acceptable the revision will be included in the first draft of Revision 4 of HASQARD, Volume 4 that is distributed for review and comment.

Dave Crawford noted that because the Chairman, Secretary and Acting Chairman all have conflicts with the scheduled September 20 date for the next HASQARD Focus Group meeting, he would like to propose it be moved to September 27. No HASQARD Focus Group members indicated a strong disagreement with this proposed date. The Secretary took the action to determine if the conference room was available for September 27 and if so to send out notice of this meeting schedule change. **NOTE:** Since the end of the meeting, and during preparation of these minutes, it was determined that the conference room is available on September 27 and notice has been sent to HASQARD Focus Group members.

Hearing neither additional new business nor objections to the proposal to adjourn, the meeting was adjourned at 3:42 PM. The next meeting is scheduled for September 27, 2011 at 2:00 PM in 2425 Stevens, Room 208.