SWGDRUG Meeting Minutes Portland, ME July 10-12, 2012

Core Committee Members (present):

Scott R. Oulton, Chair, Drug Enforcement Administration

Sandra E. Rodriguez-Cruz, Secretariat, Drug Enforcement Administration

Suzanne Bell, West Virginia University

Michael Bovens, European Network of Forensic Science Institutes

Sylvia Burns, Private Forensic Consultant, England

Conor Crean, United Nations Office on Drugs and Crime

Garth Glassburg, American Society of Crime Laboratory Directors

Linda Jackson, Mid-Atlantic Association of Forensic Scientists

Richard Laing, Health Canada

Adriano Maldaner, Iberoamerican Academy of Criminalistics and Forensic Studies

Jerry Massetti, Northwestern Association of Forensic Scientists & CA Association of Criminalists

Jack Mario, Northeastern Association of Forensic Scientists & American Society for Testing Materials

Christian Matchett, Southern Association of Forensic Scientists

Richard Paulas, Midwestern Association of Forensic Scientists

Robert Powers, Connecticut Department of Public Safety

Catherine Quinn, Victoria Forensic Science Centre, Australia

Pamela Reynolds, Federal Bureau of Investigation

Scott Vajdos, Southwestern Association of Forensic Scientists

Angeline Yap Tiong Whei, Asian Forensic Sciences Network

Udo Zerell, Bundeskriminalamt, Germany

Core Committee Members (not present):

Eric Person, California State University, Fresno

Karen Phinney, National Institute of Standards and Technology

Guests:

Betty Bleivik, Note Taker, Drug Enforcement Administration

Tuesday, July 10, 2012

Welcome/Introduction of Meeting Guests/Review of Conference Agenda

SWGDRUG chair Scott Oulton opened the meeting by welcoming the committee members. Mr. Oulton thanked Sandra Rodriguez-Cruz for her work in putting the meeting together. He noted that it was challenging to find a space that met the group's needs and also met the requirements for meetings set by the Department of Justice. Mr. Oulton also introduced invited guest Betty Bleivik (note taker).

SWGTOX Method Validation Draft Document

Mr. Oulton stated that SWGDRUG will consolidate our comments and send one response to SWGTOX. He requested for comments to be collected, compiled and submitted by Ms. Rodriguez-Cruz.

Core Committee Members Responsibilities

Mr. Oulton gave an overview of the meeting agenda. The comments received for Supplemental Document SD-5 (Reporting Examples) will be discussed. The goal is for the core-committee to vote on the document by Thursday. The core committee was reminded that Supplemental Document SD-4 (Measurement Uncertainty for Purity Determinations in Seized Drug Analysis) was voted on at last meeting to go out for public comment.

The Reference Materials Verification and Education and Training sub-committees will also be meeting to work on their pertinent sections of the SWGDRUG *Recommendations*.

MS Library Update

Mr. Oulton thanked Angeline Yap Tiong Whei for converting the mass spectral data into the Shimadzu format. Mr. Oulton stressed that SWGDRUG does not have the resources to validate submissions to the MS library; therefore, users must be aware of the disclaimer posted along with the library.

Mr. Oulton informed the committee that Cayman Chemical has provided SWGDRUG with data for incorporation into the SWGDRUG MS Library. There is ongoing discussion with Lipomed to do the same. Mr. Oulton also informed the committee that DEA has purchased 154 reference materials from Cayman Chemical. The DEA's Special Testing and Research Laboratory is validating these reference materials with the goal of developing monographs for each of them. It is expected the data will be published online within the next several months. This will provide the community a resource for validating their reference materials. This is especially important for bath salts and synthetic cannabinoids.

SWGDRUG Bylaws

Linda Jackson discussed her participation in the Interagency Working Group and the status of the creation of standardized bylaws for all SWGs. Some of the items being considered are the establishment of term limits for members and procedures involved in removing members for cause. Mr. Oulton stated that SWGDRUG will operate as is, putting any changes on hold pending completion of the draft standardized bylaws. Ms. Jackson also stated that there are some recommendations in the community to have the National Institute of Science and Technology (NIST) oversee the SWG groups with the intent that all SWGs would develop standards in a consistent manner.

Analogues

Mr. Oulton led a discussion on analogues. The discussion focused on whether or not SWGDRUG should have a formal statement on the subject and if so, should SWGDRUG define what an analogue is or should the document only provide guidance. The committee discussed this topic at length and whether or not SWGDRUG should even be involved with this subject, since in many jurisdictions the courts ultimately decide a compound's analogue status. Mr. Oulton indicated that he would consider creating a sub-committee to address this topic.

Reporting Sub-Committee Update

Robert Powers discussed the comments received regarding Supplemental Document SD-5 (Reporting Examples). The sub-committee's next step will be to address the comments and then make minor revisions to the examples.

It was emphasized that SD-5 contains examples of reporting, not required formats. The committee may consider adding additional examples to further illustrate SWGDRUG's minimum recommendations.

Uncertainty Sub-Committee Update

Suzanne Bell discussed the status of SD-4 (Measurement Uncertainty for Purity Determinations in Seized Drug Analysis), and stated that it should be completed in one day. The document requires some editing, but no major changes.

Reference Materials Sub-Committee Update

Sylvia Burns stated that she has reviewed the relevant SWGDRUG *Recommendations* sections pertaining to Reference Materials (RM) prior to this meeting; these will be discussed during the sub-committee break-out session. Issues to be discussed include RM-producing companies and the availability of RMs. The point was raised that true "Certified Reference Materials" (CRM) for controlled substances may not truly exist. Ms. Burns emphasized that it is a laboratory's responsibility to determine if a RM is fit for purpose. Also, Ms. Burns discussed adding to/amending the SWGDRUG *Recommendations* to include a section on the use of RMs. Ms. Burns intends to distribute draft work products to the core committee for discussion prior to tomorrow's break-out session.

Education and Training Sub-Committee Update

Rick Paulas informed the core-committee that the sub-committee has been compiling questions on different training subjects. During this meeting, the goal of the sub-committee will be to review, select, modify, delete and add questions as needed. Lastly, the sub-committee hopes to select an appropriate format and prepare the document for dissemination.

European Network of Forensic Science Institutes (ENFSI)

Michael Bovens informed the core-committee that although ENFSI's training and education outline has been officially released, it is currently only available on their members-only website. He indicated that since the outline is completed, SWGDRUG could post the training outline on their website. He also provided an update for their project regarding quantitative sampling.

SWGDRUG Survey

Suzanne Bell suggested that she was going to have graduate students from West Virginia University disseminate a SWGDRUG survey to the general community. Once finalized, she would provide the link so it could be added to the SWGDRUG website.

Sampling Calculator Presentation

Angeline Yap Tiong Whei presented recent issues encountered with ENFSI's sampling calculator involving the use of hypergeometric distribution. It was discovered that the calculator produces results for small sample populations that may result in under sampling of units. Users in her laboratory evaluated their findings concluding that the results obtained were a consequence of truncation and rounding events in Microsoft Excel. Ms. Yap Tiong Whei stated that her lab uses 3 different calculators to determine sample size: general software, the CLIC calculator, and the ENFSI calculator.

The core-committee also discussed making the CLIC Hypergeometric Sampling calculator available via the SWGDRUG website with permission from CLIC and the calculator's author John Gerlits.

ASTM Update

Scott Oulton provided an ASTM update. He informed the core-committee that the clan lab document, which was written with the help of CLIC, has been brought to ASTM for acceptance as an international standard. There is only one issue to address, and then it should go through the ASTM vetting process without delay.

Jack Mario discussed the application of hypergeometric sampling to an actual case brought to court in Suffolk County, NY during April 2012. He presented some of the case highlights, including trial preparation and training sessions.

International Forensic Strategic Alliance (IFSA) Overview

Angeline Yap Tiong Whei presented a report on IFSA. She described how six forensic science networks around the world have come together to form IFSA. IFSA's vision is to create opportunities for strategic collaboration across the global forensic science community. IFSA operates via annual meetings and teleconferences.

Ms. Yap Tiong Whei informed the core-committee that IFSA would like to adopt a minimized version of the SWGDRUG *Recommendations* for seized drug analysis. This issue was discussed and it was stressed that the SWGDRUG *Recommendations* should not be used in a reduced form and must be adopted in their entirety, as they were developed and adopted to reflect minimum standards. Under these circumstances, core committee members agreed that IFSA is welcome to use and adopt SWGDRUG *Recommendations*.

The core-committee briefly discussed translating the SWGDRUG *Recommendations* into other languages, but would first need to evaluate the costs associated with such projects.

Kovat's Retention Index Study Update

Angeline Yap Tiong Whei discussed the progress of establishing retention index information on the SWGDRUG website. She continues collecting data for dissemination.

Sub-Committee Break Out

The core committee members broke out into their respective sub-committees until late afternoon.

Sub-Committee Review

Documents containing preliminary revisions to the *Recommendations* were emailed from the RM sub-committee to the core committee members for review prior to tomorrow's discussion.

The Reporting Sub-committee reviewed the comments received from the public pertaining to Supplemental Document SD-5 (Reporting Examples). There will be a brief discussion tomorrow morning prior to the break-out sessions.

Wednesday, July 11, 2012

Reporting Sub-Committee Update

Linda Jackson discussed 3 comments received from the public during review of the draft Supplemental Document SD-5 (Reporting Examples).

- 1. Capitalization of drug names. Discussion regarding the use of upper vs. lower case letters resulted in the consensus that use of either one is acceptable. Both upper and lower case letters will be used in both examples (upper case in one, lower case in the other).
- 2. Weight determination is listed in the test/technique category. Discussion ensued as to whether or not weight determinations should be considered a test/technique. The committee agreed that it was a test and that the example should be left as is, with weight categorized as a "test/technique".
- 3. Analytical tests/techniques used to identify the drug are listed in the examples, but should a negative test/technique (or a test/technique not used to identify the drug) be listed? Discussion of this question resulted in a consensus that the examples should be left as is.

The core committee also discussed the most appropriate ways to address the multiple comments received from the public. Should the comments and the committee's responses be posted on the website? Should the responses be emailed only to those who made the comments? Who should respond? Should SWGDRUG use a statement such as "Comments were addressed and acted upon appropriately" or "The reporting sub-committee considered every comment and responded appropriately"? The Reporting sub-committee will prepare a document and solicit feedback from the core committee prior to potential posting.

Reference Materials Sub-Committee Update

Sylvia Burns discussed several of the issues the sub-committee is evaluating while revising the SWGDRUG *Recommendations* regarding RMs. These are:

 What is acceptable and is it even possible to obtain a Certified Reference Material (CRM) for drugs?

- Allowing laboratories to use RMs without verification if they were obtained from sources that are accredited to ISO Guide 34
- Allowing laboratories to verify RMs via other means (for example, MS interpretation) when comparison with published data is not possible
- The use of "literature" spectra for identification
- Addition of a section addressing the use of RMs

Sub-Committee Break Out

The core committee members broke out into their respective sub-committees until the afternoon.

Reporting Sub-Committee Update

The core-committee reconvened to discuss Supplemental Document SD-5 (Reporting Examples) and the comments received during the public comment period. A total of 24 comments were received. The comments and corresponding responses had been emailed to the core committee members for review prior to discussion. Linda Jackson renewed the discussion regarding how SWGDRUG should disseminate the responses to public comments. If a document including comments and SWGDRUG responses is posted on the SWGDRUG website, how long should it be made available? The committee also discussed multiple ways of addressing comments and those were considered but resulted in no changes to the document.

Dr. Robert Powers made a motion to accept Supplemental Document SD-5 (Reporting Examples) and for it to be posted on the SWGDRUG website after editorial changes are made. Scott Vajdos seconded the motion. After no further discussions, the motion passed unanimously.

Thursday, July 12, 2012

Uncertainty Sub-Committee Update

Suzanne Bell discussed Supplemental Document SD-4 (Measurement Uncertainty for Purity Determinations in Seized Drug Analysis). The core committee was reminded that the 1st version had already been approved to be posted for public comment during the previous meeting. During this meeting, minor changes were made to the document.

Christian Matchett made a motion to withdraw the previous motion to release the document for public comment as voted on at the last meeting. Linda Jackson seconded the motion. The core committee passed the motion unanimously.

Jack Mario made a motion to release the revised version of Supplemental Document SD-4 (Measurement Uncertainty for Purity Determinations in Seized Drug Analysis) out for public comment for a period of 60 days pending editorial review. Linda Jackson seconded the motion. The core committee passed the motion unanimously.

Analogues

Scott Oulton led a discussion on the issue of controlled substance analogues, reviewing and expanding on the issues previously raised. During the discussion, Robert Powers made the

comment that we can only talk about structural similarities and that we need to make it clear that physiological/pharmacological effects are significant and cannot be addressed by SWGDRUG. Sylvia Burns asked that since we can only give information on structural similarity, can we provide guidance to the community as to how to define structural similarity? The core committee discussed the role of the legal community and the fact that there are different rules for different jurisdictions, i.e. states, federal governments, countries, etc. regarding the definitions of controlled substance analogues. Catherine Quinn proposed that SWGDRUG's efforts could concentrate on emphasizing what a forensic scientist can testify to during these cases. It was decided that SWGDRUG would go forward with the formation of an Analogue Sub-Committee and the drafting of a guidance document for the forensic community.

Sub-Committee Break Out

The core committee members broke out into their respective sub-committees until late morning.

Analogue Discussion

Christian Matchett furthered the analogue discussion by presenting an example using the chemical structures of (methamphetamine and methiopropamine). A discussion ensued involving the definition of structural similarity and how to best address it.

Reference Materials Sub-Committee Update

Sylvia Burns presented the sub-committee's proposals for additions/changes to the SWGDRUG *Recommendations*.

Part III B - Methods of Analysis/Drug Identification, section 3.5

Amend section 3.5 to include what constitutes a "positive." The core-committee discussed the proposal and agreed with the ideas, but the wording needs some clarification. It was suggested to leave section 3.5 as is and make the proposals its own section as 3.5.5

Other comments included:

- How would a laboratory report a "positive" identification made, if no reference material was available?
- It was emphasized that laboratories should understand the chemical skills needed to make an identification via structural elucidation using NMR or MS data
- Catherine Quinn suggested the use of 3 tiers or levels for classifying the use of reference materials in a laboratory

Sub-Committee Break Out

The core committee members broke out into their respective sub-committees until late afternoon.

SWGDRUG Website Update

Scott Oulton reported that Supplemental Document SD-4 (Measurement Uncertainty for Purity Determinations in Seized Drug Analysis) has been made available on the SWGDRUG website. Core committee members were reminded of their responsibilities to notify their respective organizations about the posting and the 60-day public comment period.

The core-committee was also notified that the revised version of Supplemental Document SD-5 (Reporting Examples) was now posted, containing a link for accessing the public comments received and the corresponding SWGDRUG responses. The comments document will be available on the website for approximately one year.

The European Network Forensic Science Institute (ENFSI) training outline and the CLIC Hypergeometric Sampling Calculator have also been made available via the SWGDRUG website.

Sub-Committee Status Update

Mr. Oulton announced the formation of the following sub-committees and their members. Reference Material Sub-Committee: Sylvia Burns (chair), Suzanne Bell, Conor Crean, Jack Mario, Karen Phinney, Pamela Reynolds, and Angeline Yap Tiong Whei. Analogue Sub-Committee (new committee): Christian Matchett (chair), Linda Jackson, Scott Oulton, Robert Powers, Catherine Quinn, Sandra Rodriquez-Cruz, and Udo Zerell. The SWGDRUG website will be revised to reflect these sub-committee additions and changes.

Reference Materials Sub-Committee

Draft revisions to the SWGDRUG *Recommendations* will be finished and sent to the core committee within the next few months. Members were asked to send their comments directly to the sub-committee. Further discussion of the RM document followed including the possibility of doing an electronic vote or conference call before the next meeting in January 2013.

Meeting Closeout

Sandra Rodriguez-Cruz was tasked with the compilation of all comments regarding the SWGTOX Method Validation draft document. Ms. Rodriguez-Cruz will submit a formal response to SWGTOX on behalf of SWGDRUG.

The current SWGDRUG PowerPoint presentation is posted on the website. It was suggested that any future SWGDRUG presentations by members be sent to Scott Oulton for posting.

Possible locations for the next SWGDRUG meeting were discussed. The next meeting is tentatively scheduled for the week of January 7-11, 2013.

Mr. Scott Oulton thanked all committee members for all their hard work during this meeting. He also thanked Sandra Rodriguez Cruz for all her hard work setting up this meeting and Ms. Betty Bleivik for participating as the note taker. Thanks were also extended to the all sub-committee chairs.