SCAPA
Biosafety Working Group (BWG)

Highlights
BWG Teleconference 10-02
October 18, 2010, 3:00 p.m. EDT

Participants

Patricia Barbosa, NNSA/LSO
Jayne-Anne Bond, ATL
Cliff Glantz, PNL
Michael Heitkamp, SRNL
Dina Matz-Siegel, LANL
Carl Mazzola, Shaw Environmental
Beth Reeves, LLNL
Kristine Montgomery, LLNL
Frank Roberto, INL
Dan Schabacker, ANL

Roll Call and Introduction

Frank Roberto conducted a roll call and acknowledged that 10 individuals were present. Of particular note, Beth Reeves and Kristine Montgomery, LLNL, were participating in the BWG teleconference for the first time. Frank provided a brief introduction of the BWG.

Last year, the BWG addressed a number of action items. Of particular note was the preparation of posting of a report on the atmospheric dispersion of biological agents: Transport and Dispersion of Biological Agents/Toxins (2009). This year, the BWG does not have any active action items to complete for DOE/NA-41, but there are a number of technical issues we are following and activities in which the SCAPA BWG represents the interests and capabilities of the DOE biosafety community.

EMI SIG 2011 Annual Meeting

The initial call for presentation proposals for the May 2011 EMI SIG Annual Meeting and SCAPA Meeting has just been released (see the e-mail sent out on October 13th to all members of the EMI SIG or view on the EMI SIG website at http://orise.orau.gov/emi/annual-meeting/2011/default.htm). Proposals are due by **January 7, 2011**. Reminders will be sent out in advance of this deadline.

Discussion

ABSA September 2010 Meeting

The SCAPA BWG has a formal alliance with the American Biological Safety Association (ABSA) and has committed to share information on the ways DOE/NNSA sites are addressing biosafety

issues. A forum for sharing this information was the 53rd Annual ABSA Conference, held in Denver, CO, which was attended by several BWG members.

Highlights of the 2010 ABSA Denver, CO conference were presented. These included:

- Kathryn Harris, National Institutes of Health (NIH), Bethesda, MD, reported on upcoming revisions of the NIH guidelines. Expanded biosafety responsibilities in a number of areas are to be expected, such as a need to review proposals and modifications to existing projects for potential dual-use issues and inclusion of synthetic genomics for review. New guidance will be posted on genetic experimentation *(Recent and Proposed Update to the NIH Guidelines for Research Involving Recombinant DNA Molecules).*
- The status of the NIH onsite inspection program for IBCs was discussed. One hundred to two-hundred inspections, of 800 IBCs in the United States, are being performed each year, with 4-10% of them unannounced. A self-assessment checklist is posted on the NIH Office of Biotechnology Activities (OBA) website in both fillable PDF and Excel versions (http://oba.od.nih.gov/rdna_ibc/ibc.html).
- NIH also wants to see principal investigators (PIs) be trained in biosafety. Only a small percentage of facilities have formal biosafety training for their PIs.
- ABSA, the American National Standards Institute (ANSI), and the American Industrial Hygiene Association (AIHA) all have initiatives to administer biocontainment lab accreditation. In some cases, there is overlap of biosafety professionals participating in these initiatives. It will be interesting to see if a formal laboratory accreditation program is established and which organization rolls out such a program first. The ABSA plan is patterned after the animal lab accreditation program run by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).
- Among the pre-conference courses, Dina Matz-Siegel found the course on *Basic Virology and Virus-Based Gene Vectors* (by Patrick Condreay, PhD, GlaxoSmithKline, Research Triangle Park, NC) to be very worthwhile. This course provided a much needed introduction to the science of virology. Dina reported that even attendees with academic training in virology found the course to be useful and informative, as well as very useful for IBC members to understand rDNA research.
- In the DOE community, there is a self-assessment checklist that national labs can perform to evaluate their biosafety program. It might be useful to conduct this self-assessment exercise before the ABSA comes around to inspect your facility.
- There was an interesting presentation regarding a survey on hand washing (*Hand and Hygiene in the Biosafety Level 2 Lab: Is it a Matter of Training?* by James Johnston, University of Utah, Salt Lake City, UT). This survey found that lead researchers set the tone for their staff's hand washing routines. Self-reporting indicated that appropriate hand washing is occurring only 40% of the time. However, when workers were actually monitored, only 11% of workers in BSL facilities were doing appropriate hand washing. The survey also found that sick people touch their faces a lot when working in BSL labs, which is particularly problematic. It is important that workers start practicing appropriate hand washing.
- Dina and Frank discussed a recent national survey of IBC management and practices. Frank will send out the survey results to the group, which was presented at the Denver

ABSA conference (*Current Trends in Institutional Biosafety Committees (IBC) –National Survey of IBCs*).

FESAP Working Groups and EO 13546

The Federal Experts Security Advisory Panel (FESAP) working groups were convened by NIH and the United States Department of Agriculture (USDA) to follow up on Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins (BSAT) in the United States," signed by President Obama in July 2010. The FESAP is considering recommendations resulting from the Trans-Federal Working Group on Strengthening the Biosecurity of the United States. These include tiering of select agents, and possible tiering of requirements, personnel reliability (PR), and physical/cyber security.

Dina Matz-Siegel is participating on the PR and tiering working groups, and Frank Roberto is on the PR working group. The BWG also learned that Tricia Barbosa and George Anderson at LLNL have been participating on the physical/cyber security working group. The recommendations of these working groups are not yet final, but it can be said generally that recommendations from the working groups will not be radically out of line with DOE/NNSA practices for PR and physical/cyber security programs.

However, there is a lot of concern about making recommendations that would be difficult for academia to implement. The Tier 1 organisms will include infectious microbes and viruses that pose the greatest immediate risk to human and animal health. Tier 2 bio-agents will have lower requirements, and some select agents may even be removed.

Tier 1 bio-agents will have the highest PR requirements. Tier 1 will be a select group of bacterial and viral agents. However, it is unsure how much loosening of recommendations may occur for Tier 2. Compliance with the new guidelines should be easy for national laboratories, but will be much harder for the academic/university laboratories. Of particular difficulty for them is the issue on how to handle medical and psychological information collected to reduce the insider threat. They need to consider compliance with HIPAA requirements and how to fund the costs associated with an enhanced PR program. There is clearly hesitancy in the academic community to implement full-blown programs as are present at DOE labs. Three major recommendations will be coming out of an upcoming panel meeting.

Many members of the PR working group are heavy hitters who have much knowledge about establishing PR programs at various federal agencies. The PR program for biosafety at LANL is based on the PR program established for the nuclear program. It includes medical assessment, a psychological evaluation, etc.

A question was asked: "When you are at the FESAP meeting, were there people representing academia?" Answer: "The FESAP is all federal (led by Laura Kwinn at NIH)." Some individuals within the federal community are speaking up to represent the interests and capabilities of the academic community. The universities will have a say after regulations are published in the

federal register. However, universities want to have a say on future regulations earlier in the regulation-making process.

BWG doesn't have much information on the Physical and Cyber Security working group. Patricia Barbosa and other DOE professionals are participating in this working group. They are planning to pipe in as things crystallize. There is concern that restrictions on academia may put a damper on research.

Another question was asked: "How long will it take to revise the NIH guidelines for recombinant DNA research?" The process is well under way (public comment period has closed, and notice of proposed action published in the Federal Register); a draft has been submitted for review, so perhaps we will see new, final guidelines from NIH in about six months.

Round Robin

During the roundtable discussion, the possibility of including a presentation on the FESAP recommendations at the 2011 EMI SIG/SCAPA Meeting was presented. The deadline for abstracts is January 7, 2011. BWG members are encouraged to consider presenting at the BWG Meeting, during the SCAPA Meeting, or at the general EMI SIG Conference.

Adjournment

The meeting was adjourned at **2:40 p.m. EDT**. Frank thanked everyone for their time and contributions.