External Laboratory Safety Workgroup (ELSW)  
Meeting Summary  
Friday, September 26th, 2014  
8:00 A.M. – 9:00 A.M.

Members

- Joseph Kanabrocki, PhD, CBSP – Co-Chair
- Debra L. Hunt, DrPH, CBSP
- Thomas V. Inglesby, MD
- Patty Olinger, RBP
- David A. Relman, MD
- Fred Sparling, MD
- Heather J. Sheeley, BA (Hons), MS, CBiol MSB, CMiOSH, FISTR
- Domenica (Dee) Zimmerman
- In attendance

*CDC and NIH employees

Summary of Meeting Notes

Roll Call and Introductions
Elaine Baker, Designated Federal Officer (DFO), ELSW

Overview and Introductions of National Institute of Health Attendees
Dr. Joseph Kanabrocki, Co-Chair, ELSW; Herbert Jacobi, Deputy Director, Office of the Director; Jeff Potts, BioRisk Manager, BioRisk Management Program

- ELSW’s charge includes offering recommendations to the National Institutes of Health (NIH) and the Food and Drug Administration (FDA)
  - What has NIH done to date in response to the general instructions outlined in the White House memo?
  - What would NIH like the ELSW to do, and at what level of engagement?

National Institutes of Health Response
Herbert Jacobi and Jeff Potts, NIH

- A complete inventory is being conducted of all collection storage areas and stations.
  - To be completed by September 30, 2014.
  - In July 2014, Center Directors initiated a “Clean Sweep” of their areas.
    - Ensure that no other select agents were being stored in unregistered areas and/or that were not registered with the NIH Select Agent Program (SAP)
    - Inventory and document all human pathogens that could be classified as Biological Safety Level (BSL)-2 and/or higher and any vials of toxins of biological origin, including poisons
- A complete inventory is being conducted of all collection storage areas and stations. The Division of Occupational Health and Safety (DOHS) has engaged 30 people to conduct a QA survey
- A review was initiated of all of the NIH policy manual chapters that govern the use of biologic materials across NIH.
  - A review was also initiated of all policies and procedures that govern the use, transfer, and possession of select agents on NIH campuses.
    - NIH implemented a campaign to adhere to the National Biosafety Stewardship Month during September.
  - NIH has an Institutional Biosafety Committee (IBC) that oversees all of the research at NIH. The agency has 27 Institutes and Centers (ICs).
Proposed research involving human pathogens considered to be BSL-3 or BSL-4 and rDNA is submitted for a full IBC committee review.

- Centralized training is provided through the Community Health Branch for all laboratory researchers who come to work at NIH.

**Discussion Points**

*Herbert Jacobi and Jeffrey Potts, NIH*

- Recent escape of an experimental animal at NIH
  - Any such incident results in a full review of what occurred, how it was addressed, and the development of an after action review (AAR).
  - NIH to give ELSW the report of NIH animal escape incident to help better understand what occurred and the response taken.

- DOHS at NIH
  - The DOHS Director reports to the Office of Scientific Resources, which reports to the Office of the Director of NIH.

- NIH protocols for removing substances from containment and/or standard operating procedures
  - SOP that calls for submission of inactivation protocols from BSL-3 and BSL-4 laboratories; protocols are submitted to the IBC for review and approval.

- Competency Training
  - NIH only provides classroom-based training, but offers hands-on training to review proficiency if requested.
    - NIH established a training laboratory to allow individuals to acquire hands-on training for BSL-2 and BSL-3 requirements. (Awareness must be raised).

- “Operation Clean Sweep”
  - NIH instructed staff to stop all activities and call SAP if a select agent is found.
  - Personnel encouraged to report under an “amnesty”. No fear of reprisal or response.
    - Focus on identifying lapses and improvements that can be made to ensure that researchers are safe.

- NIH has extended policies and procedures on select agent regulations.
  - The DOHS is working to enhance its system to have the same electronic registration system for select agents, with the interest being in information technology (IT) security.

- Role of Safety Specialists
  - Safety Specialists visit BSL-2 laboratories once a year unless a visit is requested.
    - One Safety Specialist to approximately 1500 people.

- Each Safety Specialist is a member of the IC’s safety committee and attends each safety committee meeting to provide guidance, direction, and support for the Institutes and Centers (IC) and address safety concerns.

- ELSW Charge and NIH
  - NIH is addressing several activities; ELSW and NIH will discuss next steps once NIH activities are completed and the data reviewed.

- NIH Safety Committees within ICs
  - Each IC has a safety committee.
  - Within the DOHS, there is a Safety Operations Support Branch with 11 Safety Specialists assigned to one or more ICs.

**Wrap up and Adjournment**

*Dr. Joseph Kanabrocki, Co-Chair, ELSW*