



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

**Members**

- |  |  |
|--|--|
| ✓ Joseph Kanabrocki, PhD, CBSP – <i>Co-Chair</i>               | ✓ Kenneth I. Berns, MD, PhD – <i>Co-Chair</i>                          |
| ✓ Debra L. Hunt, DrPH, CBSP                                    | ✓ Michael A. Pentella, PhD, D(ABMM)                                    |
| ✓ Thomas V. Inglesby, MD                                       | ✓ Jill Taylor, PhD   |
| Patty Olinger, RBP   | ✓ Elaine Baker, MPH, ELSW DFO*   |
| David A. Relman, MD  | ✓ Herbert Jacobi, MS, Deputy Director, NIH<br>Office of the Director*  |
| Fred Sparling, MD  | ✓ Jeff Potts, MPH, BioRisk Manager, NIH<br>BioRisk Management Program* |
| Heather J. Sheeley, BA (Hons), MS, CBiol MSB,<br>CMIOSH, FISTR |  |
| Domenica (Dee) Zimmerman                                       |  |
| ✓ <i>In attendance</i>   |  |
| *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).



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- 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 submittal 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.
  - Past efforts have 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*