



**External Laboratory Safety Workgroup (ELSW)
Meeting Summary
Monday, September 29th, 2014
10:00 A.M. – 11:00 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 | ✓ Jill Taylor, PhD |
| ✓ Fred Sparling, MD | ✓ Domenica (Dee) Zimmerman |
| Thomas V. Inglesby, MD | ✓ Elaine Baker, ELSW DFO* |
| Patty Olinger, RBP | ✓ Stephen Ostroff, MD, FDA Acting Chief Scientist* |
| Michael A. Pentella, PhD, D(ABMM) | |
| Heather J. Sheeley, BA (Hons), MS, CBiol MSB, CMIOSH, FISTR | |
| David A. Relman, MD | |
| ✓ <i>In attendance</i> | |
| * <i>CDC and FDA employees</i> | |

Summary of Meeting Notes

Roll Call and Call to Order

Elaine Baker, Designated Federal Officer (DFO), ELSW

Overview and Introductions of Food and Drug Administration (FDA) Attendees

Dr. Joseph Kanabrocki, Co-Chair, ELSW and Dr. Stephen Ostroff, Member, ELSW

- How has FDA responded to the general instructions outlined in the White House memo?
- What would FDA like the ELSW to accomplish, and at what level of engagement?

Food and Drug Administration Response

Dr. Stephen Ostroff, Member, ELSW

- FDA's laboratory infrastructure differs from the CDC and NIH.
 - FDA's model is decentralized
 - Some reluctance to standardize laboratory safety and inventory management and control
- The Office of Medical Products and Tobacco have the following centers with laboratories:
 - Center for Biologics Evaluation and Research (CBER)
 - Center for Devices and Radiological Health (CDRH)
 - Center for Drug Evaluation and Research (CDER)
- The Office of Foods and Veterinary Medicine houses two centers with laboratories:
 - Center for Food Safety and Applied Nutrition (CFSAN)
 - Center for Veterinary Medicine (CVM)
- The National Center for Toxicological Research (NCTR) is another FDA research facility
- The Office of Regulatory Affairs (ORA) is FDA's largest component with laboratories
 - The ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products, and reviews imported products offered for entry into the United States
 - The ORA has a network of laboratories that conduct regulatory testing if there is a concern about a product being contaminated.
 - There are 13 ORA laboratories situated throughout the country.
 - Of the 13 ORA laboratories, 9 are registered for select agents.
- All FDA laboratories have inventory management approaches.
- FDA prioritized an immediate sweep of all common storage areas throughout the agency to find hazardous biological materials.
 - Completed on July 17, 2014.



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- The Laboratory Safety Policies and Procedures Working Group was created at the end of the “sweep” and tasked with the following:
 - Oversee the inventory process.
 - To be completed on September 30, 2014.
 - Develop standardized policies and practices for all FDA laboratories, including inventory management, frequency of inventory, and training.
 - Develop a mechanism to audit reported inventory from all FDA components.
- Must all FDA components that are registered for select agents actually need to be registered?
- FDA has also been involved in the National Biosafety Month activities.
- ELSW asked to assist in reviewing the agency’s response activities and reinforcing the importance of these efforts.
- ELSW to emphasize the importance of having a centralized activity to ensure standardization across the agency.

Discussion Points

ELSW members

- FDA’s Laboratory Safety Policies and Procedures Working Group
 - Co-chaired by Dr. Stephen Ostroff and the FDA Chief Operating Officer.
 - The Workgroup will meet for at least a year to a year and a half.
 - The focus has been on immediate requirements, such as completing the inventory and National Biosafety Month.
 - The Workgroup is researching best practices that could standardize policies.
 - A separate subgroup will address the development of policies and practices.
- Risk Assessment functions at FDA
 - FDA has a central Institutional Biosafety Committee (IBC), while other centers have their own IBC due to geographical location.
 - Dr. Ostroff to provide ELSW with IBC’s specific policies and procedures FDA does not have a risk assessment entity.
- Inventory tracking mechanisms at FDA
 - FDA had decentralized inventory management system. Select agent registrations are done individually by center, and there is no central submission of that of information.
- Biosafety Office in FDA’s efforts
 - Workgroup in place that meets and interacts with the Biosafety Officers within laboratories.
 - Biosafety Officers have a coordinating, rather than a regulatory role; they do not set requirements regarding certain standards.
 - Biosafety Officers coordinate training activities; while most training is in individual centers.
 - Each center has a different model for biosafety training.
- Reporting Structure at FDA
 - FDA laboratory enterprise lacks a strong centralized management component.
 - FDA welcomes feedback from ELSW pertaining to whether such centralization should be housed within the Chief Operating Office or the Office of the Chief Scientist.
 - Feedback is also welcomed as to how centralization would be organized and implemented.
- Culture of Safety at FDA



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- Centers across FDA have different culture based on several factors: location, area of research, research facilities available, and research capabilities.
- Engagement Sessions
 - FDA is planning to conduct focus groups in order to obtain feedback from laboratory staff regarding perspectives related to biosafety and procedures.
- The Laboratory Safety Policies and Procedures Working Group
 - The Workgroup will make recommendations regarding a centralized entity with a high-level official.
- FDA will reach out to the ELSW with a projected timeline for FDA's internal activities

Wrap up and Adjournment

Dr. Joseph Kanabrocki, Co-Chair, ELSW