**Attendees**

- Joseph Kanabrocki, PhD, CBSP – Co-Chair
- Thomas V. Inglesby, MD
- Patty Olinger, RBP
- Fred Sparling, MD
- Jill Taylor, PhD
- Domenica (Dee) Zimmerman
- Michael A. Pentella, PhD, D(ABMM)
- Fred Sparling, MD
- Kenneth I. Berns, MD, PhD – Co-Chair
- Heather J. Sheeley, BA, MS, CBiol, MSB, CMIOOSH, FISTR
- Debra L. Hunt, DrPH, CBSP
- Elaine Baker, MPH, Designated Federal Officer*
- Michael A. Pentella, PhD, D(ABMM)
- Kenneth I. Berns, MD, PhD – Co-Chair
- Heather J. Sheeley, BA, MS, CBiol, MSB, CMIOOSH, FISTR
- Debra L. Hunt, DrPH, CBSP
- Elaine Baker, MPH, Designated Federal Officer*
- Michael Bell, MD, Interim Director of Laboratory Safety*
- In attendance
- * CDC employee

**Summary of Meeting Notes**

**Roll Call and Call to Order**

*Elaine Baker, ELSW Designated Federal Officer (DFO)*

**Review Timeline**

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

- Plan to present findings from CDC site-visit to the ACD at the October 23, 2014, meeting.

**Discussion Points**

*ELSW members*

- Do recommendations represent ELSW Deliverables?
  - Mandate includes NIH and FDA and the timeline is intended to allow for review and input of CDC, NIH and FDA.
  - The effort to assess the NIH and FDA could be considerable, but the ELSW has had limited communication with those agencies.
- Memorandum from the Secretary of Health and Human Services (HHS)
  - Addresses external review of laboratory safety
  - Includes a request for an EAG report regarding whether the current laboratory the current laboratory safety and biosecurity rules are appropriate
  - ELSW must provide a high-level timeline to the Secretary, HHS.
- What internal processes do NIH and FDA have in place since the laboratory incidents?
  - It will be difficult to conduct formal assessments of both NIH and FDA
  - ELSW can gain insight by reading reports of internal groups from NIH and FDA
  - ELSW is not expected to examine every laboratory at every agency
- Two deliverables:
  - High-level timeline to the Secretary, HHS
  - ELSW’s update to the ACD and final recommendations
- ELSW Role in the Advisory Committee to the Director, CDC (ACD)
  - ELSW is a work group of the ACD.
  - The ACD will consider proposals from ELSW
  - If the ACD accepts proposals, they will make a recommendation to CDC.
  - The CDC Director may accept any recommendations, but the agency is not required to implement any recommendations
  - ACD October 23, 2014, meeting is a public meeting, and updates will be made available
- ELSW Timeline Recap
o September 2014: Preliminary communication with FDA and NIH
o October 2014: ACD update with findings, but not a report
o November 2014: Formal recommendations to CDC
o Pending: Formal engagement with FDA and NIH following preliminary teleconferences

Observations Following In-Person Meeting September 15-17, 2014 in Atlanta, GA
Dr. Joseph Kanabrocki – Co-Chair, ELSW

- Mission Growth:
  o The mission of the CDC has been expanded over recent years.

- Priorities:
  o There has been increasing concern in National Security as it relates to infectious agents.
  o Biosecurity (particularly within the U.S.) is being emphasized over biosafety

- Organization:
  o The CDC organization is complex and difficult to understand.
  o Some programs have undergone reorganizations, while others have not
  o Reorganizations have led to confusion

- Leadership and Buy-In:
  o Leadership commitment regarding safety is variable and needed at multiple levels.
  o Safety, including lab safety, is viewed by many as separate from the primary missions of public health and research.

- Governance Structures:
  o The Environment, Safety, and Health Compliance Office (ESHCO) is outside the chain of command for the Divisions.
  o The chain of command for the Institutional Biosafety Committee (IBC), as well as other safety-related oversight committees, is not strategic relative to authorities and responsibilities

- IBC Scope:
  o The IBC is not administratively supported; with one individual as administrator
  o IBC oversight is limited to recombinant DNA experiments, as required by NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

- Risk Assessment:
  o Risk assessments are not conducted systematically, and there are no formal processes

- Safety Protocol Review:
  o There is a lack of standardized safety protocols

- Training:
  o Much training is conducted online.
  o Lab-specific training is conducted at the program level, but the quality is inconsistent.

- Competence:
  o Observational competence occurs at the local lab, but training is not consistent.

- Resources:
  o There is a lack of adequate resources
  o Safety professionals are not seen as experts
  o The safety office is not seen as a valued resource

- Communication:
  o Communication channels to the safety office are poor
  o There is a lack of connectivity between Centers
  o Communication has increased through the formation of committees and teams
Clarifications / Suggestions

ELSW Members

- ELSW observations should not focus only on the negative
- It is not clear whether the occupational health component has adequate facilities.
- There is concern that the safety issue is simply the “flavor of the month”
- Concerns that the environment is less conducive for reporting, due to the fear of consequences
- Training needs improvement

Wrap up and Adjournment

Dr. Joseph Kanabrocki, Co-Chair, ELSW