



External Laboratory Safety Workgroup (ELSW)
Meeting Summary
Monday, September 22nd, 2014

Attendees

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

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



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- September 2014: Preliminary communication with FDA and NIH
- October 2014: ACD update with findings, but not a report
- November 2014: Formal recommendations to CDC
- 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:**
 - The mission of the CDC has been expanded over recent years.
- **Priorities:**
 - There has been increasing concern in National Security as it relates to infectious agents.
 - Biosecurity (particularly within the U.S.) is being emphasized over biosafety
- **Organization:**
 - The CDC organization is complex and difficult to understand.
 - Some programs have undergone reorganizations, while others have not
 - Reorganizations have led to confusion
- **Leadership and Buy-In:**
 - Leadership commitment regarding safety is variable and needed at multiple levels.
 - Safety, including lab safety, is viewed by many as separate from the primary missions of public health and research.
- **Governance Structures:**
 - The Environment, Safety, and Health Compliance Office (ESHCO) is outside the chain of command for the Divisions.
 - 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:**
 - The IBC is not administratively supported; with one individual as administrator
 - IBC oversight is limited to recombinant DNA experiments, as required by NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.
- **Risk Assessment:**
 - Risk assessments are not conducted systematically, and there are no formal processes
- **Safety Protocol Review:**
 - There is a lack of standardized safety protocols
- **Training:**
 - Much training is conducted online.
 - Lab-specific training is conducted at the program level, but the quality is inconsistent.
- **Competence:**
 - Observational competence occurs at the local lab, but training is not consistent.
- **Resources:**
 - There is a lack of adequate resources
 - Safety professionals are not seen as experts
 - The safety office is not seen as a valued resource
- **Communication:**
 - Communication channels to the safety office are poor
 - There is a lack of connectivity between Centers
 - Communication has increased through the formation of committees and teams



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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