

**External Laboratory Safety Workgroup (ELSW)  
Meeting Summary  
Monday, March 9, 2015  
8:00 A.M. – 10:00 A.M.**

**Attendees**

- |  |   |
|--|---|
| ✓ Joseph Kanabrocki, PhD, CBSP – <i>Co-Chair</i>           | ✓ Leslie Dauphin, PhD, <i>Acting Associate<br/>Director for Laboratory Sciences and Safety<br/>(ADLSS), CDC</i> |
| ✓ Kenneth Berns, MD, PhD – <i>Co-Chair</i>                 | ✓ Michael Shaw, PhD, CDC  |
| ✓ Debra L. Hunt, DrPH, CBSP                                | Michael A. Pentella, PhD, D(ABMM)   |
| ✓ Thomas V. Inglesby, MD                                   | David A. Relman, MD   |
| ✓ Patty Olinger, RBP                                       | Fred Sparling, MD   |
| ✓ Heather J. Sheeley, BA, MS, CBiol, MSB,<br>CMIOSH, FISTR | Domenica (Dee) Zimmerman  |
| ✓ Jill Taylor, PhD   |   |
| ✓ Sarah Wiley, MPH, <i>Designated Federal<br/>Officer</i>  |   |
- ✓ *In attendance*

**Summary of Meeting Notes**

**Roll Call and Call to Order**

*Sarah Wiley, Designated Federal Officer (DFO), ELSW*

**Follow-up from the National Institutes of Health (NIH) Site Visit**

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

**Draft Report of NIH Site Visit**

- Scope of ELSW's efforts in the NIH Review Report
  - Site visit focused on NIH's intramural program, which constitutes only 10% of NIH's budget. The charge did not indicate ELSW to review NIH's extramural program, therefore the Recombinant Advisory Committee (RAC), National Science Advisory Board for Biosecurity (NSABB), or Office of Biotechnology Activities (OBA) were not assessed during the site visit.
- Lack of clarity on what is being reviewed by NIH's Institutional Biosafety Committee (IBC) with regards to all non-recombinant pathogen work.
- Risk Assessment
  - Significant reliance on one or two individuals; lack of accountability on researchers.
  - Risk assessment review process should include a provision for consideration of alternative approaches.
  - Acknowledge that DURC is relatively new and everyone is still getting adjusted to it.
- NIH Staff Survey
  - The survey conducted by NIH included data captured from individuals who do not work in laboratories, which made the data less reliable.
  - Encourage NIH to utilize a tool similar to CDC's survey as a more robust method to obtain granular data regarding biosafety and the NIH safety culture.
- Place emphasis on the importance of the Division of Occupational Health and Safety Office (DOHS) being recognized and respected as the central authority.
- Funding
  - Funding has remained consistent, however there are some areas where funding is inadequate and may need additional support.
- Timeline for the NIH Review Report

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- The goal will be to complete the written NIH report by March 23, 2015.

**Plans for the Food and Drug Administration (FDA) Visit**

*ELSW Members and Sarah Wiley, DFO*

- Kristine Leiphart, FDA's Deputy Chief Operating Officer, Jeff Degrasse, and Matt Amann are the three individuals suggested by Dr. Ostroff to be the POC's for ELSW from FDA moving forward.
  - All three individuals have been invited to join the ELSW teleconference call on March 24.
  - FDA will provide materials to ELSW ahead of time; these materials will be similar to those provided by CDC and NIH.
  - Site visit has been confirmed for May 11-13, 2015.

**Administrative Matters**

*Sarah Wiley, DFO*

- The ELSW observations / proposals made to and approved by the ACD went forward to the HHS on February 13, 2015. CDC plans to post the document on the agency's internet site on March 16, 2015. The report was shared internally with CDC's laboratory leadership so that efforts toward addressing the ACD recommendations could begin.
- Executive summaries from ELSW teleconference calls were provided to the members for review and will be forwarded to the ACD members for review prior to their next meeting in April 2015. As with the previous summaries, the ACD will vote to adopt the summaries.
- Laboratory Leadership Service fellowship efforts are moving forward, as are trainings.
- The next ELSW teleconference will be March 24, 2015, at 8:00 am EST.

**Discussion Points**

- No formal feedback has been sent to CDC from HHS Secretary with regards to the ELSW recommendations
- Recruitment process for ADLSS
  - Interviews are underway and are anticipated to be completed by the end of the week.
  - Candidates include internal and external individuals.
  - Decisions with regards to certain initiatives and activities will not be made until the new ADLSS is hired.
- The ELSW is welcome to visit the CDC for a second time to meet the ADLSS and see the progress that has been made within CDC.
  - Formal reports of CDC's progress will be provided to ACD in addition to regular verbal updates to ELSW.
- Booz Allen Contract within a Center
  - Members expressed concern over information they had heard from external sources about CDC's splintered approach to addressing biosafety. Ms. Wiley heard the concerns from the ELSW. Further discussions around agency-wide approach to biosafety staffing are planned during the week with the leadership of all of CDC's centers with laboratories; the Environment, Safety, and Health Compliance Office (ESCHO); and Joe Henderson and Rima Khabbaz.

**Wrap up and Adjournment**

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