

**External Laboratory Safety Workgroup (ELSW)
Meeting Summary
Tuesday, March 24, 2015
8:00 A.M. – 10:00 A.M.**

Attendance	
Joseph Kanabrocki, PhD, CBSP – <i>Co-Chair</i>	√
Kenneth Berns, MD, PhD – <i>Co-Chair</i>	√
Debra L. Hunt, DrPH, CBSP	√
Thomas V. Inglesby, MD	√
Patricia Olinger, RBP	√
Michael Pentella, PhD, D(ABMM)	√
David Relman, MD, PhD	√
Heather J. Sheeley, BA, MS, CBiol, MSB, CMIOSH, FISTR	√
Fred Sparling, MD	√
Jill Taylor, PhD	√
Domenica (Dee) Zimmerman	√
Sarah Wiley, MPH, <i>Designated Federal Officer, CDC</i>	√
Leslie Dauphin, PhD, <i>Interim Lead for Laboratory Safety, CDC</i>	√
Matthew Amann, <i>Safety and Occupational Health Manager, FDA</i>	√
Jeffrey DeGrasse, PhD, <i>Regulatory Counsel, FDA</i>	√
Kristine Leiphart, <i>Deputy Chief Operating Officer, FDA</i>	√
√ In attendance	

Meeting Summary

Roll Call and Call to Order

Sarah Wiley, Designated Federal Officer (DFO), ELSW

Food and Drug Administration (FDA) Site Visit

Dr. Joseph Kanabrocki, ELSW Co-Chair, FDA Participants, and ELSW Members

Discussion of the upcoming FDA site visit scheduled for May 11-13, 2015.

- Planning
 - *Day 1:* ELSW will visit the main campus and meet with key staff, FDA leadership, and those who are responsible for laboratories. Site visits to the vivarium and laboratories (CBER), and engagement in discussion.
 - *Day 2:* ELSW will attend a discussion with the Acting Commissioner of Food and Drugs, and attend presentations of security and safety programs. Site visit to one of FDA’s external campuses (CFSAN).
 - *Day 3:* ELSW will meet with FDA leadership and provide an exit briefing.
- FDA Preliminary Documentation – the following documents were sent to ELSW:
 - Organizational charts
 - Some procedures for biological agents and toxins
 - Information regarding the laboratory information management system, the development of which is underway
 - Information on the safety training programs that are being created based on a series of 13 focus groups that have been convened
 - Engagement Session Reports: Best Practices
 - Some of the centers’ biosafety manuals
 - Descriptions of programs

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Discussion Points

ELSW Members and FDA Representatives

- Laboratory Safety Culture Survey
 - The FDA conducts an annual HHS survey on employee viewpoints that includes questions on safety, Occupational Safety and Health Administration (OSHA) requirements, and people's perception on the performance of FDA's safety program.
 - This information is collected via meetings with Safety Officers from each of the centers, rather than a survey tool.
 - ELSW will receive a finalized report at the end of March or in early April.
- Engagement Sessions of Laboratory Personnel (n=12 for Personnel and 1 for Lab Directors)
 - Though a formal survey was not conducted of all laboratory personnel, a report from engagement sessions will be prepared and should be a representative view of the FDA's laboratory operations.
- The Employee Safety and Environmental Management group
 - Regular meetings are held with Safety Officers to promote centralization and standardization of policies and procedures.
 - FDA has a plan to hire a higher level Director of Laboratory Safety and Security.
- Training
 - FDA established FDA University about a year ago; much of the training available for Safety Officers is delivered online.
 - The training program for laboratory safety is not mature enough this year to produce a statistically significant correlation for competency compliance. Going forward, as additional training programs are instituted, they will build competency into the training that is offered so that there is a loop-back mechanism to determine whether people are actually implementing what they have learned in training.
 - Laboratory personnel have been requested to include a criterion in their Performance Management Appraisal Programs (PMAPs) about implementing requirements to ensure that they understand and follow safety protocols and procedures in their laboratories.
- Audits and Inspection Programs
 - Audit checklists must be completed by all centers; certification is produced once audits are complete.
 - Safety programs are not campus-based or facility-based. They are aligned with the organizational structure of FDA.

Follow-up on Laboratory Safety Recommendations for CDC

ELSW Members and Leslie Dauphin, Interim Lead for Laboratory Safety (CDC)

Dr. Leslie Dauphin provided an update on CDC's progress towards the ACD recommendations in several function areas.

- Recruitment for permanent ADLSS
 - Internal and external candidates are being considered, and interviews with top candidates are underway.
- Risk Assessment Course
 - CDC piloted a new biological risk assessment course on February 24, 2015. This was an instructor-led course that included scenarios to walk participants through a new risk assessment tool.

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- This was conducted in a collaborative effort between the Interim Safety office and the Environment, Safety, and Health Compliance Office (ESHCO).
- The initial priority audience were select agency Principal Investigators (PIs) and members of their laboratories.
- Average pre-test score: 43%, Average post-test score: 94%
- A modified course will be taught on April 15, 2015.
- To assess competency, all of the participants have been asked to use the tool in their laboratories to conduct risk assessments with consultation from the ESCHO office. At 6 weeks and 3 months, an evaluation will be performed to determine effectiveness.
- Training
 - Since the last update, the training workgroup has completed a draft report for their formal review of the current on-line and instructor-led training, with some recommendations. The group also developed a prioritized list of courses that will be included as part of the core laboratory safety training for all staff, and have identified subject matter experts (SMEs) to provide the content for these courses.
 - The training will be developed by the Laboratory Training Branch (LTB) in the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), with review and a significant portion of the work by ESHCO.
 - An external review will be sought of the process as well, particularly with regard to identification of the competencies and learning objectives, mapping the competencies to the courses, prioritizing the courses, course contents, and application of Adult Learning Theory in the evaluation process for this entire initiative.
 - The established Laboratory Leadership Services Fellowship aligns with ELSW's suggestions regarding a laboratory fellowship. This will be a two-year post-Doctoral service learning program. The goal is to combine core public health laboratory competency-based training with practical and applied investigations and service.
- Accreditation
 - Five laboratories have been identified to participate in the pilot slated to begin in 2015. The goal of the pilot is to inform CDC about how to move forward with implementation of laboratory accreditation across the agency.
 - Initial benchmarking of internal and external laboratories that attained International Standards Organization (ISO) accreditation has been accomplished. This includes some laboratories within CDC's National Center for Environmental Health (NCEH) and National Institute of Occupational Health and Safety (NIOSH).
- Culture of Laboratory Safety
 - CDC established the Laboratory Safety Champion recognition to promote best laboratory safety practices. The first champion was selected and was featured in a *CDC Connects* article.

Discussion Points

- Review of risk assessments
 - The risk assessment tool is completed by the laboratory, and it includes a review section that is completed in consultation with a biosafety professional from the Interim Safety Office. It is not submitted to the IBC.

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- Trainers of the risk assessment course are members of ESHCO and are Certified Biosafety Professionals.
- CDC's National Center for Immunization and Respiratory Disease (NCIRD) Contract Work
 - NCIRD contracted services from Booz | Allen | Hamilton as part of their quality initiative. Dr. Dauphin's understanding is that the center requested that if additional consultants are brought on to assist with their quality initiatives, these consultants be biosafety experts. Dr. Dauphin emphasized that this is not permanent staffing for the agency, nor is it intended in any way to serve in the place of CDC's staffing of employees as biosafety professionals for the agency.
 - A panel has been formed with representatives from each of CDC's infectious diseases centers, which includes NCIRD. Points of contact will work directly with ESHCO to assure that all of CDC's laboratory safety initiatives and activities occur in a coordinated manner.
- External Accreditation Pilot Program
 - CDC is looking to A2LA to conduct some of the initial ISO standards training for the agency.
- Interim OADLSS and its relationship to ESHCO
 - The goal of this office is to continue to move forward with suggestions from the internal group and the ELSW until the permanent ADLSS position is filled. The Interim Safety Office and ESHCO work collaboratively on each of the efforts being implemented.
- LLS Fellowship
 - There are seven fellows for 2015, and there are plans for this program to expand in future years.
- ELSW Recommendations to CDC
 - Documents have been developed and published on CDC's website to summarize recommendations and provide brief updates on the ones that have been implemented and completed, as well as those that are still in progress.
 - Informal updates will be provided to the ELSW during teleconferences. A more formal report will be provided to the group in mid-April.
 - Dr. Kanabrocki expressed appreciation for and stressed the importance of keeping the ELSW updated on the progress being made.

Follow-up on National Institutes of Health (NIH) Site Visit

Dr. Kanabrocki, provided a draft report of the ELSW's observations and proposals developed as a result of the in-person NIH Site Visit. Members provided comments, input, and suggested changes and edits to the document.

Administrative Matters and Adjournment

Sarah Wiley and Dr. Joseph Kanabrocki

The next ELSW teleconference will be held on April 6, 2015 at 8:00 am (EST).