

**External Laboratory Safety Workgroup (ELSW)
Meeting Summary
Monday, May 19, 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 (DFO)</i>	✓
Leslie Dauphin, PhD, <i>Interim Lead for Laboratory Safety, CDC</i>	✓
Steve Monroe, PhD, <i>Acting Associate Director for Laboratory Science and Safety, CDC</i>	✓
Catherine Ramadei, <i>Management Program Analyst, CDC</i>	✓
✓ In attendance	

Meeting Summary

Roll Call and Call to Order

Sarah Wiley, Designated Federal Officer (DFO) and ELSW Members

Disclosure and Conflict of Interest Requirements

Catherine Ramadei, Management Program Analyst, Management Analysis and Services Office (MASO), CDC and ELSW Members

Ms. Ramadei conducted a brief presentation on ethics, disclosure, and Confidentiality of Interest (COI) to provide rationale for requiring the completion of COI forms each meeting.

Update on CDC Laboratory Safety

ELSW Members, Dr. Steve Monroe, Acting Associate Director for Laboratory Science and Safety (ADLSS), and Dr. Leslie Dauphin, Interim Lead for Laboratory Safety

During this session, ELSW members were introduced to Dr. Monroe, who provided an update on his new role as Acting ADLSS. While plans to fill the permanent position are underway, Dr. Monroe will ensure that laboratory safety efforts continue to move forward, help structure the office, and outline the office’s responsibilities. Dr. Dauphin, who will continue working with Dr. Monroe, provided an update on laboratory safety following Dr. Monroe’s introduction.

- Laboratory Safety Review Board (LSRB)
 - New procedures have been introduced to ensure that new laboratory safety protocols and procedures, as well as risk assessments, are being utilized by laboratory staff. Additionally, a Material Transfer Certificate (MTC) was established to document the transfer of materials to lower levels of containment, including information about the process for inactivation, verification, and sign-off by the Laboratory Director, Branch Chief, or designee. The LSRB has also implemented a process for quarterly reporting from all groups, and will maintain records for the transfer of materials. An annual protocol review process has been implemented, including an annual refresher training for laboratory staff.
- Training and Education

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- A draft implementation plan has been completed for the core safety training for CDC staff. All staff who work in laboratories will be required to take the core safety training, which is comprised of 19 courses. The implementation plan includes the roll-out dates and timeline, with the goal of having new core safety training available to CDC staff by May 2016.
- CDC has offered the Biological Risk Assessment Course monthly since April 2015. To meet demand, it will be offered twice in May and in Ft. Collins in June. The ELSW requested to see samples of the course during the last meeting. Since then Dr. Dauphin followed up with the course facilitator and the Laboratory Training Branch, who agreed to share materials with the ELSW upon finalization of feedback from course evaluations.
- External Accreditation
 - International Organization for Standardization (ISO) training is currently underway for Quality Managers, Laboratory Team Leads, and Branch Chiefs for each of the pilot laboratories, as well as CDC's internal laboratory quality program.
 - Upon completion of the ISO training, pilot participants will conduct benchmarking visits to federal, state, and public health laboratories.
- Laboratory Leadership Service (LLS) Fellowship
 - Class of 2015 will begin in July. Fellows will participate in applied work in laboratories and practical activities. There will be engagement with CDC's Environment, Safety, and Health Compliance Office (ESHCO). Several fellows are also participating in the ISO standards training. Interviews for the supervisor of the fellows are currently underway and should be finalized soon.

Discussion Points

- ELSW members inquired about LLS fellows. Dr. Dauphin provided additional information on the initial class that is comprised of post-Doctorate level staff who have degrees in the life sciences or related public health fields. The application criteria is that individuals must have post-graduate laboratory experience, and must have interest in applied research in public health, biosafety, and quality. LLS fellowship graduates will be prepared to pursue public health laboratory careers at CDC and elsewhere.
- Dr. Taylor asked about the agency's public relations plans. Progress updates are being made on how the agency is addressing various recommendations. A fact sheet was recently posted that includes a very high level list of some of the efforts that have been made toward improvements. Ms. Wiley will provide the link to ELSW. Members emphasized the value on having the ability to track progress on the CDC website.
- Ms. Wiley indicated that the LSIW, the internal CDC workgroup established in the summer of 2014, concluded after completing tasks charged to them in October 2014. Many of the people who served on the original LSIW have continued on the Implementation Team, and the full LSIW has reconvened a few times to complete some specific tasks related to its original charge.

Follow-up Discussion of Food and Drug Administration (FDA) Site Visit

ELSW Members and Dr. Kanabrocki, Co-Chair

Dr. Kanabrocki is in the process of incorporating additional comments from members into the ELSW's report to the Advisory Committee to the Director (ACD) on its observations concerning FDA.

- Dr. Berns reported that FDA reception was very positive.

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- Another visit to either NIH or FDA may not be necessary; a teleconference might be considered in the future. NIH has already provided initial feedback to the ELSW, but something more formal could be arranged to make it part of the record.

Administrative Matters and Adjournment

Sarah Wiley

- The ACD accepted the ELSW report on NIH. It will be submitted to the Department of Health and Human Services (HHS). CDC will include the report as part of the minutes from the April 2015 ACD meeting, but does not plan any additional public release.
- The next ELSW teleconference will be held on June 8, 2015, at 8:00 am (EST). Kathleen Ethier from CDC's Program Planning and Evaluation Office (PPEO) will provide an update on plans to administer the second rendition of the CDC Culture of Safety Survey.
- The ELSW will plan to schedule a visit to CDC during the week of October 5, 2015.