

**External Laboratory Safety Workgroup (ELSW)
Meeting Summary
Monday, April 6, 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</i> , CDC	√
Leslie Dauphin, PhD, <i>Interim Lead for Laboratory Safety</i> , CDC	√
√ In attendance	

Meeting Summary

Roll Call and Call to Order

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

Follow Up on Laboratory Safety Recommendations for CDC

Dr. Leslie Dauphin, Interim Lead for Laboratory Safety and ELSW Members

Dr. Leslie Dauphin provided an update on the agency's progress toward the ACD recommendations as well as an update on progress in additional areas in which the agency has been engaged regarding laboratory safety.

○ **Leadership**

- CDC's Director is completing interviews with the finalists for the Associate Director for Laboratory Science and Safety (ADLSS) position. Some of the changes within the organizational structure that are aligned with the ACD recommendations will be addressed once the permanent ADLSS is hired.

○ **Risk Assessment**

- The next risk assessment course will be offered on April 15, 2015.
- Given the demand for this course, it will be offered each month; facilitators and instructors are attempting to offer the course twice a month beginning in May.

○ **Laboratory Leadership Service (LLS)**

- This fellowship program was established in alignment with ELSW's suggestion to establish a fellowship for laboratory training and to help develop the agency's workforce.
- Seven fellows have been successfully matched to seven laboratories for the Class of 2015.
- The LLS will align closely to the EIS Fellowship; one of their activities is to participate in the 64th annual Epidemic Intelligence Service (EIS) Conference on April 20-23, 2015.
- The LLS curriculum is currently under development by subject matter experts from ESHCO.

○ **Staff Entrance/Exit Checklist**

- CDC has established a new entrance and exit procedure for laboratory staff so there are clear entrance and succession plans in place.

○ **Specimen Management**

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- In March 2015, the agency rolled out a new electronic specimen inventory module as part of the Laboratory Information Management System (LIMS). This now allows CDC's infectious diseases laboratories to manage their specimens electronically through LIMS.
- **Specimen Inventory**
 - In March 2015, CDC completed a self-initiated biological specimen inventory, which exceeded the requirement of the Office of Science and Technology Policy (OSTP)-mandated "Clean Sweep."
 - The Clean Sweep was a physical check for the location and storage of specimens. CDC chose to take this a step further to conduct either a box-by-box or vial-by-vial inventory of the agency's specimens in all of its laboratories.
- **Secondary Verification Methods**
 - Camera Systems in BSL-3 and BSL-4 Laboratories
 - To date, 72 cameras have been installed in BSL-3 and BSL-4 laboratories as part of the approval and sign-off process to ensure that critical steps are performed correctly.
 - A survey is currently being conducted with end-users to solicit feedback on the effectiveness of the cameras.
 - Checklists
 - CDC established that for every procedure that involves inactivation of pathogens and transfer of materials out of its BSL-3 and BSL-4 laboratories to a lower level of containment, completion of a checklist is required.
 - Each procedure has a checklist of all of the critical steps in the procedure; the checklist must be completed, transferred out, and reviewed by a second person. When video footage from the camera system is being reviewed, critical steps in the checklist are also being reviewed.
- **Tablet Implementation**
 - The agency is exploring the use of electronic tablets for the storing and use of the checklists for inactivation of pathogens.
 - ESHCO completed the disinfection testing of the tablets.
 - CDC installed Wi-Fi in all of its buildings on campuses that have laboratories, which is connected through the agency's secure intranet.
 - Proof of concept testing is currently being completed for the use of tablets in BSL-3 and BSL-4 laboratories with Wi-Fi; if proof of concept is successful, the next step will be to conduct a pilot to test the tablets in five CDC high containment laboratories.

Discussion Points

ELSW Members, Dr. Leslie Dauphin, and Sarah Wiley

During this session ELSW members asked Dr. Dauphin follow up questions to the update she provided.

- Separate from risk assessment training, is there a process change underway at CDC that will require that risk assessments be conducted?
 - CDC plans to develop a new policy pertaining to how this should be applied to experimental work. The process will involve training agency staff, with a priority focus on select agent laboratories and directors. Upon the finalization of the training process, the plan is to develop requirements for use of the risk assessment tool. The courses are filling

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- rapidly, and assessment must be done to ensure that the priority target group is registered first.
- How often is the CDC IT system hacked? This is a concern in the use of camera systems and checklists.
 - The proof of concept testing addresses security concerns with regard to select agents. The proof of concept testing team is working with the agency's Select Agent Compliance Team to ensure that all procedures and processes related to transmission of and access to specimen information is compliant.
 - While the implementation of cameras and checklists is a step forward in creating an efficient work environment, there must be careful balance between supporting laboratory staff and ensuring that they maintain responsibility and culture. If the person in the laboratory is not invested, there will be issues regardless of technologies.
 - Disinfection testing for tablet implementation
 - The reason disinfection testing is being done is because at least once per year, CDC's BSL-3 and BSL-4 laboratories go through a shutdown and decontamination procedure. This is primarily to autoclave items outside of the laboratory or to perform instrument and equipment maintenance, repairs, and updates. The tablets could be covered as part of the decontamination procedure, but it was important to ensure that if there is a need, they can put them through that process and they will still be useable.
 - CDC Lab Safety Update Presentation at ACD Meeting, April 23
 - Dr. Dauphin will make an update on the agency's progress during this meeting.
 - Media requests and public image
 - ELSW members have received questions from the press about their recommendations and about the ELSW process.
 - The timeline of the ELSW's activities and reporting should have been better explained. CDC will handle future releases differently.

Food and Drug Administration (FDA) Site Visit

ELSW Members and Sarah Wiley

The FDA is in the process of revising the agenda for the site visit in May 2015, which they plan to share with CDC prior to the next ELSW teleconference. FDA will also provide a few additional documents to the members prior to the next teleconference and representatives will join the call.

Administrative Matters and Adjournment

Sarah Wiley and Dr. Joseph Kanabrocki

- The next ELSW teleconference will be held on April 21, 2015 at 8:00 am (EST).
- The next ACD meeting is April 23, 2015.