

# **Biosafety in CDC Laboratories: The Path Forward**

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# 2014 Lapses in Biosafety at CDC

- Following laboratory safety incidents at CDC involving select agents, CDC conducted comprehensive internal reviews of each incident.
- During each review, an assessment of the event, contributing factors, and risk mitigation practices was completed.
- Each review resulted in a report of findings and recommendations.

# Full Reports of Each Incident Available on CDC Website

- Posted at <http://www.cdc.gov/about/lab-safety/>
  - June, 2014: Lab Incident Anthrax Report [744KB, posted 7/11/14]
  - July, 2014: Report on Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1 [608KB, posted 8/15/14]
  - December, 2014: Report on the Potential Exposure to Ebola Virus [566KB, posted 2/4/15]

# Lab Safety Improvements Overview

- Laboratory Safety Improvement Workgroup (LSIW)
  - Charge, Accomplishments and Products
- Current Laboratory Safety Initiatives
  - External Laboratory Safety Workgroup
    - Recommendations to the Advisory Committee to the Director (ACD)
    - CDC's progress towards the ACD's recommendations
  - Sharing of Best Practices

# LSIW Charge

- Charge Announced to CDC Staff 7/31/2014:
  - Review requests to resume transfers of biological materials (BSL-3/4 laboratories)
  - Oversee an Agency-wide inventory of biological materials
  - Engage CDC laboratory staff, stakeholders and an external group of subject matter experts to inform recommendations for laboratory safety improvements
  - Review career paths to determine how best to strengthen our culture of safety at CDC
  - **Provide recommendations to CDC Director**

# LSIW Accomplishments

- **Moratorium Resolution:**
  - 52/53 laboratory teams have resumed operations
- **External Laboratory Safety Working Group (ELSW)**
- **Biological Materials Inventory**
- **Review Data and Reports for Laboratory Incidents**
- **Communications:**
  - Staff Engagement Sessions
  - Laboratory Consultations (Piloted in 2 Laboratories)
  - Meetings with CDC Lab-related Boards and Committees
  - Laboratory Staff Survey
- **Policy:**
  - Revised Procedure for Notification of Management for Laboratory Exposures

# LSIW Accomplishments

## Enhanced Inventory Management:

- U.S. Government Safety Stand-Down:
  - Fact Sheet on Biosafety and Biosecurity in the United States: Results of the Safety Stand-Down  
<http://www.cdc.gov/about/lab-safety/factsheet.html>
  - Clean Sweep Completed on 9/30/2014
  - Initiated Biological Materials Inventory
    - >7.2 M samples in long-term storage inventoried
- Recommended enhanced Out-Processing procedures

# LSIW Products

## Communications:

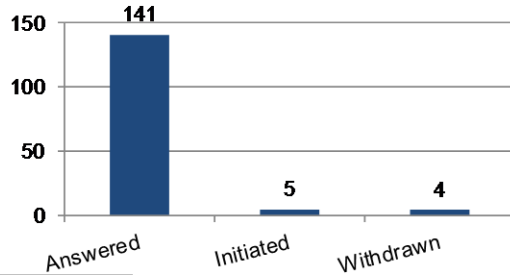
- CDC Laboratory Safety Intranet Website:
  - Lab Safety-Related Reports and Findings
  - Staff Announcements
- CDC Laboratory ListServ (>1500 members)
- Lab Safety Mailbox (Monitored Daily)
- Staff Engagement Sessions
- Laboratory Safety Survey
- *CDC Connects* (lab safety articles)



# Lab Safety Mailbox

Count of Tracking ID

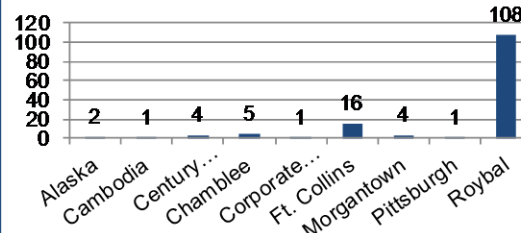
**Lab Mailbox Update by Disposition\***  
January 26, 2015 at 9:00 AM  
\*as of July 16, 2014



Disposition ▾

Count of Tracking ID

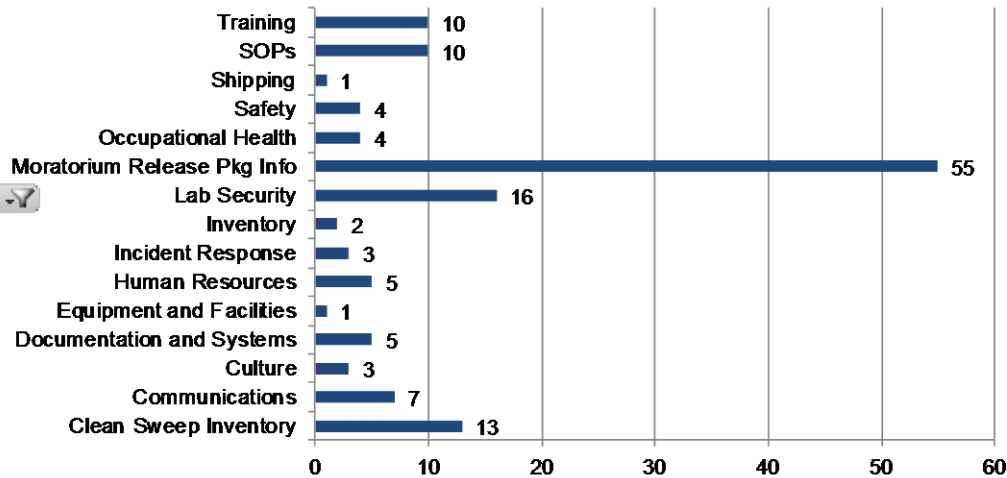
**Lab Mailbox Update by Campus\***  
January 26, 2015 at 9:00 AM  
\*as of July 16, 2014



Campus ▾

Count of Tracking ID

**Lab Mailbox Update by Category\***  
January 26, 2015 at 9:00 AM  
\*as of July 16, 2014



Category ▾

# Recommendations to CDC Director

## Report Completed (10/29/14):

- Associate Director for Laboratory Science and Safety (ADLSS)
- Recommendations for 7 Functional Areas:
  1. Leadership, Staffing, and Organizational Structure
  2. Training and Education
  3. Policy, Authority, and Enforcement
  4. Process and Standard Operating Procedures
  5. Facilities, Systems, and Software
  6. Communications
  7. Staff Feedback

# External Laboratory Safety Workgroup

- Recommendations presented to the ACD on 1/13/15
  - Aligned with LSIW recommendations
- CDC updated the ACD on its progress towards the recommendations on 4/23/15
- CDC will continue to engage ELSW and provide updates on progress towards implementing recommendations

# Leadership

- **Recommendation:**
  - Create a position for a biomedical scientist in the Director's office to lead this (*laboratory safety programs*) effort.
- **Progress:**
  - Established an Associate Director for Laboratory Science and Safety (ADLSS), who will report to the CDC Director and provide agency-wide leadership and accountability for laboratory science, safety, and quality
  - The CDC Director is currently interviewing candidates

# Leadership

- **Recommendation:**
  - Funding for laboratory safety programs and laboratory safety training should be established from a central funding source and should be considered a fundamental mission for the CDC.
- **Progress:**
  - Identified funding in FY 2015 for development of a new general safety and laboratory safety training curriculum
  - The FY 2016 budget requests an increase of \$20 million to help advance CDC's laboratory safety and capacity

# Governance

- **Recommendation:**
  - Establish governance structures that provide accountability and oversight authority to a central entity for laboratory safety and compliance committees with ultimate authority in the Office of the Director.
- **Progress:**
  - In March 2015, CDC established a Laboratory Safety Review Board to conduct safety reviews of laboratory protocols for work in BSL-3 and BSL-4 laboratories
    - ✓ Oversight and support will be in the Office of the ADLSS
    - ✓ Members are from all centers with laboratory programs to ensure accountability and consistency of practices across the agency

# Risk Assessments

- **Recommendation:**

- Risk assessments should be performed for experimental work being done at CDC. The benefits and risks of proposed experimental work should be documented before the work is undertaken.

- **Progress:**

- Piloted a new Risk Assessment Course on 2/24/15 to teach staff how to conduct and document risk assessments:
  - ✓ Course evaluation completed on 3/9/15; revised course (based on evaluation data) taught on 4/15/15
- Post-training evaluations are scheduled to assess competency and implementation
- Development of new policy to require the use of risk assessments for experimental work is underway

# Laboratory Safety Training

- **Recommendation:**

- Establish a standardized lab safety training curriculum across CDC with standardized methods for competency skills mapping and refresher training.

- **Progress:**

- Establishing a standardized, competency-based, core safety training curriculum across CDC
  - ✓ Identified and documented competencies for core safety training (1/28/15)
  - ✓ Evaluated 23 CDC safety training courses to map competencies and identify gaps (3/6/15)
  - ✓ Developed a prioritized list of courses for a standardized safety training curriculum (3/20/15)
  - ✓ Developed learning objectives for priority courses (4/12/15)



# Laboratory Safety Training

- **Recommendation:**

- Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals who serve as liaisons between the labs and ESHCO or other central lab safety entity.

- **Progress:**

- Established the Laboratory Leadership Service (LLS), a new laboratory fellowship at CDC, to begin in July 2015
  - ✓ LLS will be a 2-year postdoctoral fellowship program combining core public health laboratory competency-based coursework with practical, applied research and service
  - ✓ 7 fellows matched with 7 host laboratories for the 2015 class
  - ✓ The fellows participated in the 64<sup>th</sup> EIS Conference
  - ✓ Development of competency-based curriculum is in progress

# Culture of Safety/Incident Reporting

- **Recommendation:**

- Reporting is important for facilitating the analysis of incidents and the establishment of corrective actions to mitigate repeat occurrences. Lessons learned should be shared with the community.

- **Progress:**

- Established methods to share lessons learned and promote transparency with the community, including
  - ✓ Posting of reports and updates for laboratory-related incidents on CDC websites (internal and external);
  - ✓ Proactive communications with the CDC laboratory community via the Laboratory ListServ
  - ✓ Meetings and updates with external partners (e.g., APHL)

# Culture of Safety/Incident Reporting

- **Recommendation:**

- In this culture of safety response, ensure that scientists operating safe laboratories are recognized.

- **Progress:**

- Implemented a new program, *Laboratory Safety Champion*, to recognize staff (through a *CDC Connects* story) who promote laboratory safety and best practices. The first *Champion* was featured on 3/12/15, and the second was featured on 4/20/15.
- Utilizing the Laboratory ListServ of more than 1600 staff to acknowledge and commend staff who demonstrated responsible and safe actions in the laboratory.

# Biosafety and Occupational Medicine

- **Recommendation:**
  - Develop a division liaison program, where each division identifies individuals who can represent their needs to a centralized ESHCO committee.
- **Progress:**
  - Identified a representative from each of the infectious disease centers to represent program needs related to safety consultations and risk assessments to ESHCO

# Progress Reporting and Laboratory Accreditation

- **Recommendation:**

- CDC laboratories should go through an external review and accreditation process for all labs.

- **Progress:**

- Pilot project to begin in 2015 to attain external accreditation to International Organization for Standardization (ISO) 17025 standards.
  - ✓ Conducted stakeholder engagement sessions to solicit input and recommendations (report completed 2/26/15)
  - ✓ Conducted benchmarking interviews with ISO-accredited government laboratories (report completed 3/31/15)
  - ✓ Implementation Plan is under review
  - ✓ ISO standards training for CDC pilot beginning May 2015

# Sharing Best Practices

## 1) Laboratory Safety Review Board:

- Review laboratory protocols for safety critical control points

## 2) Laboratory Consultations:

- Peer review laboratory audit program
- Piloted in 2 CDC laboratories

## 3) Laboratory Procedure Library:

- Searchable library of approved protocols for inactivation and transfer of pathogens
- Currently in development

# Summary

- LSIW conducted a series of targeted activities to develop recommendations to the CDC Director, including:
  - ADLSS
  - Recommendations in 7 Functional Areas
- LSIW and ACD recommendations were aligned in several areas
- Current Activities:
  - Engagement of the ELSW
  - Expansion of Biosafety Training
  - External Accreditation Pilot

**THANK YOU FOR THE OPPORTUNITY  
TO PROVIDE UPDATES!**

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Department of Health and Human Services  
Centers for Disease Control and Prevention