

# **CDC Laboratory Safety Progress Update to the Advisory Committee to the Director**

**April 23, 2015**



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

# Additional Laboratory Safety Improvements

- In July 2014, CDC imposed a moratorium on transfers of biological material out of BSL-3 and BSL-4 laboratories until processes were reviewed and improved:
  - Conducted a thorough review of all procedures for inactivation or depletion of pathogens from biological materials, viability testing, containment, contamination control, transport and shipping of biological materials
  - Implemented the use of checklists for procedural steps in protocols for inactivation of pathogens
  - Established requirements for segregation of materials and exclusivity testing to minimize risks for contamination
  - Instituted a requirement for documented training plans with annual refresher training on inactivation and transfer procedures
  - A total of 80 camera systems in BSL-3 and BSL-4 laboratories thus far to verify safety critical control points for inactivation of pathogens; evaluation of the camera systems is underway
- Moratorium resolution for 52 BSL-3 and BSL-4 laboratories completed in October 2014

# Additional Laboratory Safety Improvements

- In September 2014, completed “Clean Sweep,” which included a search of ~1000 rooms at CDC facilities for biological select agents and toxins
- Implemented proactive communications
  - Conducted 13 staff engagement sessions on laboratory safety-related topics
  - Completed a laboratory staff safety survey of >600 respondents
  - Conducted listening and engagement discussions with >40 stakeholders to identify opportunities for safety improvements
  - Piloted a Laboratory Consultation Program in 2 Laboratories; revisions and enhancements to the program are underway
- In January 2015, standardized disinfection practices across CDC’s infectious diseases laboratories by developing new procedures for the use of disinfectants from an approved list
- In February 2015, CDC enhanced its procedures for custodianship of specimens with new entrance and exit procedures for laboratory staff

# Additional Laboratory Safety Improvements

- In March 2015, CDC rolled out a new electronic specimen inventory management system
  - Initial roll out to ~85 infectious disease laboratories at the Atlanta Roybal campus
  - More than 200 laboratory staff have been trained
- In March 2015, CDC completed a self-initiated biological specimens inventory, which exceeded the requirements of the OSTP-mandated Clean Sweep
  - Included box and vial-by-vial inventory of more than 7 million samples in long-term storage for the infectious disease laboratories
- On April 1, 2015, CDC updated the Select Agent Incident Response Plan to include specific decontamination procedures to follow in the event of a release. The plan has been implemented in 13 select agent-registered laboratories at the Atlanta Roybal campus

# **CDC'S PROGRESS TOWARDS RECOMMENDATIONS FROM THE ACD**

# **CDC's Progress towards Recommendations from the ACD**

- Towards the ACD's recommendations concerning laboratory safety, CDC has made progress in the following areas:
  1. Leadership
  2. Governance
  3. Risk Assessments
  4. Laboratory Safety Training
  5. Culture of Safety/Incident Reporting
  6. Biosafety and Occupational Medicine
  7. Progress Reporting and Laboratory Accreditation

# 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

# 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 conducting interviews with candidates

# Governance

- Recommendation:
  - Establish governance structures that provide accountability and oversight authority to a central entity for laboratory safety and compliance committees with ultimate authority at the level of 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 new 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:
  - Broaden the scope of the IBC to include work with pathogenic microorganisms and biological toxins or establish a centralized, standardized mechanism for consistent and thorough review and risk assessment of proposed research activities.
- Progress:
  - The new Laboratory Safety Review Board has established criteria to conduct consistent and thorough reviews of laboratory protocols for safety elements
  - The board convened on 3/5/15 and 4/2/15 and will meet monthly to conduct reviews

# 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:
  - CDC is working to establish 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 that combines core public health laboratory competency-based coursework with practical, applied research and service
    - 7 fellows have successfully matched with 7 host laboratories for the 2015 class
    - The fellows will participate in the 64<sup>th</sup> EIS Conference (4/19 – 4/23/15)
    - Development of competency-based curriculum is in progress

# Laboratory Safety Training

- Recommendation:
  - Responsibilities and facilities for lab safety training should be in-house.
- Progress:
  - Lab safety training curriculum is under development
    - Standardized, competency-based
    - Addresses general safety and biosafety for all laboratory staff
    - Includes online and instructor-led training courses
  - Identified funding in FY 2015 for development of a new laboratory safety training curriculum and products, which are currently being developed within CDC
  - In November 2014, CDC developed a proposal for a new laboratory training center

# Culture of Safety/Incident Reporting

- Recommendation:
  - Efforts to establish a culture of *responsible science* and *accountability* are of critical importance. This culture of responsible science will require prompt and accurate reporting of incidents or breaches in standard protocol without fear of reprimand or punishment.
- Progress:
  - CDC has implemented new and enhanced procedures for prompt reporting of laboratory incidents including
    - The Lab Safety Helpdesk, which allows reporting of safety issues or requests for safety service
    - Updated Laboratory Incident Notification procedures for accurate and timely notification

# 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 from these activities should be shared with the community.
- Progress:
  - Established several 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 for their work.
- 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 *Champion* is scheduled to be 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 (e.g., CDC Lab Safety Update, 4/1/15)

# Biosafety and Occupational Medicine

- Recommendation:
  - Raise the stature of ESHCO in the CDC organization by staffing it with scientists with professional qualifications in research and/or laboratory safety as well as an understanding of requirements for compliance.
- Progress:
  - To raise the stature of biosafety in the CDC organization, in February 2015, CDC developed new standard position descriptions for Laboratory Quality Management and Safety & Occupational Health Specialists to accelerate staffing of scientists with professional qualifications
  - Potential organizational changes will be considered once the permanent ADLSS is on board

# 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

# Biosafety and Occupational Medicine

- Recommendation:
  - Expand the scope and capabilities of the Occupational Medicine Program to facilitate a more robust and active effort in monitoring employee health and in responding to laboratory incidents.
- Progress:
  - CDC's Occupational Health Clinic has already made some improvements regarding monitoring of staff. Through its engagement with hundreds of staff deployed for the Ebola response, the clinic has established new procedures to enhance this capacity, including the addition of a clinic administrator. Additional changes to clinic procedures are underway.

# Progress Reporting and Laboratory Accreditation

- Recommendation:
  - CDC should track and report on its progress in establishing programmatic elements and processes recommended in this report in some formal way.
- Progress:
  - CDC provided verbal updates to the external Laboratory Safety Workgroup (ELSW) during conference calls on 2/24/15, 3/24/15, and 4/6/15
  - On 3/24/15, CDC proposed providing a formal update in April 2015, and ELSW agreed with the proposal
  - CDC's website includes updates on its progress towards recommendations from laboratory-related incidents

# Progress Reporting and Laboratory Accreditation

- Recommendation:
  - CDC laboratories should go through an external review and accreditation process for all labs.
- Progress:
  - CDC is planning a pilot project to begin in 2015 to attain external accreditation to International Organization for Standardization (ISO) standards. The purpose is to apply lessons learned for implementation across the agency.
    - 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 (due date is 4/30/15)
    - ISO standards training for CDC pilot is scheduled for May 2015

# Next Steps

- CDC will continue to work towards addressing and implementing the recommendations from the ACD and recommendations from laboratory incidents
- CDC has invited the ELSW to a second on-site visit at CDC later this year to assess progress

# Acknowledgements

CDC acknowledges the valuable and timely contributions of the ELSW members and the thoughtful recommendations of the ACD.

**QUESTIONS?**



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