

**OADLSS Report of Progress towards Addressing the Recommendations of
The Advisory Committee to the Director (ADC), CDC
October 29, 2015**

Background

In an effort to elevate its laboratory science and safety programs, the Centers for Disease Control and Prevention (CDC) sought internal and external input on strategies to mitigate laboratory safety concerns. The [External Laboratory Safety Workgroup](#) (ELSW) of the Advisory Committee to the Director (ACD), CDC, was formed to provide an external perspective of how CDC could improve laboratory science and safety within the agency. Members of the ELSW are subject matter experts in the fields of biosafety, laboratory science, and research. In 2014, they reviewed CDC's policies and procedures related to laboratory safety and quality, visited CDC laboratories, conducted a laboratory safety culture survey, and engaged CDC staff and leadership. In culmination of these activities, the ELSW reported their findings to the Advisory Committee to the Director (ACD). The ACD provided [recommendations](#) to enhance best practices in laboratory safety and quality within CDC.

CDC concurred with these recommendations and immediately began implementing them. This report addresses progress in implementation of laboratory science and safety initiatives made by CDC to address the ADC's recommendations and those from other internal and external reviews. Through this work, CDC's aim is to improve the culture of laboratory safety across the agency and minimize the risks associated with laboratory work.

Previously Reported Progress

On April 23, 2015, the CDC reported its [progress](#) toward addressing ACD's recommendations and on other laboratory safety improvements being implemented at the agency. Key activities included:

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| July 2014 | CDC imposed a moratorium on transfers of biological material out of BSL-3 and BSL-4 laboratories |
| Sep. 2014 | Completed "Clean Sweep" for biological select agents and toxins |
| Oct. 2014 | Moratorium resolution for 52 BSL-3 and BSL-4 laboratories completed |
| Jan. 2015 | Standardized disinfection practices across CDC's infectious diseases laboratories |
| Feb. 2015 | CDC enhanced its custodianship of specimen procedures with new onboard and offboard instructions |
| March 2015 | CDC rolled out a new electronic specimen inventory management system |
| March 2015 | CDC completed a self-initiated biological specimen inventory |
| April 2015 | CDC updated the Select Agent Incident Response Plan to include specific decontamination procedures to follow in the event of a release; it was implemented in all 13 CDC select agent-registered laboratories working with live agents. |

ACD Recommendations and CDC's Most Recent Progress

Since April, CDC has continued to make progress towards implementing strategies aimed at addressing the ACD's recommendations. Most importantly, a permanent, single point of accountability for laboratory science and safety has been appointed to lead these efforts.

Leadership

Create a biomedical scientist position in the Director's office to lead laboratory science and safety efforts and support the agency's laboratory scientists

Dr. Steve Monroe was named the Associate Director for Laboratory Safety and Science (ADLSS) in September 2015. In this role, he will provide agency-wide leadership and accountability for laboratory science, safety, and quality. A priority for Dr. Monroe is to engage with and advocate for CDC's laboratory scientists. Throughout the month of October, he reached out to laboratory leadership from each laboratory-containing division to receive input on initiatives and improvements to laboratory safety and science. He and his office (OADLSS) will use the information received from these meetings to inform future communications with CDC's laboratory programs and to promote their important public health work.

A laboratory All-Hands meeting will occur October 30, 2015. This forum will provide the OADLSS an opportunity to communicate the ACD's findings with laboratory staff, review key OADLSS initiatives, and provide laboratory staff an opportunity to provide feedback and ask questions. Over the next year, Dr. Monroe will meet with bench-level laboratory staff from each laboratory branch at CDC to better understand the breadth of work conducted at the agency, provide value-added resources for their everyday work, and strengthen relationships with CDC's laboratory community.

Establish and communicate a "CDC Way" regarding responsible, safe science and improve mechanisms for sharing information about safety incidents

Laboratory safety is a top priority for CDC's Director and its leadership. In order to increase uniformity of incident notification, CDC updated its procedures for prompt reporting of laboratory incidents. On July 20, 2015, CDC laboratory safety leadership distributed a Laboratory Infectious Agent Exposure Risk Assessment: Response and Notification Flow Chart. Leadership from OADLSS and CDC's Office of Safety, Security, and Asset Management (OSSAM) held a follow-up forum on August 21, 2015, to answer questions concerning the updated notification system. In response to feedback received at that forum, OADLSS has been collaborating with OSSAM to update its internal website to include incident reporting FAQs, provide examples of "near miss" scenarios, and revise the incident notification flow chart to increase clarity for notification responsibilities of the affected individuals and their supervisors.

Consider laboratory safety programs and training as a fundamental mission for CDC and establish central funding source for these activities

CDC sought funding to further enhance laboratory science, safety, and training initiatives at the agency. Central funding for laboratory safety and training programs was established in fiscal year 2015. The fiscal year 2016 President's Budget requested an additional \$20 million to build CDC's laboratory safety capacity.

Governance

Establish a central entity at the level of the Office of the Director for accountability and oversight authority for laboratory safety and compliance committees

OADLSS serves as the central entity for accountability and oversight authority for laboratory safety and compliance committees. In this capacity, it is the governing office for the Institutional Biosecurity Board (IBB), Institutional Biosafety Committee (IBC), and the Laboratory Safety Review Board (LSRB), providing both administrative support and scientific guidance to the various boards and committees. OADLSS will hold a retreat with these three boards and committees to jointly outline how they will interact and be supported by OADLSS. The Institutional Animal Care and Use Committee (IACUC) continues to report to the Office of the Associate Director for Science (OADS), also in CDC's Office of the Director.

In addition to supporting these review boards, OADLSS is now responsible for reporting all Dual-Use Research (DUR) and Dual-Use Research of Concern (DURC)-related research to the Department of Health and Human Services (HHS). CDC leadership is currently assessing whether organizational improvements or realignments will further enhance biosafety in the agency.

Risk Assessments

Establish a centralized, standardized mechanism for consistent and thorough review and risk assessment of proposed research activities

CDC's Laboratory Safety Review Board (LSRB) is a new centralized board formed with the purpose of standardizing review of high-risk research activities. This board was established in lieu of an IBC expansion to conduct reviews and risk assessments. The LSRB, comprised of laboratory science experts from across the agency, reviews and approves all protocols for the inactivation and transfer of biological materials from BSL-3 and BSL-4 laboratories to those of lower containment. The LSRB also issues guidance and recommendations for biosafety training related to inactivation protocols.

Risk assessments should be performed and documented before experimental work is done

OADLSS has developed new agency-level policy to require the use of risk assessments for experimental work. A new biological risk assessment course has been created for CDC staff. This monthly course trains scientists to identify risks associated with laboratory procedures involving work with biological agents. A post-training evaluation was also administered to assess competency of students and program implementation effectiveness. To date, the course has been offered 10 times with a total of 161 laboratory and support staff trained, representing a majority of laboratories that work with biological select agents and toxins at the agency.

Training

Establish a standardized lab safety training curriculum with methods for competency skills mapping and refresher training

OADLSS has established a core safety training curriculum. In January 2015, the Biosafety Training Work Group (now the Laboratory Safety Training Board) identified and documented competencies for core safety training. They reviewed 23 existing safety trainings at CDC, mapping competencies and identifying gaps in knowledge. The BTWG developed a prioritized list of courses for development of a standard safety training

curriculum, developing learning objectives for these primary courses, and finalized an implementation plan for rollout of competency-based, core safety training across CDC.

CDC subject matter experts (SMEs) were engaged with the development of these biosafety training materials. In September, OADLSS hosted a SME forum to present timelines for roll-out, roles and responsibilities; the importance of SMEs in the creation of standardized biosafety training was also emphasized. The first four courses are nearing completion and will be released this calendar year.

OADLSS has procured a contract for and will conduct an external review of CDC's entire curriculum development process to identify lessons learned and opportunities for improvement.

Establish a fellowship program to train scientists to serve as laboratory safety professionals

The [Laboratory Leadership Service](#) (LLS) was formed in 2014 as a program designed to train scientists to serve as leaders and safety professionals. The fellowship combined core public health laboratory competency-based coursework with practical, applied research and service. The first class of fellows began their two-year commitment on July 1, 2015. Finalists for the 2016 LLS class and host laboratories have been selected. Currently, finalists are being interviewed by potential host laboratories to establish a good match between the two groups. Lessons learned from the 2015 class will inform revisions and improvements to the curriculum for next year.

Responsibilities and facilities for lab safety training should be in-house

OADLSS has made concentrated efforts to house responsibilities and facilities for laboratory safety training within the agency. The office initiated the development of a standardized biosafety training curriculum, identified funding for development of a new general laboratory safety training curriculum, and developed a proposal for a new state-of-the-art laboratory training center. If funding is identified, the new laboratory training center will be designed to provide hands-on training for laboratory staff across the CDC.

OADLSS established the Laboratory Safety Training Board to review laboratory safety training materials for regulatory compliance and best practices. This chartered group serves as the governing body for CDC's laboratory safety training curriculum. The board's first meeting took place in October 2015.

Culture of Safety and Incident Notification

Establish a culture of responsible science and accountability

Recognizing that prompt incident notification is a key part of laboratory safety efforts, OADLSS has implemented enhanced procedures for swift and easy reporting. The office created the Lab Safety Helpdesk, which allowed reporting of safety issues and requests for safety service. Staff are also able to report issues and concerns anonymously, if they choose to do so.

CDC also updated their procedures for prompt reporting of potential biological agent exposure related laboratory incidents. On July 20, 2015, CDC laboratory safety leadership distributed a Laboratory Infectious Agent Exposure Risk Assessment: Response and Notification Flow Chart. Leadership from OADLSS and OSSAM held a follow-up forum on August 21, 2015, to answer staff questions concerning the updated notification system. In response to feedback received at that forum, OADLSS has been collaborating with OSSAM to update its website to include incident reporting FAQs and revise the incident notification flow chart to increase clarity for notification responsibilities of the involved individuals and their supervisors.

OADLSS and OSSAM will also work together to provide examples and develop guidance concerning “near misses.” In order to identify trends, it is important for the office to capture “near misses” to analyze these non-events. This analysis can provide insight into potential laboratory safety issues that have not yet reached a critical point.

Report and analyze incidents and corrective actions; share lessons learned with the community

OADLSS provides progress updates related to CDC’s major laboratory incidents in 2014 on its internal and external websites. OADLSS also alerts staff and provides remediation instructions to laboratory staff following laboratory incidents and near misses through the CDC laboratory list serve. This provides a transparent mechanism that details how CDC and OADLSS responds to laboratory safety incidents.

CDC has ongoing partnerships with other federal agencies, including FDA and NIH, to share best practices around lab safety and leverage resources among the agencies. OADLSS leadership has presented on its lab safety practices at scientific meetings and will continue to seek additional opportunities for collaboration.

OADLSS will continue to engage the Division of Select Agents and Toxins (DSAT) about potential implications for select-agent regulated entities.

Ensure scientists operating safe laboratories are recognized for their work

OADLSS implemented a new program called the Laboratory Safety Champion, which recognizes staff who promote laboratory safety and best practices through stories on CDC Connects, CDC’s internal news site. To date, five laboratory scientists and engineers have been recognized in this way. OADLSS intends to highlight new laboratory staff each month in order to promote good laboratory safety and quality standards.

The laboratory e-mail distribution listserv reaches more than 1600 staff; OADLSS uses this medium to congratulate staff who demonstrate responsible and safe actions in their laboratories. The Office also hosted a Laboratory Safety Innovation Championship designed to recognize innovative laboratory safety solutions. This fall, OADLSS will also begin recognizing teams of laboratory scientists who demonstrate a culture of excellent laboratory science and safety through CDC Connects stories.

OADLSS is currently developing an internal grant mechanism to award funding for innovative laboratory safety solutions with the potential for implementation throughout CDC laboratories.

[Biosafety and Occupational Medicine](#)

Raise the stature of ESHCO through hiring of additional scientific staff

CDC has developed new standard position descriptions for Laboratory Quality Management and Safety and Occupational Health Specialists to accelerate staffing the Environment, Safety, and Health Compliance Office (ESHCO) with scientists who have professional biosafety qualifications. Organizational improvements to increase the efficiency of CDC laboratory facility oversight are being proposed.

Appoint Division liaisons to represent the programs’ needs to a centralized ESHCO committee

OADLSS identified a representative from each of the infectious disease centers to represent program needs related to safety consultations and risk assessments to ESHCO. The office also developed new position descriptions for safety and occupational health managers at several levels to create a mechanism for

programs to hire safety experts. Going forward, OADLSS will convene a panel to address progress toward safety concerns and standardization of safety practices across laboratories.

Expand the scope and capabilities of the Occupational Medicine Program to facilitate active monitoring of employee health and ability to respond to laboratory incidents

CDC requested assistance from the Federal Occupational Health to conduct an assessment of clinic operations; implementing improvements now, with a follow-up review pending. CDC also established an internal health advisory group to review and improve operations, leading to new procedures to enhance the Occupational Health Clinics' capacity for monitoring employee health, including hiring a clinic administrator.

[Progress Reporting](#)

Track and report progress in establishing programmatic elements and recommended processes

OADLSS provides on-going updates on progress towards addressing internal and external recommendations. They provide verbal regular updates to the external Laboratory Safety Workgroup (ELSW) in addition to formal updates to the ACD on [April 23](#), July 17, and October 29, 2015. CDC also provides monthly updates to HHS, reporting on progress. In addition to these groups, OADLSS posts regular written updates on its [website](#).

[External Accreditation](#)

Pursue external review and accreditation for CDC laboratories

In 2015, OADLSS initiated a pilot program with five infectious diseases laboratories to attain external accreditation to International Organization for Standardization (ISO) standards. The purpose of this pilot is to assess best practices and apply lessons learned for implementation across the agency. Key activities of this pilot have included: (1) conducting stakeholder engagement sessions to solicit input and recommendations; (2) conducting training for pilot laboratories in ISO 17025 standards and in internal auditing techniques; and (3) conducting several benchmarking interviews and eleven site visits with ISO-accredited government laboratories. Following these activities, the OADLSS completed a gap analysis comparing the Infectious Diseases Laboratory Quality Manual to ISO 17205 requirements and is drafting a template Quality Manual for use by the pilot laboratories. Next steps for the pilot include reviewing and implementing the Quality Manual Template, developing documentation for the Quality Management System, and implementing ISO 17025 processes and procedures in pilot laboratories.