



## Next Steps: Biosafety and Biosecurity at Centers for Disease Control and Prevention (CDC)

Department of Health and Human Services | Centers for Disease Control and Prevention | Office of the Director

### Summary

On August 18, 2014 Assistant to the President for Homeland Security and Counterterrorism Lisa Monaco and Assistant to the President for Science and Technology John Holdren issued a memorandum titled, *“Enhancing Biosafety and Biosecurity in the United States,”* which urged all United States Government departments and agencies that work with infectious agents to take immediate and long-term steps to enhance safety and security of research to minimize the potential for future incidents. All United States Government departments and agencies that possess, use, or transfer human, animal, or plant infectious agents or toxins were urged to perform a Safety Stand-Down, to include an immediate sweep of their facilities to verify that all Biological Select Agents and Toxins in their possession were appropriately registered, stored, and disposed of in accordance with applicable regulations.

In July 2014, the Centers for Disease Control and Prevention (CDC) initiated a careful and deliberate review of its biosafety and biosecurity protocols and implemented a series of measures to improve laboratory safety practices across the agency, including a comprehensive search of laboratory and associated spaces to identify Biological Select Agents and Toxins (BSAT) and ensure their proper registration, safe stewardship, and secure storage or disposal, among other measures. These measures also fulfill the immediate and long-term steps called for in the August 18, 2014 memorandum. CDC released a fact sheet describing its activities undertaken as part of the “Safety Stand Down.”

For a summary of the U.S. Government-wide Safety Stand-Down, click here: <http://www.cdc.gov/about/lab-safety>.

### Process and Findings

During CDC’s comprehensive search and the “Safety Stand-Down” period, CDC conducted a search of approximately 1,000 rooms of laboratory space at CDC facilities across the United States, which included inventory and documentation for over 8 million samples.

CDC’s review found no instances in which select agents were stored in non-secured areas.

CDC identified eight instances in which BSAT were stored securely and safely but were outside of areas registered for those particular agents. In each instance, multiple vials of material were found, totaling 100 vials. The individual vials each contained 0.5 milliliters or less of material (with the exception of one vial that contained 1 milliliter). These vials were found in two laboratories at CDC’s Roybal campus in Atlanta, Georgia, and at the CDC and ATSDR Specimen Packaging, Inventory, and Repository (CASPIR), CDC’s long-term specimen storage facility.

These reported instances reflect findings of select agents including:

Entity	Discovery Date	Discovered Agent or Toxin	Quantity (out of over 8 million samples reviewed)	Resolution of Sample	Indication of human exposure prior to or during BSAT discovery
CDC	9/17/2014	<i>Clostridium botulinum</i>	8 vials	Destroyed	No
CDC	9/17/2014	<i>Burkholderia pseudomallei</i>	1 vial	Transferred to registered laboratory	No
CDC	9/17/2014	<i>Brucella abortus</i> , <i>B. melitensis</i> & <i>B. suis</i>	6 vials	Destroyed	No
CDC	9/18/2014	<i>Francisella tularensis</i>	3 vials	Destroyed	No
CDC	9/25/2014	<i>Clostridium botulinum</i> , <i>Francisella tularensis</i> , <i>Bacillus anthracis</i> , <i>Yersinia pestis</i> , <i>Burkholderia pseudomallei</i> , <i>B. mallei</i> , <i>Brucella abortus</i> , <i>B. melitensis</i> & <i>B. suis</i>	27 vials	Transferred to registered laboratory	No
CDC	9/26/2014	<i>Burkholderia pseudomallei</i> , <i>Clostridium botulinum</i> , <i>Brucella melitensis</i> & <i>B. suis</i>	14 vials	Transferred to registered laboratory	No
CDC	9/30/2014	<i>Bacillus anthracis</i> , <i>Burkholderia pseudomallei</i> , <i>Brucella abortus</i> , and <i>B. melitensis</i>	5 vials	Transferred to registered laboratory	No
CDC	9/30/2014	<i>Clostridium botulinum</i> , <i>Francisella tularensis</i> , <i>Bacillus anthracis</i> , <i>Burkholderia pseudomallei</i> , <i>B. mallei</i> , <i>Brucella abortus</i> , <i>B. melitensis</i> & <i>B. suis</i>	36 vials	Transferred to registered laboratory	No

- *Bacillus anthracis*, the bacterium that causes anthrax;
- *Brucella* species (*B. abortus*, *B. melitensis*, *B. suis*). *Brucella* is the cause of brucellosis, which is typically transmitted to humans from infected animals;

- *Burkholderia mallei*, the bacterium that causes glanders, which is primarily a disease affecting horses, but can also rarely affect humans;
- *Burkholderia pseudomallei*, a bacterium that infects humans and animals and causes the disease melioidosis;
- *Clostridium botulinum*, a bacterium that can produce the neurotoxin botulinum; and
- *Francisella tularensis*, the bacterium that causes tularemia in animals and humans.

All of these agents have either been destroyed or transferred to the correct designated area. In no case was there an indication of human exposure, including staff or the general public, to any of these agents or toxins.

## Additional CDC Actions

### Plans for Sustained Inventory Monitoring

Following the “Safety Stand-Down,” CDC has taken action to improve specimen management practices including:

- Revising procedures to improve inventory management and plans to implement enhanced out-processing procedures for departing staff that will include accounting for samples put into storage during that person’s tenure, to ensure proper subsequent disposition of samples.
- Implementing a new electronic inventory system for all diagnostic specimens, human and animal sera, and potentially pathogenic materials requiring BSL-2 or greater containment.

### Comprehensive Review of Current Biosafety and Biosecurity Protocols

Also as part of the “Safety Stand-Down,” CDC is updating laboratory protocols and expanding training programs to advance best practices in biosafety and biosecurity. For example:

- CDC ceased all transfers of biological materials from all biosafety level 3 (BSL-3) and 4 (BSL-4) laboratories at all CDC facilities until each laboratory individually documented its practices and received approval to resume transfers of biological materials.
- CDC established an external workgroup to examine laboratory safety and security.

### Opportunities for Improving Research Safety and Local Oversight Systems

- CDC hosted sessions with laboratory researchers and other staff to emphasize the importance of rigorously adhering to established practices for storing, handling, and working with infectious agents, toxins, and other biological derived materials.
- CDC hosted a series of Laboratory Safety Engagement Sessions to provide a laboratory-specific forum to elicit suggestions and concerns from staff regarding laboratory safety.
- CDC created an internal listserve and website for more frequent communication with the CDC laboratory community.

- CDC worked with the Federal Experts Security Advisory Panel (FESAP) and other departments and agencies to identify needs and gaps and make recommendations to optimize biosafety, biosecurity, oversight and inventory management and control for BSAT and identify changes to guidance or policy necessary to improve biosafety and biosecurity.

### **Next Steps**

Moving forward, CDC will continue to work to institutionalize the recommendations that stem from the “Safety Stand-Down” findings. For example:

- CDC is establishing an Associate Director for Laboratory Science and Safety, reporting directly to the CDC Director, to provide agency-wide leadership and accountability for laboratory science, safety, and quality.
- CDC is identifying best practices to standardize electronic inventory documentation and management systems in BSAT and non-BSAT laboratories
- CDC is enhancing biosafety and biosecurity training for laboratory staff, management, and leadership.
- CDC is clarifying policies regarding handling and disposition of remaining laboratory samples when researchers, staff members or trainees depart from positions that involve BSAT.
- CDC is implementing mechanisms to designate responsible individuals to oversee samples stored in common storage areas, including for non-BSAT facilities.
- CDC is participating in an interagency group, established by the National Science and Technology Council, to conduct a comprehensive review of the impact that the select agent regulations have had on science, technology, and national security.

The recommendations from these reviews will continue to inform CDC’s future policy to advance biosafety and biosecurity. CDC is committed to advancing biosafety and biosecurity in the United States and around the world as an integral component of the Global Health Security Agenda (GHTSA). For the latest updates and information regarding laboratory safety, visit <http://www.cdc.gov/about/lab-safety>.