December 16, 2014

FACT SHEET: Biosafety and Biosecurity in the United States

In the summer of 2014, lapses in biosafety practices in Federal laboratories served as a reminder of the importance of constant vigilance over the implementation of biosafety standards.

As a result of these biosafety lapses, 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, 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 (BSAT) in their possession were appropriately registered, stored, and disposed of in accordance with applicable regulations.

Departments and agencies provided written documentation of activities, including facility sweeps, comprehensive safety, security and inventory activities, and captured best practices and plans for systemic strengthening of biosafety oversight. These results are summarized below. Staff from across the United States Government embraced this effort. Going forward, the United States Government will support and reinforce this strong culture of responsibility, which is essential to protecting laboratory personnel and the public.

Overall findings

During the Safety Stand-Down, departments and agencies conducted sweeps at over 4,000 facilities across the United States and in U.S. facilities abroad, which included examining inventory and documentation for over 40 million samples. As a result of this comprehensive review, there were 27 instances in which BSAT materials, while safely and securely stored, were not properly registered with the United States Federal Select Agent Program (FSAP). In each instance, departments and agencies reported the adjudication and final disposition for the materials, and there were no indications of human exposure, including staff or the general public, to any of these agents or toxins.

Department of Defense (DOD) laboratory leadership re-assessed biosafety and biosecurity operating procedures, training, and inventory management practices, and many DOD laboratories have decided to increase the frequency of their inventory sweeps and add monitoring of inventory sweeps to their quality control programs.

The Department of Homeland Security (DHS) has updated inventory software and is evaluating additional ways to improve the effectiveness of inventory management going forward.

The Department of Energy (DOE) improved standardization for elements of its inventory management process and DOE National Laboratories paused BSAT activities until a comprehensive sweep was conducted.

As a result of rigorous effort to advance biosafety and inventory management, the Department of Commerce National Institute of Standards and Technology tracks all chemical and biological samples on campus and conducts an annual audit of the database contents.

In addition to reports received from federal agencies, the United States Government also received reports from entities outside of the federal government, which conducted independent inventory reviews during the 2014 Federal Safety Stand Down period, and some reported updates for training and inventory management and undertook campus-wide sweeps. The United States Government received 15 of these reports from 13 different organizations. In all cases, the FSAP worked with these organizations to ensure that all select agents and toxins discovered were either destroyed on site or transferred to an organization registered to possess select agents and toxins.

Comprehensive Review of Current Biosafety and Biosecurity Protocols
As a result of the Safety Stand-Down, departments and agencies are updating laboratory protocols and expanding training programs to advance best practices in biosafety and biosecurity. Examples include:

An audit of all training records performed by the DHS National Biodefense Analysis and Countermeasure Center verified 100 percent completion of mandatory training and mentorship participation, and all staff at the Plum Island Animal Disease Center completed additional training even though no improperly stored BSAT was discovered.

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

NIH performed a review of NIH policies that govern the use of biological materials, and NIH will finalize a new manual chapter on internal biosafety and biosecurity policy to strengthen and enhance the oversight of high risk biological materials.

The Department of Veterans Affairs (VA) convened a Biosafety and Biosecurity Advisory Group to identify best practices and areas for enhancement of the existing VA Research Safety and Security Programs, including an existing centralized system for reporting research noncompliance and/or unexpected adverse events and plans to clarify oversight for VA research conducted in non-VA facilities.

The U.S. Department of Agriculture reported strengthened awareness about biosafety, biosecurity, and inventory management as a result of Safety Stand-Down, including participation from both management and staff.

The Environmental Protection Agency (EPA) is evaluating procedural and operational enhancements to its existing laboratory-safety and security program. Currently, EPA laboratories are required to complete an annual safety, health and environmental self-assessment including the topics of proper handling, storage, inventory and disposal of infectious and hazardous materials.

The FDA has established an agency-wide Laboratory Safety Policies and Practices Workgroup to conduct a comprehensive review of laboratory safety and security policies and procedures, including inventory management, identify and address any gaps in policies and procedures, and standardize safety and security aboratories.

Departments and agencies also hosted sessions with laboratory researchers and other staff to elicit input and to emphasize the importance of rigorously adhering to established practices for storing, handling, and working with infectious agents, toxins, and other biological derived materials. For example:

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CDC	9/18/2014	*Francisella tularensis*	3 vials	Destroyed	No
CDC	9/25/2014	*Clostridium botulinum, Francisella tularensis, Bacillus anthracis, Yersinia, pestis, Burkholderia pseudomallei, B. mallei, Brucella abortus, B. melitensis & B. suis*	27 vials	Transferred to registered laboratory	No
CDC	9/26/2014	*Burkholderia pseudomallei, Clostridium botulinum, Brucella melitensis & B. suis*	14 vials	Transferred to registered laboratory	No
CDC	9/30/2014	*Bacillus anthracis, Burkholderia pseudomallei, Brucella abortus, and B. melitensis*	5 vials	Transferred to registered laboratory	No
CDC	9/30/2014	*Clostridium botulinum, Francisella tularensis, Bacillus anthracis, Burkholderia pseudomallei, B. mallei, Brucella abortus, B. melitensis & B. suis*	36 vials	Transferred to registered laboratory	No
FDA	7/15/2014	Staphylococcal enterotoxin	8 mg	Destroyed	No
FDA	9/7/2014	*Clostridium botulinum*	3 vials	Destroyed	No
VA Medical Center	9/3/2014	*Brucella melitensis*	1 vial	Destroyed	No
VA Medical Center	9/8/2014	*Brucella abortus*	1 vial	Destroyed	No
NIH	7/29/2014 8/11/2014	Botulinum neurotoxin	2 vials, 0.9 mg total	Destroyed*	No
NIH	8/14/2014	*Burkholderia pseudomallei*	2 vials	Destroyed*	No
NIH	8/27/2014	Ricin	5g	Destroyed*	No
USDA APHIS	9/11/2014	Botulinum neurotoxin	2 vials	Destroyed	No

USDA APHIS	9/12/2014	Classical swine fever virus	16 vials	Not select agent sample, does not contain agent
USDA APHIS	9/24/2014	Classical swine fever virus	2 Vials	Not a select agent; USDA licensed vaccine
USDA ARS	9/9/2014	Ricin	0.9 mg	Not a select toxin: less than regulated amount (<100mg)
USDA ARS	9/9/2014	Diacetoxyscirpenol	3.2 mg	Not a select toxin: less than regulated amount (<1000mg)