

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

SUPPLEMENTAL MEMORANDUM

July 16, 2014

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

**Re: U.S. Department of Agriculture's Animal and Plant Health Inspection Service
Inspection Reports of the CDC Roybal Campus**

I. INTRODUCTION

In June 2014, Centers for Disease Control (CDC) employees at the agency's Bioterrorism Rapid Response and Advanced Technology (BRRAT) lab transferred potentially live samples of anthrax to two other labs, exposing dozens of CDC employees to this public health threat. The Committee is holding a hearing on this incident today.

A CDC after-incident report that was released to the public identified a series of failures that caused the exposure.¹ Another report on the incident, prepared by the USDA Animal and Plant Health Inspection Service (APHIS), was conducted in June 2014; it has not been released to the public, but its findings have been publicly reported.²

The June inspection was not the only recent APHIS inspection at the CDC Roybal facility. As part of their joint oversight of select agents that pose a threat to both human and animal health, CDC's Division of Select Agents (DSAT) and APHIS conduct inspections of

¹ Centers for Disease Control and Prevention, *Report on the Potential Exposure to Anthrax* (July 11, 2014).

² Memorandum from Republican Staff to Members of the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, *Hearing on Review of CDC Anthrax Lab Incident* (July 14, 2014).

facilities that handle select agents to evaluate whether they meet the regulatory requirements.³ APHIS conducted six of these inspections at the CDC Roybal campus facilities between January 2013 and March 2014.⁴

The Committee requested and obtained copies of these inspections reports, which are summarized in this memorandum.

II. SUMMARY OF FINDINGS OF 2013-2014 APHIS INSPECTIONS AT CDC'S ROYBAL CAMPUS

The APHIS reports show that in the 18 months prior to the June Anthrax release, inspectors identified numerous safety problems in CDC laboratories. Many of these safety problems were paperwork violations, such as the failure to provide appropriate documentation of staff training or missing signatures on biosafety plans. Others involved potentially more significant problems, such as a malfunctioning exhaust systems on biosafety cabinets.

- **Problems with facilities or equipment were observed 29 times by APHIS inspectors in the six inspections between January 2013 and March 2014.** Equipment failures included broken or nonfunctioning machinery, the failure to use filters or replace filters on a regular basis, the use of equipment that was not sufficient to contain the select agent or toxin (e.g., equipment used on a laboratory bench top instead of in a biosafety cabinet), and biosafety cabinet grilles obstructed with pens or other items. During one inspection, APHIS inspectors smoke-tested the exhaust flow on the biosafety cabinets in laboratory rooms and discovered the exhaust flowing into the laboratory instead of being safely sucked away.
- **Safety and security problems were observed 27 times by APHIS inspectors in the six inspections between January 2013 and March 2014.** These included failures by lab workers to wash their hands after working with potentially hazardous materials and a case where the outermost of two gloves a lab worker handling vials of select agents and toxins was wearing had a tear across the palm. Other observed safety concerns included failures to post entrance and exit procedures for some rooms and failures to post appropriate signage (such as signs indicating toxins or biohazards in use) in laboratories. Observed security failures included unauthorized access to laboratories and the failure to properly document entry and exit from laboratories. In two inspections, APHIS inspectors noted security failures, particularly with regard to recording entry into labs (e.g., recording only the first names or initials of visitors and escorts).

³ Letter from Robbin S. Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, and Freeda E. Isaac, Director, Agriculture Select Agent Program, Animal and Plant Health Inspection Service, to Joanne Jones, Responsible Official, Centers for Disease Control and Prevention (June 14, 2013).

⁴ The APHIS inspections occurred on January 14-17, 2013, April 24, 2013, August 19-23, 2013, September 30, 2013, January 6-13, 2014, and March 3-12, 2014.

- **Problems with the failure to use or denote appropriate procedures were observed 25 times by APHIS inspectors in the six inspections between January 2013 and March 2014.** These failures included the absence of or inconsistent procedures in connection with safety, security, and documentation. These included cases where a biosafety plan did not contain decontamination procedures for a gross contamination incident, the absence of procedures to inform law enforcement or the CDC’s designated responsible official of potentially criminal suspicious activities in labs, and the failure to include written procedures to be followed to test and treat workers in the event of a biohazard incident.
- **Problems with documentation and recordkeeping were observed 39 times by APHIS inspectors in the six inspections between January 2013 and March 2014.** These were the most common types of problems observed by APHIS inspectors. They included 11 instances in which written inventories of select agents were inconsistent with physical inventories (exposing a failure to properly account for all samples of select agents that were in storage on site) and cases where important safety or security procedures were not included in written plans. During one inspection, APHIS inspectors reported that the inspected facility did not submit required forms for an incident related to possible exposure or release of a select agent or toxin.
- **Problems with employee training were observed four times by APHIS inspectors in the six inspections between January 2013 and March 2014.** Problems identified by APHIS included absence of records or observed conditions indicating that staff had not received full or appropriate training regarding inventory control, threat awareness, security, incident response, and biosafety.

III. PROBLEMS IDENTIFIED BY APHIS IN THE JUNE ANTHRAX TRANSFER

In June 2014, after the anthrax transfer, APHIS inspectors conducted an investigation of the incident and the CDC facility.

In the report describing the June 2014 investigation, APHIS identified problems with facilities and equipment (finding that decontaminant solutions and materials were expired); problems with the failure to use appropriate procedures (noting that CDC staff failed to use appropriate procedures and protocols to inactivate the transferred anthrax and that “the clinic was inadequately prepared to respond to the exposure of a large number of individuals”); problems with staff training (finding that staff “in registered laboratories were not appropriately trained in use of the inactivation protocol” and were “not appropriately trained in the characteristics, properties, and risks of the agent”); problems with paperwork and documentation (noting that “no formal approval process was in place for a new inactivation procedure” and that no documentation was created for potentially contaminated samples transferred between CDC labs); and problems with safety and security (finding that laboratories containing potentially live anthrax samples were not appropriately secured and that samples were stored in unlocked refrigerators).