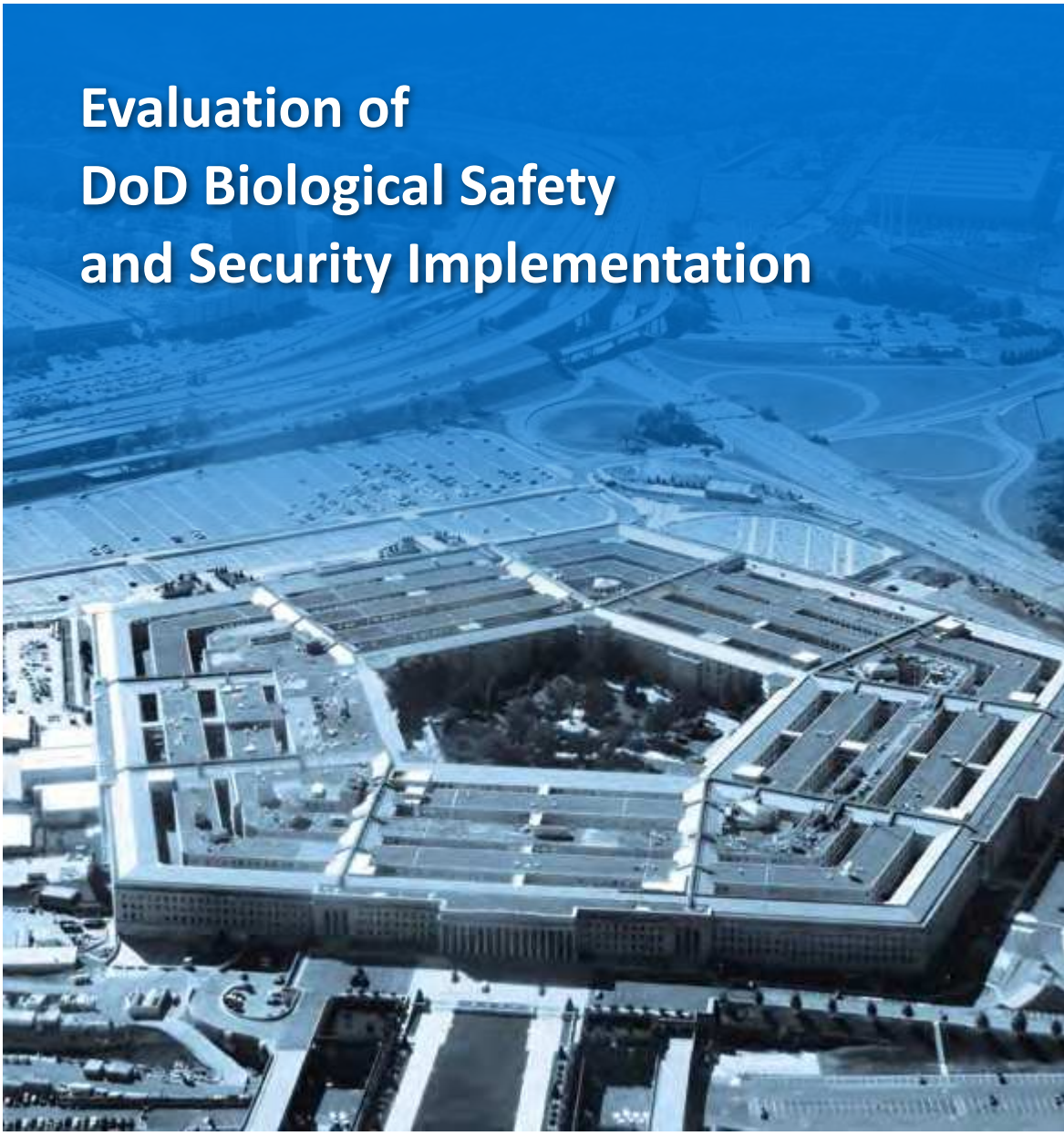
Report No. DODIG-2016-078

# INSPECTOR GENERAL

*U.S. Department of Defense*

APRIL 27, 2016

# Evaluation of DoD Biological Safety and Security Implementation



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# Results in Brief

*Evaluation of DoD Biological Safety and Security Implementation*

**April 27, 2016**

## Objective

The objectives of this project were to: 1) assess the uniform application of biosafety and biosecurity policy and directives, plans, orders, and guidance across DoD Component laboratories that were conducting research using biological select agents and toxins (BSAT) and 2) evaluate DoD biological safety and security oversight at laboratories; DoD Component biological safety and security compliance with Federal, DoD, and Service policy; and DoD and Component actions on recommendations from previous Government Accountability Office, Defense Science Board, and Defense Health Board reports.

## Findings

We found that:

- DoD had not maintained biosafety and biosecurity program management, oversight, and inspections of its BSAT laboratories according to applicable Federal regulations.
- BSAT laboratories in Military Services were inspected according to different guidance, standards, and procedures, risking dangerous lapses in biosafety practices.
- Lack of coordinated oversight of DoD laboratories led to multiple, missing, and duplicative inspections, and, therefore, an excessive administrative burden that could interfere with scientific research performance.

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### *Findings (cont'd)*

- Inspection quality varied as inspection team members sometimes lacked necessary training or sufficient experience and expertise, or a combination of each.
- DoD did not require that deficiencies identified by inspections were tracked and remain corrected after they were initially closed.
- DoD lacked a single coordinating entity to oversee and manage biosafety and biosecurity deficiencies in high risk BSAT laboratories.

As a result, DoD BSAT laboratories have:

- used protocols that were not validated for their intended use,
- been inspected irregularly or not at all, and
- had significant deficiencies and vulnerabilities that were not corrected by DoD management.

Consequently, the health and safety of the public was put at risk of inadequate protection from exposure to biological pathogens.

DoD leadership has taken actions to address the anthrax biosafety protocol failures identified at Dugway Proving Ground in May 2015, including those based on the recommendations of a Comprehensive Review Committee established by the Under Secretary of Defense for Acquisition, Technology, and Logistics.

Several of the DoD leadership actions based on recommendations from the Review Committee may be difficult to implement as they appear contradictory to oversight community standards.

# Results in Brief

*Evaluation of DoD Biological Safety and Security Implementation*

## Recommendations

We recommend that the Deputy Secretary of Defense appoint a single Executive Agent responsible for biosafety and biosecurity to perform the following tasks:

- track all internal and external inspection results and ensure appropriate corrective actions are taken,
- ensure that all BSAT laboratories are inspected regularly according to a standardized set of criteria,
- coordinate external technical and scientific peer reviews, and
- develop standardized training for inspectors, and ensure inspection teams consist of personnel with appropriate experience and expertise.

We recommend that the Under Secretary of Defense for Acquisition, Technology, and Logistics:

- issue guidance that all Department of Defense BSAT laboratories implement internal technical and scientific peer review functions that address both biosafety and biosecurity issues, and
- develop implementing guidance that requires site-specific laboratory security vulnerability assessment findings be included during Biological Select Agent and Toxins laboratory inspections.

## Management Comments and Our Response

The Under Secretary of Defense for Acquisition, Technology, and Logistics responded to the recommendations in this report on behalf of the Deputy Secretary of Defense, and agreed with all recommendations.

The Under Secretary of Defense for Acquisition, Technology, and Logistics stated that the Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD Executive Agent for the DoD BSAT Biosafety and Biosecurity Program.

Management's responses addressed all specifics of the recommendations in this report, and no further comments are required. We request that the draft DoD Directive be forwarded to us for review.

Management comments to the draft report are included, beginning at page 92 of this report. Please see the Recommendations Table on page iii. If you have additional comments on this report, please forward them by May 31, 2016.

## *Recommendations Table*

| Management | Recommendations Requiring Comment | No Additional Comments Required |
|---|---|---|
| Deputy Secretary of Defense | | 1.a, 1.b.(1), 1.b.(2), 1.b.(3), 1.b.(4), 2.a, 3.a, 3.b., 3.c, 3.d, 4.a |
| Under Secretary of Defense for Acquisition, Technology and Logistics | | 2.b, 4.b |

Please provide Management Comments by May 31, 2016.


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April 27, 2016

MEMORANDUM FOR DEPUTY SECRETARY OF DEFENSE
UNDER SECRETARY OF DEFENSE FOR ACQUISITION, TECHNOLOGY, AND LOGISTICS

SUBJECT: Evaluation of DoD Biological Safety and Security Implementation (Report No. DODIG-2016-078)

We are providing this report for information and appropriate action. We conducted this assessment from December 2014 to April 2016 in accordance with the "Quality Standards for Inspections and Evaluations," published in January 2012 by the Council of Inspectors General on Integrity and Efficiency.

We considered management comments on a draft of this report when preparing the final report. DoD Instruction 7650.3 requires that the recommendations be resolved promptly. Comments from the Under Secretary of Defense for Acquisition, Technology, and Logistics, on behalf of the Deputy Secretary of Defense, addressed all the specifics of the recommendations. The Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics has been directed to draft and coordinate a DoD Directive that outlines the roles and responsibilities that will meet the intent of all recommendations contained in this report. We request that this draft DoD Directive be forwarded to us for review prior to its issuance.

Should you have further comments to this report, please send them in a PDF file to SPO@dodig.mil. Copies of your comments must have the actual signature of the authorizing official for your organization. We cannot accept the /Signed/ symbol in place of the actual signature. If you arrange to send classified comments electronically, you must send them over the SECRET Internet Protocol Router Network (SIPRNET).

We appreciate the courtesies extended to the staff. Please direct questions to [redacted] at [redacted]) or [redacted]. We will provide a formal briefing on the results if management requests.

Kenneth P. Moorefield
Deputy Inspector General
Special Plans and Operations


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# Contents

# Contents (cont'd)



## Appendixes

# Contents (cont'd)


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# Introduction

The Department of Defense maintains a Chemical and Biological Defense Program as part of its layered, integrated defense against chemical, biological, radiological, and nuclear threats. Research using biological agents and toxins takes place in military and civilian laboratories, and is critical for the development of public health and medical tools, such as vaccines, drugs, and sensors, to protect both the civilian and military populations. Because these biological agents and toxins are inherently dangerous to laboratory workers and the general public, Congress has enacted legislation to provide oversight of all laboratories that use these pathogens.

Biological Select Agents and Toxins (BSAT) is the term used to designate biological agents[1] and toxins[2] that could pose a severe threat to public health and safety, animal and plant health, or animal and plant products. The Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) regulate the possession, use, and transfer of BSAT under the Select Agent Regulations, and jointly enforce the Federal Select Agent Program through the HHS Centers for Disease Control and Prevention (CDC) and the USDA Animal Plant Health Inspection Service (APHIS) at the CDC's Division of Select Agents and Toxins in Atlanta, Georgia.

The CDC maintains a list of BSAT that might be harmful to humans, while APHIS determines which BSAT may be harmful to animal or plant health. The combined list currently numbers more than 60; the total number can change because the list is reviewed biennially as biological materials are added or taken off the list. On the BSAT list are biological materials such as anthrax, the Ebola virus, plague (*Yersinia pestis*), avian influenza virus, smallpox (*Variola major*) virus, and the SARS [Severe Acute Respiratory Syndrome] virus.

[1] Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsia, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment. Public Health-Select Agents and Toxins, 42 C.F.R. 73.1.

[2] Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsia, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance. Public Health-Select Agents and Toxins, 42 C.F.R 73.1.

## BSAT Legislation and Executive Orders

### *2001–02*[3]

Following the anthrax attacks of 2001 that resulted in five deaths, Congress significantly strengthened oversight of select agents by passing the USA PATRIOT Act in 2001 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. These two acts required HHS and USDA to publish regulations for possession, use, and transfer of select agents (Select Agent Regulations, 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73).

### *2009*

On January 9, 2009, President Bush signed Executive Order No. 13486, 74 *Federal Register* 2289, "Strengthening Laboratory Biosecurity in the United States," January 9, 2009, which established a working group to review the effectiveness of biosecurity policies regarding select agents.

### *2010*

President Obama issued Executive Order No. 13546, 75 *Federal Register* 130 "Optimizing the Security of Biological Select Agents and Toxins in the United States," July 8, 2010, that directed HHS and USDA to, as a part of their ongoing review, tier and consider the reduction of the select agent list, and to establish physical security standards for select agents with the highest risk of misuse. A final rule published on October 5, 2012, designated Tier 1 select agents, reduced the number of agents on the select agent list, and established physical security for Tier 1 select agents. The subset of select agents designated as Tier 1 present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence.

## BSAT Research in the Department of Defense

According to the 2014 DoD Annual Report to Congress, the mission of the DoD Chemical and Biological Defense Program (the Program) is to enable the warfighter to deter, prevent, protect, mitigate, respond, and recover from chemical, biological, radiological, and nuclear threats and effects as part of a layered, integrated defense. The Program develops medical and physical countermeasures to protect the warfighter from chemical and biological threats.[4]

[3] www.selectagents.gov/history.html.

[4] 2014 Department of Defense Chemical and Biological Defense Annual Report to Congress, March 2014, p. 3.

Research on biological select agents and toxins is critical for the development and availability of public health and medical tools that are needed to detect, diagnose, recognize, and respond to outbreaks of infectious disease of both natural and man-made origin. Such tools developed by the Program consist of the following:

- vaccines and drugs,
- personal protective equipment,
- environmental sensors,
- decontamination protocols, and
- environmental and medical surveillance capabilities.

The Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs is responsible for developing policies, providing advice, and making recommendations on biological safety and security within the Department of Defense.[5]

## Definitions

- **Biosafety**: the development and implementation of administrative policies, microbiological practices, facility safeguards, and safety equipment to prevent the transmission of potentially harmful biological agents to workers, other persons, and the environment.[6]
- **Containment**: safe methods, facilities, and equipment for managing infectious materials in the laboratory where they are handled or maintained.[7]
- **Risk assessment**: considers engineering controls, practices, protective equipment, and facility design determined to be appropriate for the specific operations performed with infectious agents. It allows for the categorization of the work into four biological safety levels (BSLs), which are assigned in ascending order based on the degree of risk.[8]
- **Biosecurity (laboratory)**: the protection of, control of, and accountability for high-consequence biological agents and toxins and critical relevant biological materials and information within laboratories to prevent unauthorized possessions, loss, theft, misuse, diversion, or intentional release.[9] Biosecurity is achieved through an aggregate of practices

[5] Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006.

[6] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, "Report of the Working Group on Strengthening the Biosecurity of the United States," October 1, 2009, pages 143/149.

[7] ibid.

[8] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, "Report of the Working Group on Strengthening the Biosecurity of the United States," October 1, 2009, page 7/149.

[9] Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, "Report of the Working Group on Strengthening the Biosecurity of the United States," October 1, 2009, page 143/149.

including the education and training of laboratory personnel, security risk assessments, BSAT access controls, physical security (facility) safeguards, and the regulated transport of BSAT.[10]

## BSAT Laboratory Oversight

The Federal Select Agent Program[11] enhances the Nation's oversight of the safety and security of dangerous biological agents and toxins. The program promotes laboratory safety and security to minimize the inherent risks that accompany work with select agents. This is done by strengthening oversight, inspecting entities working with select agents, and assisting the regulated community by providing guidance and support. There are 347 entities registered with and inspected by the Federal Select Agent Program, and approximately 11,000 individuals who have been approved to access select agents.[12] Nine of these 347 entities are in the DoD.

DoD is required to provide oversight of DoD BSAT laboratories in accordance with Department of Defense Directive 5210.88, "Safeguarding Biological Select Agents and Toxins," February 11, 2004; Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006; Department of Defense Manual 6055.18-M, "Safety Standards for Microbiological and Biomedical Laboratories," May 11, 2010; and Service regulations. To provide some measure of the scope of the DoD BSAT laboratory research effort and the diversity of inspection agencies, Table 1 lists the names and locations of DoD BSAT facilities, the major command with oversight responsibilities, and the Service inspection agencies that provide oversight.

[10] ibid.

[11] The Federal Select Agent Program is jointly enforced by the HHS CDC and the USDA APHIS, as described on page 2.

[12] http://www.selectagents.gov/about.html.

*Table 1. DoD BSAT Laboratory, Major Command with oversight responsibilities, and Corresponding Service Inspection Agencies*

| Service | Laboratory Name | Laboratory Location | DoD Inspection Agencies and Major Commands |
|---|---|---|---|
| Army | U.S. Army Medical Research Institute for Infectious Diseases | Fort Detrick, Maryland | • Dept. of the Army Inspector General<br>• Army Medical Command, Office of the Surgeon General |
| | West Desert Test Center | Dugway Proving Ground, Utah | • Dept. of the Army Inspector General<br>• Army Testing and Evaluation Command |
| | Edgewood Chemical & Biological Center | Aberdeen Proving Ground, Maryland | • Dept. of the Army Inspector General<br>• Army Materiel Command |
| Navy | Naval Medical Research Center | Fort Detrick, Maryland | • Navy Bureau of Medicine and Surgery Inspector General |
| | Dahlgren | Dahlgren Naval Surface Warfare Center, Dahlgren, Virginia | • Navy Bureau of Medicine and Surgery Inspector General |
| Air Force | 711 Human Performance Wing | Wright Patterson Air Force Base, Dayton, Ohio | • Air Force Materiel Command Inspector General |

Source: DoD OIG

## Objectives

The objectives of this assessment were to:

- assess the uniform application of biosafety and biosecurity policy and directives, plans, orders, and guidance across DoD Component laboratories that are conducting research using BSAT, and
- evaluate DoD biological safety and security oversight at laboratories; DoD Component biological safety and security compliance with Federal, DoD, and Service policy; and DoD and Component actions on recommendations from previous Government Accountability Office, Defense Science Board, and Defense Health Board reports.


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# Background

## Biosafety and Biosecurity Lapses

The chief suspect in the 2001 *Bacillus anthracis* (anthrax) attacks[13] was a United States Government researcher. The scope and impact of these attacks demonstrated the need to increase domestic preparedness for biological attacks, and BSAT infrastructure and resources expanded significantly. The suspected involvement in the attack by a trusted researcher raised concerns regarding protection against insider threats and the need to ensure that BSAT were properly secured against deliberate misuse to harm public health and safety, animals, plants, or the environment.

On January 9, 2009, Executive Order No. 13486, "Strengthening Laboratory Biosecurity in the United States," was issued to ensure facilities that possess BSAT have appropriate security and personnel assurance practices to protect against theft, misuse, or diversion to unlawful activity. An administrative review by a Federal interagency working group of Federal policies and procedures associated with the security of BSAT highlighted the need for significant improvements in the structure, coordination, and oversight of BSAT activities across the Federal Government. The following year, in 2010, the President issued Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," which directed fundamental changes to securing hazardous pathogens and toxins against misuse.

Executive Order 13546 directed full coordination of Federal oversight for securing BSAT under a revised Select Agent Program/Select Agent Regulations. It also established the Federal Experts Security Advisory Panel to provide recommendations related to the security of BSAT.

## Anthrax Inactivation Incident at the Centers for Disease Control and Prevention, June 2014

Managers at the CDC investigated an incident at its Royal Campus in Atlanta, Georgia, that occurred between June 5–13, 2014, in which an ineffective *Bacillus anthracis* inactivation may have caused 70 workers to be at risk of

[13] In 2001, letters laced with powder form of anthrax were mailed to members of the media and Congress. As a result of exposure to anthrax-tainted mail in the fall of 2001, 22 individuals contracted anthrax disease in four states—Connecticut, Florida, New Jersey, and New York—as well as in Washington, D.C. Of these 22 individuals, 5 died. (GAO-09-1045T)

exposure when *Bacillus anthracis* samples were moved from a high containment laboratory to a laboratory with lesser protection of workers and the public.[14] According to a CDC review of this incident, the contributing actions included:

- use of unapproved sterilization techniques,
- transfer of material not confirmed to be inactive,
- inadequate knowledge of the peer-reviewed literature by the scientists using the inactivation techniques, and
- lack of a standard operating procedure or process to document inactivation in writing.

Furthermore, while investigating this anthrax inactivation failure, CDC officials learned that a different BSAT agent, highly pathogenic H5N1 avian influenza virus, had contaminated low-pathogenic influenza virus specimens, leading to samples being shipped without the appropriate level of permitting, notifications, or safety precautions. This contamination and the response to it was conducted without notification of the supervisory chain of command, including division, center, and CDC leadership.

On August 18, 2014, as a result of continued biosafety and biosecurity lapses, senior White House staff issued a memorandum stating all United States Government departments and agencies that operate facilities that possess, use, or transfer human, animal, or plant infectious agents or toxins are urged to perform a "Safety Stand-Down" which required senior leaders to review laboratory biosafety and biosecurity best practices and protocols, and to develop and implement plans for sustained inventory monitoring.

## Federal Recommendations Applicable to BSAT Inspections or Oversight

Following the announcement of the safety stand-down, the White House National Security Council tasked the Federal Experts Security Advisory Panel (FESAP) in September 2014 to identify recommendations to optimize biosafety, biosecurity, oversight, and inventory management and control for BSAT within 90 days. FESAP responded by issuing a report in December 2014, providing such recommendations.[15] The National Science and Technology Council also formed a Fast Track Action Committee (FTAC) on the Select Agent Regulations to organize

[14] Report on the Potential Exposure to Anthrax, *Centers for Disease Control and Prevention*, Atlanta, Georgia, July 11, 2014.
[15] Report of the Federal Experts Security Advisory Panel, December, 2014.

listening sessions with persons who regularly work with BSAT. As a result of these listening sessions, FTAC issued another set of recommendations to reform Federal and private BSAT programs.[16] Refer to Appendix C to read FESAP recommendations and Appendix D for FTAC recommendations.

Following more BSAT incidents, including one at Dugway Proving Ground in May 2015, senior White House staff issued a memorandum on October 29, 2015, outlining next steps to improve U.S. biosafety and biosecurity. This memorandum included a plan for implementing recommendations made by FESAP and FTAC in their reports. However, the efforts by FESAP and FTAC represent the latest of multiple, sometimes overlapping, efforts across the Government and within the Department of Defense to scrutinize and evaluate BSAT programs. Previous initiatives included reports from a number of Federal and DoD task forces and panels, such as the Defense Science Board's Department of Defense Biological Safety and Security Program (2009), the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (2009), the Working Group on Strengthening Biosecurity (2009), and a 2010 report of the Federal Experts Security Advisory Panel.[17]

As part of this evaluation, the DoD OIG reviewed each of these reports and identified those most relevant to the scope of this evaluation; that is, the inspection and oversight of DoD-owned and operated BSAT laboratories. Brief summaries of these reports follow, and specific recommendations relevant to this evaluation are discussed in the body of this report.

- On October 3, 2008, the Under Secretary of Defense for Acquisition, Technology, and Logistics asked the chairman of the Defense Science Board to create a task force to take a fresh look at biological safety, security, and personnel reliability programs of Army, Navy, and Air Force laboratories. The resulting report addressed the adequacy of current and proposed programs along with standards for the use, storage, and transport of BSAT; barriers to an effective BSAT program; and recommendations to improve it. Refer to Appendix E for a list of compiled recommendations.

[16] Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement, October 2015.

[17] Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Programs, May 2009; Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, July 2009; Report of the Working Group on Strengthening the Biosecurity of the United States, October 2009; Report of the Federal Experts Security Advisory Panel, November 2010.

- On January 9, 2009, Executive Order No. 13486, "Strengthening Laboratory Biosecurity in the United States," established a working group co-chaired by the Secretary of Defense and the Secretary of Health and Human Services.[18] This working group was tasked to review and evaluate the efficiency and effectiveness of existing laws, regulations, guidance, and practices relating to physical, facility, and personnel security and assurance at Federal and non-Federal facilities. Its resulting report summarized that review and evaluation. Refer to Appendix F for the working group's compiled recommendations.
- The Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight issued a report in July 2009. The purpose of the task force was to propose options and recommendations to improve biosafety and biocontainment oversight of research and research-related activities at high and maximum containment laboratories in the United States, without hindering the progress of science. Refer to Appendix G for the task force's compiled recommendations.

## Dugway Proving Ground Anthrax Inactivation Incident and DoD Response

### *Dugway Proving Ground Anthrax Inactivation Incident*

In May 2015, a DoD-contracted laboratory notified authorities at the CDC that it had received live *Bacillus anthracis* instead of inactivated samples from Dugway Proving Ground via the Edgewood Chemical Biological Center. Within days of that report, CDC inspectors launched an onsite investigation at Dugway Proving Ground and Edgewood Chemical Biological Center. CDC investigators discovered that Dugway Proving Ground had, over the course of the last decade, sent low concentrations of live *Bacillus anthracis* spores to dozens of facilities in the United States and abroad. By December 2015, DoD had determined that 194 laboratories in all 50 states and 9 foreign countries had received low concentrations of anthrax in samples sent by Dugway Proving Ground.

[18] Other members of the working group included designees of the Secretaries of State, Agriculture, Commerce, Transportation, Energy, and Homeland Security; the Directors of National Intelligence and the National Science Foundation; the Administrator of the Environmental Protection Agency; and the Attorney General.

### *Implications of Shipping Live BSAT Agent*

According to our analysis, the inadvertent shipment of live BSAT agent from Dugway Proving Ground illustrated deficiencies in the existing DoD BSAT enterprise with respect to:

- managing biosafety and biosecurity concerns by scientific and technical review,
- tracking and addressing issues and deficiencies over time, and
- reviewing the effectiveness of BSAT laboratory oversight and inspections.

## *DoD Response*

On May 29, 2015, the Deputy Secretary of Defense directed the Under Secretary of Defense (USD) for Acquisition, Technology & Logistics (AT&L) to commission a 30-day review of DoD's safety practices for generating and handling inactivated *Bacillus anthracis*. USD(AT&L) established the Committee for Comprehensive Review of DoD Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* Spores (the Review Committee), and tasked the Review Committee to address the following critical areas:

- the root cause for the incomplete inactivation of *Bacillus anthracis* samples at DoD laboratories,
- why post-inactivation viability testing did not detect the presence of live *Bacillus anthracis*,
- existing DoD laboratory biohazard safety protocols and procedures,
- DoD laboratory adherence to established procedures and protocols,
- identification of systemic problems, and
- identification of the steps required to fix identified systemic problems.

The Review Committee issued its report on July 13, 2015. The findings and observations from the Review Committee's report are located in Appendix I.

In response to the Review Committee's report, USD(AT&L) issued a July 22, 2015, action memorandum to the Deputy Secretary of Defense. This memorandum recommended that the Deputy Secretary direct a set of five actions to ensure the Review Committee's recommendations were effectively implemented. The USD(AT&L) action memorandum with its five recommendations is located at Appendix J.

In response to USD(AT&L)'s action memorandum, the Deputy Secretary issued a memorandum on July 23, 2015, regarding the implementation of the recommendations in the Review Committee's Report. He directed five tasks for USD(AT&L) to ensure DoD immediately implemented the recommendations from the Review Committee's report. He also directed a set of five more actions to the Secretary of the Army for the same reason. Refer to Appendix K for the list of the Deputy Secretary's instructions.

In addition, the Deputy Secretary of Defense designated the Secretary of the Army as the DoD Executive Agent for the DoD BSAT Biosafety Program, with the responsibility for the technical review, inspection, and harmonization of biosafety protocols and procedures across DoD laboratories that handled BSAT. This designation included tasking authority of all DoD components for that purpose. He also tasked the U.S. Army to designate a certified biological safety officer to execute the responsibility as DoD Executive Agent for the DoD BSAT Biosafety Program.

Subsequently, on September 2, 2015, the Secretary of the Army, as the DoD Executive Agent for the DoD BSAT Biosafety Program, directed a safety review of all DoD BSAT laboratories and facilities involved in producing, shipping, and handling of live or inactivated BSAT. The Secretary of the Army also directed that these laboratories, in coordination with the Assistant Secretary of the Army for Acquisition, Logistics, and Technology, review existing policies, procedures, and safety manuals to ensure their adequacy. This direction also included seeking peer review of laboratory safety manuals from other DoD laboratories.

The Secretary of the Army also expanded the moratorium that prohibited Dugway Proving Ground from producing, handling, testing, or shipping any live or inactivated *Bacillus anthracis* to a moratorium that prohibits producing, handling, testing, or shipping any type of BSAT.[19]

[19] The Deputy Secretary of Defense originally placed a moratorium on producing, working with, and shipping inactivated anthrax July 23, 2015.

The Secretary of the Army's directions included:

- Edgewood Chemical Biological Center (ECBC), U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) and the Naval Medical Research Center Biological Research Directorate cease production, handling, testing, or shipping of any materials associated with the Critical Reagent Program.[20]
- ECBC, USAMRIID, and Naval Medical Research Center shall not produce handle, test, or ship live or inactivated *Bacillus anthracis* except as required for the development of standardized, peer-reviewed, validated protocols for inactivation and viability testing.
- There shall be no production or shipping of live or inactivated BSAT not associated with the Critical Reagent Program, without the Secretary of the Army's approval.

## *DoD OIG Evaluation*

The Department of Defense Office of Inspector General (DoD OIG) announced this evaluation of DoD biological safety and security implementation six months before the Dugway Proving Ground anthrax inactivation incident was discovered. Because the Review Committee had already identified inherent deficiencies in protocols for the inactivation of anthrax and the Secretary of the Army, as the DoD Executive Agent for the DoD BSAT Biosafety Program, had already started to address those deficiencies, we have not repeated those deficiencies in this report.

The DoD OIG evaluation results generally agree with the Deputy Secretary of Defense and the Secretary of the Army responses and direction regarding BSAT biosafety. In addition, we have made recommendations regarding how to further improve the DoD laboratory oversight inspection program. While DoD has made and intends to make additional changes directed to prevent incidents similar to what occurred at Dugway Proving Ground, this report has identified some of the Review Committee's recommendations that appear contradictory to oversight community standards and Service Inspector General regulations. These recommendations will be difficult to fully implement within the current organizational and administrative structure of the DoD BSAT enterprise. These issues are discussed in Findings 1 and 2 of this report. See Appendixes I, J, and K for more detail on the Dugway Proving Ground laboratory anthrax incident.

[20] The Critical Reagent Program is the principal resource of high quality, validated, and standardized biological detection assays and reagents that meet requirements of the warfighter and Joint biological defense systems and support the biological defense community by facilitating the transition of new technologies and coordinating their advanced development, efficient production, and timely distribution. Critical Reagent Program products include antibodies, inactivated antigens, genomic materials, electrochemiluminescence assays, polymerase chain reaction assays, lateral flow immunoassays, and biological sampling kits.


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# Finding 1

## Standardized Laboratory Oversight and Inspections

DoD did not maintain biosafety and biosecurity program management, oversight, and inspections of BSAT laboratories in accordance with the applicable Executive Order, Federal regulations, and DoD Instructions.[21]

This occurred because there was no single DoD coordinating function to track and correct deficiencies and to ensure that Services' BSAT laboratory management, oversight, and inspections included all mandatory guidance and technical requirements.

As a result, Service BSAT laboratory management, oversight, and inspections failed to identify significant deficiencies and vulnerabilities, and DoD management did not implement needed corrective actions to eliminate possible risks to public health and safety.

## Discussion

DoD and the Services did not maintain biosafety and biosecurity program management, oversight, or inspection programs in accordance with relevant Federal regulations. We found that DoD had not harmonized its internal BSAT administrative procedures, nor had it established standardized oversight of BSAT laboratories in accordance with Executive Order No. 13546,[22] Code of Federal Regulations (C.F.R.) (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73), and Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006.

The Services conducted inspections of their respective BSAT laboratories, using their own Service-level guidance and inspection procedures. Previous reports, such as the Report on the Working Group on Strengthening the Biosecurity of the United States, dated October 2009, found that inspections across the U.S. Government were characterized by "non-uniform standards, expectations, and interpretations."[23]

[21] Executive Order No. 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," July 2010, Code of Federal Regulations (C.F.R.) (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73); Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006.

[22] "Optimizing the Security of Biological Select Agents and Toxins in the United States," July 2010.

[23] Report of the Working Group on Strengthening the Biosecurity of the United States, October 2009, p. 4.

The 2009 working group report also recommended that U.S. Government agencies "develop coordinated training and oversight programs for inspectors from various [U.S. Government] agencies and offices with oversight responsibilities"[24] for BSAT. Similarly, the Trans-Federal Task Force recommended in 2009 that national training standards and core competencies be established for all personnel at high containment laboratories,[25] including for individuals who inspect these facilities.[26] No national training standards have been developed yet. Nevertheless, training standards and coordinated training requirements across the Services is necessary to ensure individuals who work in BSAT laboratories are properly trained. We found that DoD and the Services did not have training that met BSAT scientific proficiency levels within their inspection teams, as described below.

## *Non-uniform Oversight and Inspection Standards*

The primary DoD BSAT directive, DoD Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," dated April 18, 2006, did not specify laboratory inspection criteria. It required only that the heads of the DoD components "ensure compliance" with the instruction. Based on the particular Service regulations, our analysis found at least seven inspection variations across the Services and sometimes within a Service:

- the frequency of inspections,
- the average length of inspections,
- the professional composition and size of inspection teams,
- the categories of the inspection findings,
- the training of inspectors and inspection augmentees,
- consideration given to vulnerability assessments by inspectors, and
- the process by which findings are communicated or negotiated with the inspected entity.

[24] Report of the Working Group on Strengthening the Biosecurity of the United States, October 2009, p. 31.

[25] Laboratories with microbiological practices, safety equipment, and facility safeguards for handling Biosafety level 3 (BSL-3) agents, those with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections, and that are indigenous or exotic in origin; and Biosafety level 4 (BSL-4) agents (exotic agents that pose a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available). Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, U.S. Department of Health and Human Services, (revised December 2009) p. 4.

[26] Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, July 2009, p. 96.

All three Services required periodic internal inspections:

- Army regulation required a Department of the Army Inspector General (DAIG) inspection every 24 months.
- The Navy's Bureau of Medicine and Surgery (BUMED) Inspector General conducted inspections at Navy laboratories every 36 months.
- The Air Force Materiel Command Inspector General conducted the inspection at its single facility every 36 months.

Supplementing the DAIG's efforts were the Army Materiel Command Surety Division and the Army Medical Command; both conducted periodic inspections or staff assistance visits during a year when the DAIG inspection team was not scheduled. Both entities used different compositions of teams, made observations or findings differently, and closed recommendations using different methods, as described below.

The varying missions, sizes, and vulnerabilities of the BSAT laboratories required an inspection approach that was customized according to the unique characteristics of the laboratory. We found, however, that beyond considering unique laboratory characteristics, three factors contributed to noncompliance with existing guidance and Federal regulations and risked significant, if not dangerous, lapses in biosafety and biosecurity practices:

- non-uniform training of inspectors,
- team composition for BSAT laboratory inspections, and
- failure to track internal and external inspection findings and recommendations and ensure improvements were made and were sustained.

## *Training, Expertise, and Team Composition*

Service inspection teams varied in terms of their training, team member composition, and professional qualifications; as a result, they risked not having the overall capability that a specific inspection mission required. An Army subordinate command's inspection entity had no formal training for BSAT inspectors, while the DAIG inspection team included two former BSAT facility laboratory personnel. The Air Force Materiel Command's Inspector General's team had no full-time inspectors who were subject matter experts with biological materials, but augmented its team with subject matter experts. However, in some cases, the expert's area of expertise was not BSAT. Moreover, supplemental training that the Air Force provided these augmentees did not focus on criteria relative to BSAT.

The Defense Science Board has concluded that while standardized training could educate a subject matter expert regarding the inspection procedures and criteria, it cannot easily substitute for professional experience or expertise. Personnel at some laboratories we visited believed that the utility of the inspections by different teams varied. An experienced researcher/inspector interviewed reported that an inspection by a team with inexperienced inspectors provided insufficient capability to implement inspection standards. He said that inspectors simply referred to checklists prepared on the basis of regulations without assessing the overall biosafety and biosecurity in the local institutional context.

An inspection by personnel with laboratory research experience, on the other hand, may more effectively contribute to the intended outcome of the inspection. However, in the interview mentioned above, the researcher/inspector stated that relatively inexperienced inspectors without the necessary scientific, technical, or research background could not be assured of making the substantive recommendations leading to necessary improvements in laboratory safety and operations. Moreover, an inspection review of particular protocols and procedures would be difficult for an inspection team lacking personnel who were knowledgeable and experienced in the specific type of BSAT research being inspected.

## *Tracking Inspection Results*

We did not observe any Service inspection entities that had a formal process for conducting tracking of their own or other inspection entities' findings and recommendations after a recommendation was closed. We found no evidence that Service inspection agencies conducted continuous follow-up of high-risk BSAT laboratory issues previously identified, such as transferring BSAT material from a high containment laboratory[27] to a non-high containment laboratory. For example, a DAIG inspection report at Dugway Proving Ground did not include a review of the laboratory's protocols for inactivating, shipping, or transferring BSAT, despite these issues contributing to a failing deficiency in a Dugway inspection report issued in 2011.

Similarly, our team observed a Navy BUMED inspection of an overseas DoD BSAT laboratory and noted that, although inspection personnel conducted a review of the laboratory's practices consistent with Service guidance, the team did not examine all of the deficiencies identified in a 2012 oversight report that resulted in the laboratory being temporarily shut down.

[27] High or maximum containment laboratories are those that work with dangerous biological pathogens and have a building BSL of either 3 or 4. (GAO-09-547)

Tracking corrective actions is a key component of program management at the laboratory, the Service component, and senior DoD levels. Although ongoing corrective actions should be implemented at the local level, these actions require management oversight to ensure that the desired effect is achieved and sustained. To effect enterprise-wide tracking of the implementation of BSAT standards, processes, and procedures, and corrective actions taken after inspections may well require a senior DoD oversight group. While the Secretary of the Army, as Executive Agent for the DoD BSAT Biosafety Program, has tasking authority for the technical review, inspection, and harmonization of biosafety protocols and procedures across the Department, it lacks the authority for DoD-wide tracking of corrective actions taken after inspections, and for ensuring that implementation of corrective actions has been effective.

Since the Department has lacked a centralized coordinating entity, it did not have the management capability or authority to ensure that Services' BSAT laboratory management and oversight functions implemented all guidance and technical requirements. Furthermore, no single DoD management entity had the authority and responsibility to oversee the effectiveness of Service BSAT laboratory inspections. This would include tracking high-risk biosafety and biosecurity issues over time and elevating unresolved issues to the appropriate DoD management level.

## *DoD Review Committee Findings and Recommendations*

We identified that the Dugway Proving Grounds Life Science Division had a history of errant pathogen shipments (see Appendix H), indicating the need for a thorough scientific review of the processes and procedures for handling BSAT. The DoD Review Committee's subsequent recommendation regarding audits and inspections[28] seeks to ensure that such a scientific review is addressed in the future, and that an incident, such as the inadvertent shipping of anthrax by Dugway Proving Ground (detailed in the 2015 Review Committee's report[29]), is avoided.

However, the Review Committee's recommendation may be inappropriate as written because it requires DoD audit and/or inspection agencies, such as Military Service Inspectors General, to provide scientific peer review,[30] and it recommends that inspection teams include major command staff, actions that may violate inspection agency independence guidance. Service component Inspector General

[28] Review Committee recommendations B.d, Audits and Inspections, page 21.

[29] Review Committee Report: Inadvertent Shipment of Live Bacillus Anthracis Spores by DoD, Committee for Comprehensive Review of DoD Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* Spores, July 13, 2015.

[30] The scientific peer review process focuses on evaluation of proposals for scientific and technical merit, and includes considerations of conflict of interest, overall impact of the research, significance, innovation, strategy and methodology, and the scientific environment in which the work will take place.

requirements for independence discourage actions that may cause inspector independence to be questioned.[31] External audits and inspections should be impartial and not be led by or include staff from the major command surety program managers, or anyone else in the chain of command of the entity being inspected. An alternative approach might include scientists from one DoD BSAT laboratory site providing expertise to conduct peer review of protocols and procedures under consideration for use at other DoD BSAT laboratory sites.

The failure of the current DoD inspection process to uncover and rectify more than a decade of pathogen inactivation and shipping issues at Dugway Proving Ground suggests that a DAIG inspection every two years, which has been its practice, may be insufficient to provide timely and thorough oversight of important BSAT issues. Furthermore, the less-frequent oversight inspections by the Navy and the Air Force Inspectors General may, therefore, also allow biosafety and biosecurity deficiencies to go undetected.

## Conclusion

DoD did not consistently manage biosafety and biosecurity inspections or assess their efficacy for BSAT laboratories' safety and operations. As a result, some laboratories remained vulnerable to biosafety and biosecurity lapses, such as Dugway's inadvertent shipments of live agents. A single DoD entity with appropriate authority could:

- ensure inspection entities' processes and procedures are appropriate;
- provide an additional level of oversight to ensure that successful implementation of corrective actions are sustained over time;
- track, report, and cross-share findings, deficiencies, and best practices from inspections and internal assessments; and
- report progress and identify barriers to correcting vulnerabilities to the appropriate DoD management level.

[31] Army Regulation 20-1, "Inspector General Activities and Procedures;" Secretary of the Navy Instruction 5430.57G, "Missions and Functions of the Naval Inspector General;" Air Force Instruction 90-201, "The Air Force Inspection System."

# Recommendations, Management Comments, and Our Responses

## *Recommendation 1.a*

**Deputy Secretary of Defense appoint a single Executive Agent responsible for biosafety and biosecurity.**

### *Deputy Secretary of Defense Comments*

The Under Secretary of Defense for Acquisition, Technology, and Logistics, responding for the Deputy Secretary of Defense, agreed. He noted that the Secretary of the Army was designated as the Executive Agent for the Department of Defense Biological Select Agent and Toxins Biosafety Program in a July 23, 2015, memorandum, and stated that the Executive Agent authority would be expanded to oversee both the biosafety and biosecurity programs for the Department. The Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics has been directed to draft and coordinate a DoD Directive outlining the roles and responsibilities of the Army Executive Agent.

### *Our Response*

Comments from the Under Secretary of Defense for Acquisition, Technology, and Logistics meet the intent of the recommendation. We request that the draft DoD Directive be forwarded to us for review.

## *Recommendation 1.b*

**Deputy Secretary of Defense direct the Executive Agent for Biosafety and Biosecurity to:**

**(1) Conduct standardized oversight and inspections in accordance with applicable Federal regulations of Department of Defense Biological Select Agent and Toxins laboratories.**

**(2) Track all internal and external inspection results and report status of all findings, recommendations, and actions taken to address deficiencies to the appropriate Department of Defense management level.**

**(3) Develop and implement training for Biological Select Agent and Toxins laboratory inspectors and subject matter expert inspection team augmentees.**

**(4) Ensure that all personnel included in inspection teams have sufficient scientific expertise and experience.**

### *Deputy Secretary of Defense Comments*

The Under Secretary of Defense for Acquisition, Technology, and Logistics, responding for the Deputy Secretary of Defense, agreed. He stated that the Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD Executive Agent for the DoD BSAT Biosafety and Biosecurity Program. The roles identified in this recommendation are listed in the draft directive.

### *Our Response*

Comments from the Under Secretary of Defense for Acquisition, Technology, and Logistics meet the intent of the recommendation. We request that the draft DoD Directive be forwarded to us for review.

# Finding 2

## Technical and Scientific Peer Review

DoD BSAT laboratories did not consistently have internal and external technical and scientific peer review functions.

This occurred because there was no single DoD-wide biosafety and biosecurity entity with the authority to manage and coordinate technical and scientific peer reviews.

As a result, DoD BSAT laboratories independently used protocols that were not validated for their intended use, which potentially posed significant risks to public health and safety.

## Discussion

### *Biosafety and Biosecurity in Life Sciences Research*

The HHS announced on October 4, 2007, the formation of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. The purpose of this Task Force was to propose options and recommendations to improve biosafety and biocontainment oversight of research and research-related activities at high and maximum containment laboratories in the United States, but without hindering the progress of science.

The Task Force recommendations included requiring a trained biosafety professional at each institution responsible for oversight of all biosafety and biocontainment programs. It also recommended establishing an appropriately constituted review body that performs a thorough risk assessment of all laboratory protocols potentially requiring high containment. Further recommendations included not only training in biosafety for all research, managerial, and support personnel at these institutions, but also a centralized, integrated information sharing mechanism for analyzing incidents and sharing information and lessons learned.

Defense Department guidance on institutional level biosafety[32] requires a Biological Safety Committee composed of representatives from occupational health, industrial hygiene, facility maintenance, and safety that meets at least quarterly. At a minimum, this committee is required to review the results of compliance inspections. Defense Department guidance on biosecurity[33] has no requirement for an institutional level review body to address biosecurity issues.[34] Additionally, DoD does not have guidance that requires DoD-level reporting and tracking of physical security and personnel reliability incidents. Nor is there guidance that incorporates biosecurity lessons learned into ongoing BSAT laboratory security practices and oversight inspections.

## *Biosafety and Biosecurity Evaluation Observations*

Implementation of the DoD guidance on the use of Biological Safety Committees at the level of laboratories was mixed. One large DoD BSAT laboratory inspected had an Institutional Biosafety Committee that met regularly to review scientific protocols, inspection results, and other biosafety matters. Managers at another large DoD BSAT laboratory had no such committee, but believed that there was a need to implement one to review protocols. Researchers at another small DoD BSAT laboratory held monthly biosafety committee meetings to discuss protocols and laboratory repair issues. This committee included scientific researchers and personnel representing industrial hygiene, occupational health, information management, and physical security. There was no forum at any laboratory inspected to discuss biosecurity issues.

## *Anthrax Inactivation Protocol Review Issues*

The resulting investigation of the accidental exposure to anthrax that occurred at the CDC in Atlanta, Georgia, in June 2014, had conclusions that were relevant for DoD BSAT laboratory oversight, particularly at Dugway Proving Ground. The CDC investigations found that the overriding factor contributing to the CDC incident was the lack of an approved, written study plan that had been reviewed by CDC senior staff, such as laboratory, branch, or division scientific leadership, to ensure that the pathogen research design plan was appropriate and met all laboratory

[32] Department of Defense Manual 6055.18-M, "Safety Standards for Microbiological and Biomedical Laboratories," May 11, 2010, page 13.

[33] Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006.

[34] Laboratory biosecurity is defined as "the protection of, control of, and accountability for high-consequence biological agents and toxins and critical relevant biological materials and information within laboratories to prevent unauthorized possessions, loss, theft, misuse, diversion, or intentional release. Biosecurity is achieved through an aggregate of practices including the education and training of laboratory personnel, security risk assessments, BSAT access controls, physical security (facility) safeguards, and the regulated transport of BSAT." Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, "Report of the Working Group on Strengthening the Biosecurity of the United States," October 1, 2009, pages 143/149.

safety requirements.[35] Three of the CDC recommendations are relevant to the DoD because they provide a roadmap for how a leading federal BSAT research agency deals with multiple biosafety lapses:

1. CDC announced plans to establish a lead laboratory science position accountable for laboratory safety across the CDC.
2. CDC announced that it would institute a process where all procedures, techniques, or manufacture methods being considered would be formally reviewed and evaluated to assess their risk.
3. CDC stated it would establish an external advisory committee to provide ongoing advice and direction for laboratory quality and safety.

The Life Sciences Division at Dugway Proving Ground had an Institutional Biological Committee that met quarterly or would conduct online evaluations as needed, based on the project workload.[36] All researchers were required to present and acquire approval for new projects or procedures that used BSAT.

## *Review Committee Findings and Recommendations*

The Review Committee's report identified laboratory safety protocols and procedures at all four DoD laboratories they visited,[37] but found that the laboratories were using procedures that had not been standardized across the laboratories. The Review Committee also observed deviations from protocols that had not undergone a peer review. If the protocols had undergone a peer review, the biosafety vulnerabilities that were identified by the Review Committee may have been detected. Furthermore, the committee found that some internally established procedures and protocols lacked technical rigor.

In response to these findings, the Review Committee made several recommendations to DoD to ensure that scientific and technical components were considered by internal and external audits, and that more information sharing took place between laboratories. As stated in Finding 1 on page 19 (DoD Review Committee Findings and Recommendations), the recommendation regarding peer review[38] may be difficult to implement as written because of Service component Inspector General requirements to maintain inspection agency independence.[39]

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[35] "Report on the Potential Exposure to Anthrax," Centers for Disease Control and Prevention, July 11, 2014, page 8.

[36] The Dugway Proving Ground Institutional Biological Committee consisted of the Life Sciences Division Biosafety Officer, the Life Sciences Division Chief, representatives from the Dugway Proving Ground Safety Office, the Scientific Technical Director, and may include representatives from the clinic, industrial hygiene, support contractors, installation surety, the command office, and community, state, and local health agencies. The Institutional Biological Committee's responsibilities included assisting in the development and review of the deliberate risk assessment and reviewing and implementing local policies.

[37] The Review Committee visited Edgewood Chemical Biological Center, Maryland; the United States Army Medical Research Institute for Infectious Diseases, Maryland; the Naval Medical Research Center, Maryland; and Dugway Proving Ground, Utah.

[38] Review Committee Recommendations B, Peer Review, page 20.

[39] See discussion on page 19 (DoD Review Committee Findings and Recommendations) of this report.

Scientific peer review[40] functions are rarely associated with audit functions within DoD or other Federal agencies. For example, peer review at the National Institutes of Health is an integral part of reviewing scientists' grant applications.[41] The peer review process focuses on evaluation of proposals for scientific and technical merit, and includes considerations of conflicts of interest, overall impact of the research, significance, innovation, strategy and methodology, and the scientific environment in which the work will take place.

According to the Review Committee's report,[42] the contributing causes to the *Bacillus anthracis* spore inactivation failures at Dugway Proving Ground included the use of scientific protocols that had not been subjected to peer review that validated their intended use. Our review of the capabilities of Service-level inspection teams determined that it would be unrealistic to expect that an internal (major command) or external (Service component inspection agency) audit team would have the scientific expertise to validate the numerous protocols normally in use, during an inspection that occurs every few years and lasts for only several days.

As a result of these findings, we concluded that DoD at an enterprise level, specifically the Executive Agent for the DoD BSAT Biosafety and Biosecurity Program (Recommendation 1.a), should be responsible for managing the scientific and technical review, and harmonization, of both biosafety and biosecurity components of all current scientific protocols and procedures and future modifications. Additionally, an independent DoD BSAT inspection component should periodically inspect all DoD BSAT laboratories according to inspection criteria required by applicable regulations.

The Review Committee recommended that scientific and technical review of protocols and procedures be improved, and that inspections include an assessment of the processes and procedures for handling select agents.[43] The Deputy Secretary of Defense has established an Executive Agent for the DoD BSAT Biosafety Program that is intended to accomplish this for biosafety protocols. To enhance the effectiveness of safety and security of the overall BSAT laboratory research program, these Executive Agent responsibilities should include biosecurity issues as well.

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40 A peer review is a process that includes an independent assessment of the technical scientific merit of research by peers who are scientists with knowledge and expertise equal to that of the researchers whose work they review according to a GAO review of the peer practice in Federal agencies, GAO/RCED 99-99.

41 Peer Review Process, National Institutes of Health, accessed October 2, 2015 at http://grants.nih.gov/grants/peer_review_process.htm.

42 Review Committee Report, pages 5-6.

43 Review Committee Report, pages 20-21 (Peer Review, Audits and Inspections).

## Conclusion

Not all military installations had established institutional biosafety committees in accordance with DoD guidance.[44] Furthermore, none of the laboratories had internal committees that considered both biosafety and biosecurity issues. Additionally, we found in our review that some Service inspection teams lacked the technical and scientific expertise to provide technical review of protocols and procedures.

The DoD BSAT laboratory research program would benefit from a single DoD-wide leadership entity with two capabilities: a management function and an inspection function. The management function responsibility would include coordinating and harmonizing a continuous process of scientific and technical peer review of both its biosafety and biosecurity components. In addition, the inspection function (as described in Recommendation 1.b) would evaluate BSAT protocols and procedures to ensure that each has been reviewed and approved by DoD scientific and technical peer review.

## Recommendations, Management Comments, and Our Responses

### *Recommendation 2.a*

**Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity (Recommendation 1.a) to implement an external technical and scientific peer review function that addresses both biosafety and biosecurity issues to support all Department of Defense Biological Select Agent and Toxins laboratories.**

#### *Deputy Secretary of Defense Comments*

The Under Secretary of Defense for Acquisition, Technology, and Logistics, responding for the Deputy Secretary of Defense, agreed. He stated that the Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD Executive Agent for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

[44] Department of Defense Manual 6055.18-M, "Safety Standards for Microbiological and Biomedical Laboratories," May 11, 2010, page 13.

### *Our Response*

Comments from the Under Secretary of Defense for Acquisition, Technology, and Logistics meet the intent of the recommendation. We request that the draft DoD Directive be forwarded to us for review.

## *Recommendation 2.b*

**Under Secretary of Defense for Acquisition, Technology, and Logistics issue guidance that all Department of Defense Biological Select Agent and Toxins laboratories implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity issues.**

### *Under Secretary of Defense for Acquisition, Technology, and Logistics Comments*

The Under Secretary of Defense for Acquisition, Technology, and Logistics agreed. He stated that the Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD Executive Agent for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

### *Our Response*

Comments from the Under Secretary of Defense for Acquisition, Technology, and Logistics meet the intent of the recommendation. We request that the draft DoD Directive be forwarded to us for review.

# Finding 3

## Laboratory Inspections

Multiple, missing, and duplicative inspections at DoD BSAT laboratories by different agencies using different standards were not in accordance with Executive Order No. 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," July 2010.

This occurred because there was no single DoD coordinating function to ensure internal DoD BSAT laboratory inspections occurred at the required intervals, used appropriate standards, and were coordinated externally with the CDC and APHIS.

As a result, some BSAT laboratory inspections occurred irregularly or not at all. In addition, inspection frequencies and intervals, and the use of varying inspection standards could interfere with scientific research performance, putting the warfighter and public at risk of inadequate detection of, and protection from, biological pathogens.

## Discussion

Executive Order No. 13546, 75 *Federal Register* 130 (2010),[45] directed harmonization of BSAT security policies and practices and coordination of related oversight activities of the Federal Government. In this Executive Order, the President directed heads of executive departments and agencies to articulate a mechanism for coordinated and reciprocal inspection of, and harmonized administrative practices for, facilities registered with the Select Agent Program.

The Army, Navy BUMED, and Air Force signed memorandums of agreement or understanding with CDC and APHIS to conduct BSAT laboratory inspections to reduce the burden on registered entities and facilitate the coordination of oversight efforts. All three Service IGs and CDC and APHIS agreed to coordinate inspections and other site visits to regulated entities within the resources available to all parties. However, in practice, not all Service IGs and CDC and APHIS inspection teams coordinated their visits or activities to reduce the burden on the inspected entity. For example, the Navy BUMED IG did not coordinate with CDC and APHIS, resulting in two inspections in less than one month. In another instance, the Navy BUMED IG did not coordinate with another Service to gain access to a

[45] Executive Order No. 13546, 75 *Federal Register* 130, "Optimizing the Security of Biological Select Agents and Toxins in the United States," July 8, 2010.

Navy BSAT laboratory that was housed within an Army BSAT laboratory, resulting in the laboratory not being inspected by a Service IG in more than 3 years. The Air Force Materiel Command IG stated that they were unable to coordinate with CDC and APHIS.

We also observed overlap and duplication, even when the Service IG and CDC and APHIS inspection teams coordinated a joint inspection of a DoD BSAT laboratory. At the site, each inspection agency independently reviewed most of the same standard operating procedure documents, required many of the same biosafety training records, and simultaneously conducted biosafety level laboratory and inventory inspections. While the two inspection teams met at the end of each day to share findings and potential deficiencies, they published separate reports requiring separate responses from the inspected entity. Coordinated Service IG and CDC and APHIS inspection schedules reduced the burden on registered entities. The current combined inspections lacked coordination of oversight inspection efforts and results, and, therefore, do not comply with the intent of Executive Order 13546.

Our evaluation noted that each Service developed unique Service-level guidance based on DoD Instruction 5210.89.[46] Each Service IG conducted inspections focused on regulatory compliance with their respective Service-level guidance. Since Service-level guidance was not standardized, these inspections were also not standardized. For example, Services implemented the security requirements of DoD Instruction 5210.89 differently.

Laboratory managers at several DoD BSAT laboratories gave examples of how the administrative burden of complying with regulations, guidance, and BSAT oversight inspections that used different interpretations of standards was onerous, and, in several cases, even limited their scientific research. A manager at one Service's laboratory, for example, described an inspection by an untrained inspector who used criteria that were not included in that Service's guidance. Additionally, the Navy overseas tropical medicine research laboratories have a mission of identifying unique infectious diseases in the local population, ultimately enhancing the protection of U.S. forces. Due to restrictive BSAT regulations concerning pathogen access, we learned that they have had to cease this type of BSAT research support at several of their laboratories.

[46] "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006.

### *Bacillus anthracis Spore Inactivation Protocol Review Issues*

The *Bacillus anthracis* spore inactivation incident involving Dugway Proving Ground, identified in May 2015, was comparable in certain aspects to the June 2014 CDC spore inactivation incident at CDC, which is described in Finding 2 of this report. Dr. Thomas Frieden, CDC Director, testified before Congress in July 2014 that the CDC intended to improve laboratory safeguards by incorporating lessons learned from the CDC laboratory inactivation protocol incident into the CDC's Division of Select Agents and Toxins regulatory program.[47] These lessons learned included the formal review of all procedures and techniques to assess their risk.[48] In July 2015, the Review Committee identified the primary systemic issue responsible for Dugway's failures in the preparation of inactivated *Bacillus anthracis* spores as the lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures.[49] As indicated by Dr. Frieden's testimony, the Division of Select Agents and Toxins regulatory program, for which CDC and APHIS are responsible on behalf of the Federal Government, intended to emphasize that future BSAT practices have validated inactivation protocols and use improved testing to verify inactivation of pathogens prior to distribution.[50]

## Conclusion

Inspections help ensure safety and compliance with regulations and are necessary for oversight of the DoD BSAT biosafety and biosecurity program. However, the lack of a standardized and coordinated approach between DoD and CDC and APHIS resulted in multiple, overlapping, and duplicative inspections. DoD BSAT laboratory inspections by these agencies that consist of coordinated efforts to conduct an inspection at the same time, following the same criteria, would also help reduce the frequency of overlapping inspections and the resulting administrative burden on BSAT laboratory management and research performance.

47 HHS Testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, "Review of CDC Anthrax Lab Incident," July 16, 2014.

48 See discussion page 7 (Anthrax Inactivation Incident at the Centers for Disease Control and Prevention, June 2014) of this report.

49 Committee for Comprehensive Review of DoD Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* Spores, "Review Committee Report: Inadvertent Shipment of Live *Bacillus anthracis* Spores by DoD," July 13, 2015.

50 HHS Testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, "Review of CDC Anthrax Lab Incident," July 16, 2014.

# Recommendations, Management Comments, and Our Responses

## *Recommendation 3*

**Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity to:**

**a. Serve as the single Department of Defense point of contact with the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service for coordinating and participating in inspections of Department of Defense Biological Select Agents and Toxins laboratories.**

**b. Develop and implement an agreement with the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service for scheduling combined inspections of Department of Defense Biological Select Agents and Toxins laboratories.**

**c. Define combined inspection criteria and guidance with the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service for Department of Defense Biological Select Agents and Toxins laboratories.**

**d. Serve as the formal communication entity with the Federal Select Agent Program regarding findings and lessons learned from the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service relevant to the Department of Defense Biological Select Agents and Toxins program.**

### *Deputy Secretary of Defense Comments*

The Under Secretary of Defense for Acquisition, Technology, and Logistics, responding for the Deputy Secretary of Defense, agreed. He stated that the Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD Executive Agent for the DoD BSAT Biosafety and Biosecurity Program. The roles identified in this recommendation are listed in the draft directive.

### *Our Response*

Comments from the Under Secretary of Defense for Acquisition, Technology, and Logistics meet the intent of the recommendation. We request that the draft DoD Directive be forwarded to us for review.

# Finding 4

## Site-Specific Laboratory Vulnerability Assessment Consideration

Some service inspectors did not review site-specific BSAT laboratory vulnerability assessments during BSAT laboratory inspections to ensure previous shortcomings identified had been mitigated. Furthermore, some laboratories had not ever conducted vulnerability assessments or had not conducted them annually as required.

This occurred because DoD did not ensure that vulnerability assessments were always performed. Also, the DoD Instruction that establishes requirements for vulnerability assessments does not require that site-specific vulnerability assessment findings be considered during DoD laboratory inspections.

As a result, not all identified site-specific vulnerabilities were known and examined by DoD BSAT inspectors. Therefore, DoD management could not be confident that the full range of threats to the security of personnel and resources were addressed by DoD BSAT laboratory inspection programs and that security risks from unique vulnerabilities had been mitigated.

## Discussion

DoD Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006, establishes requirements for vulnerability assessments.[51] The instruction defines a vulnerability assessment as a DoD, command, or unit-level evaluation (assessment) to determine vulnerability of an installation, unit, exercise, port, ship, residence, facility, or other site to attack from the full range of threats to the security of personnel and resources. A security vulnerability assessment identifies areas of improvement to withstand, mitigate, or deter acts of violence or terrorism.[52]

[51] Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006, page 2.

[52] Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006, page 11.

DoD Instruction 5210.89 requires that vulnerability assessments be reviewed annually and updated as required based on changes to the threat or security posture of the facility.[53] Furthermore, DoD Instruction 5210.89 requires that an appropriate risk management process be used to assess the threat and vulnerabilities, and provide the Responsible Official[54] or facility commander or director with courses of action to mitigate the vulnerabilities or provide justification for risk acceptance.[55] However, this instruction does not require the consideration of site-specific vulnerability assessments for planning or conducting BSAT laboratory inspections. The absence of guidance in the primary directive for BSAT laboratory security to consider site-specific vulnerability assessments for planning or conducting BSAT laboratory inspections resulted in dissimilar or no use of vulnerability assessments during DoD BSAT laboratory inspections.

We observed that one Service considered vulnerability assessments while conducting inspections, while two Services did not. We also observed that installation vulnerability assessments had been conducted at some, but not all, of the BSAT facilities we visited. One Service's command staff reported that one of their BSAT laboratories had not ever had a vulnerability assessment conducted, while a program manager at another site said that an installation vulnerability assessment existed, but the vulnerability assessment did not include the BSAT laboratory. Refer to Appendix M for a listing of Service vulnerability assessment requirements.

DoD Instruction 5210.89 states that vulnerability assessments are the mechanism used by DoD to determine vulnerability with respect to the full range of threats to the security of personnel and resources, and to identify areas of improvement to withstand, mitigate, or deter acts of violence or terrorism. Therefore, inspection entities that did not use, or did not have access to, vulnerability assessments risked not providing oversight for necessary security measures to withstand, mitigate, or deter acts of violence or terrorism.

[53] Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006, page 33.

[54] According to the Responsible Official Resource Manual, 7 C.F.R. Part 331, 9 C.F.R. part 121, and 42 C.F.R. Part 73, October 2014, the Responsible Official is the individual at the entity who is accountable for entity compliance with the Select Agent Regulations. The Responsible Official must be approved by the Federal Select Agents Program, be familiar with the regulations, have the authority to act on behalf of the entity, maintain the required records, and conduct annual inspections.

[55] Department of Defense Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006, page 13.

## Conclusion

The applicable DoD Instruction does not require that site-specific vulnerability assessments be reviewed during DoD BSAT laboratory inspections, while some sites had no or infrequent vulnerability assessments. Therefore, Service inspectors did not consistently perform this review, or verify that a vulnerability assessment existed, while inspecting BSAT laboratories.

As a result, DoD laboratory inspectors were not consistently aware of all site-specific vulnerabilities and DoD management could not be confident that mitigation of the full range of threats to the security of personnel and resources had been undertaken.

## Recommendations, Management Comments, and Our Responses

### *Recommendation 4.a*

**Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity to implement criteria for inclusion of site-specific security vulnerability assessment findings into Department of Defense Biological Select Agent and Toxins laboratory biosafety and biosecurity inspections.**

#### *Deputy Secretary of Defense Comments*

The Under Secretary of Defense for Acquisition, Technology, and Logistics, responding for the Deputy Secretary of Defense, agreed. He stated that the Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD Executive Agent for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

#### *Our Response*

Comments from the Under Secretary of Defense for Acquisition, Technology, and Logistics meet the intent of the recommendation. We request that the draft DoD Directive be forwarded to us for review.

## *Recommendation 4.b*

**Under Secretary of Defense for Acquisition, Technology, and Logistics develop implementing guidance that requires site-specific laboratory security vulnerability assessment findings be included during Biological Select Agent and Toxins laboratory inspections.**

### *Under Secretary of Defense for Acquisition, Technology, and Logistics Comments*

The Under Secretary of Defense for Acquisition, Technology, and Logistics agreed. He stated that the Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD Executive Agent for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive. He also indicated that the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs will review DoD Instruction 5210.88 to reinforce this issue.

### *Our Response*

Comments from the Under Secretary of Defense for Acquisition, Technology, and Logistics meet the intent of the recommendation. We request that the draft DoD Directive and the results of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs review be forwarded to us for review.

# Appendix A

## Scope and Methodology

We conducted this assessment from December 2014 through April 2016 in accordance with the "Quality Standards for Inspections and Evaluations," published in January 2013 by the Council of Inspectors General on Integrity and Efficiency. The objective of this work was to assess the uniform application of biosafety and biosecurity policy and requirements across DoD component laboratories that are conducting research using BSAT. We believe that the evidence we obtained is sufficient and appropriate and provides a reasonable basis for our conclusions with regard to our assessment objective.

This assessment focused on DoD component compliance with, as well as the effective implementation of, DoD Directive 5210.88, "Safeguarding Biological Select Agents and Toxins," February 11, 2004; DoD Instruction 5210.89, "Minimum Security Standards for Safeguarding Biological Select Agents and Toxins," April 18, 2006; Department of Defense Manual 6055.18-M, "Safety Standards for Microbiological and Biomedical Laboratories," May 11, 2010; and other relevant statues and regulations. The assessment also included a review of Office of Secretary of Defense-level policy development, implementation, and oversight, as well as observations of different types of inspections of a sample of Military Department facilities that have custody of BSAT.

We limited our scope by excluding an inspection of physical security or biological safety and security programs at BSL 3 or 4 laboratories and Special Access Programs with a biological safety and security component. We did not review how DoD biological laboratories apply regulations issued by the U.S. Departments of Agriculture, Health and Human Services, and Transportation.

To assess our objectives, we collected and reviewed documents from the Air Force Materiel Command; Army Medical Command; Army Research, Development, and Engineering Command; Army Test and Evaluation Command; Office of the Under Secretary of Defense for Acquisition, Technology and Logistics; Centers for Disease Control and Prevention Division of Select Agents and Toxins; Defense Threat Reduction Agency; Defense Health Board; Defense Science Board; Department of the Army Inspector General; and the Navy Bureau of Medicine and Surgery. We also collected documents at facilities, such as Dugway Proving Ground, ECBC, USAMRIID, Naval Medical Research Center, Naval Surface Warfare Center (Dahlgren Division), Wright Patterson Air Force Base, and Naval Medical Research Unit #6.

We conducted interviews throughout the entire period of our assessment with officials from each component as well as the laboratorians and safety and security officials in each facility we visited. We conducted interviews throughout the entire period of our assessment with officials from each Service inspection agency or component as well as the laboratorians and safety and security officials in each facility we visited.

We identified related previous program reviews or reports from the Defense Science Board, the Defense Health Board, Federal Experts Security Advisory Panel, the Government Accountability Office, the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, and the Working Group on Strengthening the Biosecurity of the United States.

We considered locations both within and outside the United States. We chose six locations for site visits based on two criteria: one, the site was being inspected by either the CDC or a component inspection entity during our data collection timeframe; and, two, the site was performing research using BSAT or had used BSAT in the past.

We visited the following locations:

- U.S. Army Dugway Proving Ground, Dugway, Utah,
- Dahlgren Naval Surface Warfare Center, Dahlgren, Virginia,
- U.S. Army Edgewood Chemical Biological Center, Aberdeen, Maryland,
- Naval Medical Research Unit #6, Lima, Peru,
- U.S. Army Medical Research Institute for Infectious Diseases, Fort Detrick, Frederick, Maryland,
- Wright Patterson Air Force Base, Dayton, Ohio.

## Limitations

We did not encounter any limitations.

## Use of Computer Processed Data

We did not use computer-processed data to perform this assessment.

## Use of Technical Assistance

We did not require technical assistance to perform this assessment.

# Appendix B

## Prior Coverage

### *GAO*

High-Containment Laboratories: National Strategy for Oversight Is Needed. GAO-09-574. Washington, D.C.: September 21, 2009.

### *DoD*

Defense Science Board, Task Force on Department of Defense Biological Safety and Security Program, May 2009

### *Interagency Groups*

Report of the Working Group on Strengthening the Biosecurity of the United States, 2009

Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, July 2009

# Appendix C

## Previous Recommendations of the Federal Experts Security Advisory Panel

The FESAP successfully completed the tasks enumerated by Executive Order 13546 "Optimizing the Security of Biological Select Agents and Toxins." The FESAP issued a report in November 2010 with recommendations on the following issues:

- Designation of Tier 1 BSAT,
- Reduction in the number of BSAT on the Select Agent List,
- Establishment of appropriate practices to ensure reliability of personnel with access to Tier 1 BSAT at registered facilities,
- Establishment of appropriate practices for physical and cyber security for facilities that possess Tier 1 BSAT,
- Other emerging policy issues relevant to the security of BSAT.

### *Highlights of the FESAP's Recommendations*

#### *Designation of Tier 1 BSAT*

The FESAP identified 20 criteria for use in determining appropriate Tier 1 BSAT, including the ability to produce a mass casualty event or devastating effects to the economy, communicability, low infectious dose, and a history of or current interest in weaponization based on threat reporting. The FESAP proposed the designation of the following 10 select agents as Tier 1 BSAT:

- *Bacillus anthracis*,
- *Burkholderia mallei*,
- *Burkholderia pseudomallei*,
- Ebola virus,
- Foot-and-mouth disease virus,
- *Francisella tularensis*,
- Marburg virus,
- *Variola major* virus,
- *Variola minor* virus,
- *Yersinia pestis*.

At this time, the FESAP does not recommend including botulinum toxin and/or toxin-producing strains of *Clostridium botulinum* on the list of Tier 1 BSAT, and recommended that HHS and USDA use the rule-making process to solicit public comment regarding their inclusion.

### *Reduction in Number of Agents on the Select Agent List*

The FESAP recommended the removal of 25 agents on the list, including 7 HHS and HHS/USDA overlap agents, 12 USDA animal agents, and 6 toxins. The HHS and HHS/USDA overlap agents recommended for removal include: *cercophithecine herpesvirus* 1 (Herpes B virus), *Coccidioides posadasii*, *Coccidioides immitis*, Eastern equine encephalitis virus (only South American genotypes), flexal virus, tick-borne encephalitis viruses (only European subtypes), and Venezuelan equine encephalitis virus (only enzootic subtypes ID and IE). Toxins recommended for removal from the select agent list include: *Clostridium perfringens* epsilon toxin, conotoxin, diacetoxyscirpenol, shiga toxin, shiga-like ribosome inactivating proteins, and T-2 toxin.

### *Establishment of Appropriate Practices to Ensure the Suitability and Reliability of Personnel who seek or have Access to BSAT*

The FESAP developed several recommendations that focus on enhancing the current security risk assessment performed by the FBI, pre-access suitability assessment at the Federal and local levels, and continued monitoring of personnel reliability at the local level. The FESAP recommended that the current security risk assessment process be enhanced and clarified to better assess disqualifiers and assess foreign nationals. The Select Agent Program should provide guidance on pre-access suitability assessments of personnel to assist local entities in identifying the qualities of suitability for personnel who seek access to BSAT. Because elements of suitability, such as credit and criminal status, can change over time, these should be periodically rechecked as part of an ongoing review of personnel reliability. Finally, the Select Agent Program should provide guidance to entities regarding self- and peer- reporting of circumstances, conditions, activities, actions, or behaviors that may pose a safety or security concern.

### *Establishment of Appropriate Practices for Physical Security and Cyber Security for Facilities that Possess BSAT*

Physical and cyber security encompass the application of operational and security equipment; personnel and procedures used to protect facilities; and information, documents, or material for preventing or responding to theft, sabotage, diversion, or other terrorist or criminal acts. For all facilities housing BSAT, the FESAP recommended the use of a Government-furnished risk assessment tool to ensure

that facilities are consistently evaluating their vulnerability to particular threats, are implementing security measures appropriate to their level of risk, and are enabling consistent inspection activities across multiple regulatory and oversight agencies. Specifically for facilities that house Tier 1 BSAT, the FESAP recommended specific, enhanced performance standards to ensure the physical and cyber security of the entity and BSAT. This enhanced security should be coordinated.

## *Recommendations from October 2015 Report*

### *1.1 Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences*

Create and strengthen a culture that emphasizes biosafety, laboratory biosecurity, and responsible conduct in the life sciences. This culture of responsibility should be characterized by individual and institutional compliance with biosafety and laboratory biosecurity regulations, guidelines, standards, policies, and procedures, and enhanced by effective training in biorisk management.

### *1.2 Appropriate Organizational and Governance Structure to Ensure Compliance with Biosafety and Biocontainment Regulations and Guidelines*

Require that all research institutions in which human, plant, and/or animal infectious agents and toxins research is conducted have an appropriate organizational and governance structure to ensure compliance with biosafety, biocontainment, and laboratory biosecurity regulations and guidelines.

### *1.3 Appropriately Constituted Review Entity*

Require that an appropriately constituted and qualified review entity validate local policies, laboratory protocols, and mitigation plans involving the inactivation, sterilization, or decontamination of biohazardous materials at research institutions.

### *1.4 Security Awareness Education Programs/Curriculum Development*

Support the development and implementation of security awareness education programs/curriculum that underscore personal responsibility for safeguarding potentially hazardous biological agents.

### *1.5 Share Information about Security Breaches that have Occurred Involving Infectious or Toxic Materials*

Emphasize the need for self and peer reporting. Discuss material protection strategies and explain exploitation of life sciences research.

### *1.6 Applied Biosafety Research*

Develop and maintain a robust, federally supported program of applied biosafety research to create additional evidence based practices and technologies and to update existing practices and operations.

### *1.7 Incident Reporting System*

Establish a new voluntary, anonymous, nonpunitive incident reporting system for research laboratories that would ensure the protection of sensitive and private information, as necessary.

### *1.8 Material Accountability Procedures*

Increase awareness about existing material accountability best practices, and support the establishment of material accountability procedures where none currently exist.

# Appendix D

## Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement, October 2015

### *Recommendations*

1. **Regulation Interpretations**: The FTAC recommends developing a formal mechanism for issuing, publicizing, and accepting requests for interpretations of the select agent regulations.
2. **Public Release of Information**: The FTAC recommends that information about BSAT research, including laboratory incidents, be periodically provided to the public, and that Federal BSAT laboratories adopt, to the maximum extent feasible, a policy of transparency regarding both the agents used and laboratory incidents.
3. **Sharing Best Practices**: The FTAC recommends members of the regulated community establish a mechanism for sharing best practices.
4. **Individual-based Security Risk Assessments**: The FTAC recommends that in the absence of specific information indicating otherwise, individuals who have been granted access to select agents or toxins at one BSAT institution be able to move to another BSAT institution without having to wait for a new security risk assessment.
5. **Emergency Situations**: The FTAC recommends development of a mechanism to expedite approvals or to relax Federal Select Agent Program (FSAP) requirements in response to time-urgent emergency situations.
6. **Inventory Control Requirements**: The FTAC recommends retaining requirements to maintain inventories of samples containing biological select agents and toxins, while ensuring that BSAT institutions are not requested to characterize biological agents quantitatively.
7. **Consistency of Inspections**: The FTAC recommends development of an approach to improve the consistency of the inspection process across inspectors, inspecting agencies, and inspected sites.
8. **Improve Customer Service in Communicating with Regulated Entities**: The FTAC recommends improving communication before and after site inspections and improving the timeliness of inspection reports.
9. **Categorize Inspection Findings**: The FTAC recommends developing a system to categorize findings on inspection reports.
10. **Appeals Process**: The FTAC recommends expanding the appeals process for institutions to adjudicate disputed findings in inspection reports.

11. **Peer Advisory Mechanism**: The FTAC recommends creating an expert panel or Federal Advisory Committee to serve as an external group that could share best practices or make recommendations to the FSAP.
12. **International Engagement**: The FTAC recommends international engagement to explore harmonization of pathogen security standards and ensure understanding of the rationale for and implementation of the select agent regulations or equivalent standards by collaborating foreign governments.
13. **Guidance for Customs Inspectors**: The FTAC recommends providing better training and guidance for customs inspectors who process BSAT shipments.

## *Issues for Further Analysis*

A. **Institutional Scope of Regulation**: Consider whether to bring all bioscience institutions, or at least all those operating at or above Biosafety Level 3 or "high containment," under Federal biosafety regulation.

B. **Possible Exemptions for Quality Assurance**: Consider creating exemptions from certain security regulations for laboratories that retain certain select agents only for the purposes of positive control material availability and quality-assurance procedures.

C. **Security Expenses**: Examine mechanisms for funding security-related expenses for use of BSAT; determine if those mechanisms are adequate; and if not, propose options to ensure that funding is available for necessary security measures.

D. **Consistent Disclosure Policies**: Seek to ensure that institutions regulated under the select agent regulations fall under consistent information-disclosure policies, to the extent that state and local laws and regulations pertaining to these institutions can be reconciled with Federal requirements.

E. **Common Chemical, Biological, and Radiological Security Framework**: Explore the feasibility of establishing a common interface for institutions with respect to personnel vetting and personnel reliability—for people with access to chemical, biological, and radiological materials of security concern.

F. **Risk-based Approach**: Explore the feasibility of adopting a "risk-based" approach to managing the safety and security oversight of biological agents and toxins.

G. **Shipping Regulations**: Review domestic and international shipping regulations and requirements, as well as related guidance, with a view to simplifying and clarifying, and to facilitating compliance by other countries.

# Appendix E

## Defense Science Board: Report of the Defense Science Board Task Force on Department of Defense Biological Safety and Security Programs, May 2009

### *Recommendations*

**Recommendation #1. Cyber Red Team**

Conduct red team reviews of the computer systems at USAMRIID (and, depending on the results, other DoD labs).

**Recommendation #2. Monitoring Activities**

Make minor changes in the procedures to monitor activities in labs to improve effectiveness without introducing significantly obtrusive measures that are unwarranted by the threat.

**Recommendation #3. Biological Personnel Reliability Program [BPRP]**

Maintain use of the BPRP tailored to bio-defense work; balance risk from malevolent insider against detriment to laboratory mission.

**Recommendation #4: OCONUS Laboratories**

Issue blanket waiver to use Department of State background investigations (conducted by U.S. Embassy Regional Security Office) in place of National Agency Check with Local Agency Check and Credit (NACLC), among local national personnel working with BSAT in labs outside the continental United States.

Grant waiver authority to laboratory commanders to determine minimum security measures for shipments based on local risk assessment and conditions for which shipments must occur (e.g., public health, forensic analysis).

**Recommendation #5: Compliance Inspections**

Provide resources for an independent inspection team comprising authoritative and successful individuals.

**Recommendation #6: BSAT Transportation**

Review use of two-person rule for BSAT shipments.

**Recommendation #7: Public Education and Relations**

Educate the public in the regions near the labs on mission, safety measures, and level of risk, to counter an attack intended to inflame the media and close the facility.

# Appendix F

## Report of the Working Group on Strengthening the Biosecurity of the United States

The working group prepared a report summarizing its review of the efficiency and effectiveness of existing laws, regulations, guidance, and practices related to physical, facility, and personnel security and assurance at Federal and non-Federal BSAT. The report's compiled recommendations follow.

# Working Group Report



## Appendix 6: Compiled Recommendations

*A. Recommendations for Improving the SAR*

The WG proposes the following recommendations for improving the SAR as it relates to the select agent list, oversight and inspections, and inventory management.

**1. Risk Assessment**

**a. Task the HHS and USDA Select Agent Program (in consultation with subject matter experts from the scientific, intelligence and security communities from the Federal and non-Federal sectors as appropriate) to conduct a risk assessment of all the BSAT on the select agent list to develop a stratification scheme (or reduce the list) to guide implementation of security policy at registered entities.**

The risk assessment should consider the criteria (Appendix 2-B) developed by the subgroup on the SAR as well as those published by other groups (Appendix 2-A). In addition, the team tasked with performing the risk assessment should consult with other federal agencies performing similar risk assessments of BSAT. This team should also engage statisticians to ensure a high level of rigor when establishing stratification. The results of the risk assessment may also lead to a recommendation for the removal of BSAT from the list or other modifications of the list, in addition to stratification.

One concern regarding BSAT stratification, and its use to guide implementation of biosecurity controls, is that a complex stratification scheme may lead to confusion regarding what measures to apply to what agents. It is therefore critical that any stratification scheme be simple and easily implemented.

**b. Task the HHS and USDA Select Agent Program (in consultation with subject matter experts from the scientific, intelligence and security communities from the Federal and non-Federal sectors as appropriate) to develop standard security risk assessment methodology for use at all BSAT facilities.** Guidance on how to properly execute the standard risk-assessment method should be developed and provided to all registered entities.

A standard security risk assessment methodology should takes into account the risk of the BSAT, the threat of an unintentional release of the BSAT (taking into account the activities performed, insider and external threats), and the vulnerabilities in physical, personnel, or operational security.

A standard security risk assessment methodology will ensure that registered entities are using common approaches to measuring risk and will mitigate the possibility of varied results among similar facilities. Security personnel at registered entities will have a better understanding of their security requirements as they relate to the risk.

# Working Group Report (cont'd)

**APPENDIX 6**

By combining the use of a stratified list of BSAT based on risk and a standardized security risk assessment methodology, registered entities will be better able to determine the security risk at their facility and apply security measures commensurate with the risk.

**2. Oversight and Inspection**

Listed below are two sets of recommendations to improve the oversight process. The first set relates to better coordination between the various oversight groups. These recommendations are designed to improve the efficiency and consistency of inspections. The second set relates to improved compliance by regulated entities. These recommendations address some of the common compliance challenges that the regulated community has faced since the expansion of the SAR in 2003. These recommendations should not require statutory changes, and only minimal rulemaking. Most, if not all, of these could be implemented by policy if concurrence can be obtained by the Agencies involved.

**a. Approaches to enhance US Government (USG) coordination on oversight and inspections**

1. **Identify or establish a Federal entity to coordinate biosecurity oversight activities, and to ensure comprehensive and effective Federal oversight for all select agent research facilities and activities. This would include input from various stakeholder agencies (e.g., CDC, APHIS, NIH, DoD, DHS, DOE, DOT, EPA, OSHA).** Given the statutory responsibility placed on USDA and HHS, these Departments would be the most likely sponsors of this activity. This coordinating body would work on the following objectives:
   - Convene meetings on a regular basis among key oversight agencies to facilitate information sharing on and coordination of regulations, policies, and inspection schedules/activities (prior to establishing permanent coordinating office).
   - Promote and enable ongoing information sharing on oversight and inspection processes, activities, and reports (facilitated by coordinating office).

This Federal entity should formally engage the regulated community in order to fully understand the needs of the regulated community with respect to the oversight and inspection process.

2. **Plan better coordination of inspections.** In conjunction with the recommendation above, oversight agencies should strive to implement joint or multi-agency inspections at complex select agent entities. This may reduce the "down time" and associated indirect costs for the entity while potentially allowing for each oversight agency to focus on areas that fall outside the scope of the SAR (such as personnel reliability programs).

3. **Promote the oversight-of-oversight approach, whereby USG regulatory and oversight bodies place significant focus on reviewing laboratory-specific and**

# Working Group Report (cont'd)

APPENDIX 6

**institutional oversight efforts, and utilize existing information on the oversight efforts of other USG bodies.**

- Review the current oversight regarding registered entities' inventory management and auditing plans to determine if the processes are well-defined and communicated (e.g., additional guidance or regulatory change may be needed).
- Collect and review registered entities' annual select agent program review and facility inspection reports to enable ongoing oversight between inspection cycles.
- Ensure that stakeholder agencies have access to relevant information and reports on oversight efforts pertaining to entities for which they have shared responsibilities and interests.

4. **Develop coordinated training and oversight programs for inspectors from various USG agencies and offices with oversight responsibilities.**
   - Develop formal and ad hoc partnerships between USG oversight bodies. Invite representatives from partner offices to join site visits and inspections in "observe and assist" roles.
   - Hold joint training sessions to develop cross-cutting skill sets and shared knowledge bases regarding USG oversight processes. CDC and APHIS might consider the establishment of a "certification" program for inspection teams from agencies or departments that have internal oversight programs.
   - Develop common standards and guidelines for inspectors whenever practical. One means for the development of these standards is the creation of a certification program by CDC/APHIS to train inspectors from other agencies with internal oversight programs.
   - Conduct joint inspections and other collaborative oversight efforts when appropriate.

b. **Approaches to enhance institutional implementation, compliance, oversight and accountability.**

1. **Provide guidance for and require entities to conduct comprehensive annual BSAT program reviews and facility inspections.**
   - Consider using the Institutional Animal Care and Use Committee (IACUC) and American Academy for Laboratory Animal Science (AALAS) models for conducting both comprehensive program reviews and facility inspections. Under this model, entities would be required to submit an annual report to CDC or APHIS that must address key compliance issues (to include documentation and/or verification of inventory audits) for review, inclusion in files, and ongoing oversight by these regulatory bodies.

2. **Require entities to provide, as a part of registration, a select agent management plan that outlines the roles and responsibilities of the RO and other key managers for oversight to ensure compliance with the regulations.**

# Working Group Report (cont'd)

APPENDIX 6

- The plan identifies a senior official (may or may not be the RO) who is identified that takes ultimate responsibility.
- The plan describes the linkage between the chain of command for the RO and the senior official

3. **Continue to enhance existing guidance for registered entities on select agent program implementation and oversight at the institutional level.**
   - Focus new guidance on areas which may require clarification to avoid ongoing misinterpretation or inadvertent noncompliance.
   - Provide specific, detailed guidance regarding approval procedures and select agent access for visiting scientists.
   - Develop a guidance document detailing escorting requirements for laboratory and non-laboratory staff (including escort of inspectors/auditors).
   - Provide further guidance and tools for RO and laboratory staff training (e.g. briefing modules, sample drills and exercises).
   - Establish a periodic select agent program bulletin or other notification system for dissemination of new guidance and regulatory information to registered entities.
   - Update and expand the "Frequently Asked Questions" section of the National Select Agent Program website to provide standardized guidance on common issues.

3. **Inventory of BSAT**

**Provide comprehensive guidance on inventory management and recordkeeping requirements, approaches, and templates.**

a. Expand and clarify existing guidance produced by the Select Agent Program "Guidance on the Definition of Long Term Storage as Used in the Select Agent Regulations" to ensure uniform understanding and facilitate compliance.
b. Develop and distribute various inventory record templates to be adapted and utilized by registered entities on an optional basis.
c. Support the implementation of improved recordkeeping standards and practices for working stock samples (e.g., laboratory notebooks, signature verifications, audits).
d. Provide guidance for and encourage entities to develop standard operating procedures for the transition and management of inventories held by departing principal investigators (PIs).
e. Require entities to submit detailed facility-specific inventory management plans as part of the registration or renewal of registration process.
   - Review the current oversight regarding registered entities' inventory management and auditing plans to determine if the processes are well-defined and communicated (e.g., additional guidance or regulatory change may be needed).
   - Require entities to conduct, document, and report to CDC/APHIS on the completion of periodic (at least annual) inventory audits in accordance with their approved inventory management plans.

# Working Group Report (cont'd)

APPENDIX 6

Providing formats for records and more prescriptive requirements on inventory management should help ensure a more consistent application of the SAR by registered entities and reduce the current confusion among many entities as to the appropriate standards for inventory records. These requirements should include guidance on intra-entity transfers to address transfers of select agents between principal investigators in an entity, including a requirement for appropriate inventory and tracking of these transfers and as well as notification of the transfers to the RO.

4. **Other Recommendations for Amending the SAR. Some of these recommendations will require legislative changes.**

a. **Amend 18 U.S.C. 175(b) to add "attempts or conspires to possess".**

Pursuant to 18 U.S.C. 175(b), a person is prohibited from knowingly possessing a BSAT under circumstances that are "not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose." Anyone violating this provision may be subject to a fine and/or imprisonment of not more than 10 years. The FBI has encountered a situation in which an individual was attempting to acquire a BSAT for a purpose that was not reasonably justified under section 175(b). Because a violation of section 175(b) required the individual to take actual possession of the BSAT, the FBI needed to allow the material to be shipped to the individual before he could be arrested. Although the FBI carefully monitored the transfer, a safer option would be to expand the scope of section 175(b) to prohibit any knowing attempts by individuals to acquire BSAT for a nefarious purpose. Therefore, we recommend that the words "or attempts or conspires to possess" be added to 18 U.S.C. 175(b).

b. **Revise the SAR to provide for DOJ access to conduct investigations.**

The SAR should include specific language permitting DOJ officials access to laboratories in which evidence is being held in order for them to conduct their investigations. We recommend that the SAR be amended to address the DOJ concerns outlined below:

The DOJ may need to conduct forensic examinations in an investigation authorized under a federal law, on an item or material that is, bears, or contains a BSAT. When such an item or material, identified or collected as evidence during the investigation has been transferred to and is in the possession of an entity registered under this part. These entities will provide access to the DOJ to conduct forensic examinations on these items or materials, provided:
(1) The DOJ personnel have undergone a Security Risk Assessment conducted by the FBI-CJIS and the results of that assessment are submitted to the RO for the entity or individual in possession of the item or material,
(2) The DOJ personnel possess the appropriate education or experience, or will receive the appropriate training from the individual or entity in possession of the item or material, to handle an item or material that is, bears, or contains the BSAT at issue; and
(3) The DOJ personnel are escorted by personnel from the entity with the appropriate training at all times when in the presence of the BSAT.
(4) In addition, the SAR should be clear that the DOJ has a responsibility to insure that any subsequent removal or transfer of material containing BSAT from the registered entity at which

# Working Group Report (cont'd)



the investigation is being performed occurs only after that entity gets approval for the transfer in accordance with section 16 of the SAR.

In addition, entities should maintain an accurate inventory and adequate security of all materials in their facility which are part of such an investigation. The Department of Justice will also maintain appropriate documentation addressing the inventory of evidentiary items. The documentation will identify which items or material that are, bear, or contain a BSAT, if the presence of a BSAT has been confirmed. The documentation will also contain the amount of BSAT, if it has been determined. The RO of the entity storing the evidentiary items will be notified of any changes to the amounts of the BSATs that may occur during the course of the investigation. The Department of Justice may also choose to augment the security of the entity storing the evidentiary materials.

c. **Options for addressing the potential regulatory gap for *de minimis* quantities of select toxins**

The WG deliberated on options for filling the potential regulatory gap for *de minimis* quantities of select toxins identified in the previous section of this report; however, no one option was agreed upon. For this reason, the three options discussed are listed here with their respective rationales. The WG recommends that these options be revisited during the policy making process:

- **Option #1: Continue current practice of not tracking, regulating, or reporting orders and shipments of *de minimis* quantities of select toxins**

There is a perceived regulatory gap in which unregistered individuals or entities can repeatedly order, and potentially stockpile, *de minimis* quantities of a toxin for an illegitimate purpose, while eluding registration with the Select Agent Program. There have been documented incidences of this occurring but the frequency and intent of the individuals who have done this is unknown. Most commonly, repeated orders are necessary to support continued studies in which the materials are consumed. There are only a very few companies that supply select toxins and the major ones report that they already track who they ship to, amounts, and purpose, even in the absence of regulatory mandate, however, the extent to which they do so is unknown. The majority of select toxins are either ubiquitous in the environment or very difficult to obtain in any quantity. Finally, there is little risk that a *de minimis* amount of select toxin could be used for a large scale biological attack.

- **Option #2: CDC and APHIS, with input from relevant collaborating agencies, should work with suppliers of select toxins to develop toxin ordering and verification processes that require individuals and entities ordering select toxins to:**

1) verify that the entity/individual is either registered with the Select Agent Program or is exempt from registration due to only ordering exempt quantities of select toxins;

2) designate and provide contact information for the responsible investigator for the toxin to be obtained; and

# Working Group Report (cont'd)



3) designate and provide contact information for the biosafety officer or another authorized institutional official (other than the responsible investigator) at the ordering entity who can confirm that:

a) the order aligns with a legitimate program, requirement, or activity,

b) the appropriate risk assessment has been conducted for the receipt, possession, storage, and use of the toxin, and

c) subsequent toxin orders and aggregate quantities will be documented and tracked to ensure compliance with exempt quantity limits and enable ongoing institutional accountability and oversight.

To support implementation of this recommendation, CDC and APHIS would also provide guidance to suppliers on straightforward approaches for verifying the information provided by the ordering individuals and entities.

- **Option #3: Amend the SAR such that CDC and APHIS require that all individuals/entities ordering *de minimis* quantities of select toxins enroll in a tracking system with the Select Agent Program.**

1) Enrollment in a tracking system will allow for verification that the individual/entity is a legitimate user of the toxin (user must submit credentials to indicate legitimate use, and supplier verifies with CDC/APHIS they are enrolled prior to shipment)
2) Toxin orders would proceed using the APHIS/CDC Form 2 (or a modified version), which would allow the reporting of the toxin shipment to the CDC or APHIS.
3) Individuals/entities will not be required to register with the Select Agent Program unless the amount of a select toxin in their possession exceeds the amounts subject to the SAR. CDC/APHIS would be authorized to request these records at any time.
4) Periodic reporting of select toxin usage to CDC/APHIS must be considered (perhaps on modified Form 2 when ordering more toxins)
5) This option would require a regulatory change.

d. **Consider revising the SAR to require that regulated entities maintain their select agent records for at least 10 years.**

Current SAR require registered entities to maintain their records for three years. Consideration should be given to expanding this requirement to 10 years to allow a more comprehensive review of the history of the entity's possession, use, or transfer of BSAT. Many investigations involving violations of the regulations can easily require that inventory and other records be reviewed for trends in reporting or inaccuracies which could extend historically beyond three years. Records required to be maintained for 10 years would include all those required by the SAR such as those for inventory, security, training, or incidence response. Consideration should be given to the burden this requirement may place on regulated entities. For example, records that are expensive or difficult to maintain, and/or are not required by the SAR, such as surveillance videotape, should be excluded from this requirement.

# Working Group Report (cont'd)



c. **The recommendation below should be revisited at the policy phase since there was insufficient time for the WG to complete its deliberations:**

**Consider the feasibility of revising the statute to grant the Secretary of HHS similar authorities to those of the Secretary of the USDA to determine appropriateness of BSAT access denials for cases of prior committal to a mental institution or juvenile felony convictions.**

The WG had a concern that persons who were committed to mental institutions or were convicted of felonies as juveniles are not being given the opportunity to work in fields requiring BSAT access even though they may be well-adjusted. Adjudicators for national security clearance decisions can provide waivers for some of the areas specifically prohibited by the USA PATRIOT Act including felony convictions and noted drug use. If exemptions can be made for access to classified information, it should also be considered for BSAT access. Any consideration of this statutory change must include participation of the HHS political leadership, the CDC Director, and the HHS General Counsel.

***B. Recommendations for Enhancing Personnel Security***

**1. Overarching Recommendations**

Because there is no requirement that the RO report derogatory information to the CDC or APHIS if they have removed an individual from BSAT access due to the derogatory information, the research community is potentially at risk of transferring personnel who may represent a security risk from one lab to the next. Furthermore, the WG identified that other than the restricted and prohibited criteria, ROs have not been provided guidance on determining an individual's suitability for access to BSAT or for determining when to temporarily suspend or permanently terminate that access. For this reason, the WG recommends the following:

**a. Establish a working group (WG), including Federal and non-Federal subject matter experts from the scientific, intelligence, security, human resources and healthcare (including mental health professionals) communities, that will investigate and establish guidance and training on suitability criteria, above and beyond restricted and potential prohibited categories, for use by:**

1. ROs, in addition to the Security Risk Assessment, to determine whether to grant an individual's initial access to BSAT or to temporarily or permanently restrict (or terminate) an individual's access to BSAT
2. PIs, researchers, and technicians to continuously monitor themselves and others for suitability to access BSAT
3. Occupational health professionals, to determine the suitability for BSAT access based on activities performed with the BSAT and the individual's physical and mental health, to include medications that may affect an individual's ability to perform duties with BSAT.

# Working Group Report (cont'd)



In developing suitability criteria, this WG should, at a minimum, consider aspects of personal and professional conduct, physical and mental health, and behaviors that indicate an individual is at risk of harming themselves or others.

**b. Assess the feasibility of the following recommendations:**

1. **An amendment to the SAR requiring that ROs report the details of derogatory information leading to permanent termination of BSAT access to CDC or APHIS for inclusion in a registry or repository.** Derogatory information may be related to suitability criteria, determined by the WG above, or restrictive/prohibitive categories. This may require a legislative change.
2. **A registry or repository containing derogatory information reported by the RO that can be used, in combination with results of the security risk assessment, for determining whether an individual should be granted BSAT access.** The FBI-CJIS, CDC, APHIS, DHS, Director of National Intelligence, Homeland Security Council, and National Security Council should collaborate to determine if adjudicative standards should be used for granting BSAT access. If such a registry is deemed legal, amend the SAR to allow the use of this registry by CDC and APHIS, in combination with Security Risk Assessment results, to grant or deny BSAT access. This will require a legislative change.

**2. Granting Initial BSAT Access**

**a. Security Risk Assessments**

**1. Foreign Nationals**

**Screening: Identify a Federal agency that will 1) develop guidelines for vetting FNs that require BSAT access and 2) will screen FNs according to these newly established criteria. The SAR should be amended such that this Federal agency, CJIS-BRAG, CDC, and APHIS collaborate to consider both the Security Risk Assessment results and the newly established criteria to grant or deny BSAT access.** This screening may require providing information on their prior history in their country of origin as well as up to date information on their occupation, background, and research as well as include results from prior visa screens by the Department of State (DOS). Use of the Collective Foreign Threat Assessment tool (Appendix 3-B) may be considered.

**Visas: Require that the DOS provide a list of visa types that are appropriate for work with BSAT to the Select Agent Program. Require the Select Agent Program to disseminate this information to Responsible Officials.** The CDC/APHIS Select Agent Programs will provide information and guidance to institutional officials (IOs), ROs, and funding agencies on the types of visas that are adequate for work with BSAT. Inappropriate visa types will require a visa change, or a specific waiver, prior to Security Risk Assessment processing. Amend 18 U.S.C. 175b or the Bioterrorism Response Act to include "an inappropriate visa type" as a restrictor for access to BSAT.

# Working Group Report (cont'd)

APPENDIX 6

Provide the Department of Justice and the Department of Homeland Security (DHS) with the statutory authority to perform immigration status checks on Security Risk Assessment-approved FNs at least every six months.

2. **The CJIS-BRAG should either a) be provided the statutory authority to access the mental health component of the NICS database or b) establish a separate mental health database to allow CJIS-BRAG to determine if an individual is ineligible to have access to BSAT for mental health reasons.** Moreover, in either instance, an increased emphasis must be made for states to report information regarding persons who have been "adjudicated as a mental defective or have been committed to a mental institution" in a timely and consistent manner to maintain the integrity and utility of any such database.

**b. Suitability for Initial BSAT Access**

1. **Assess the feasibility of requiring drug testing (urinalysis) for initial BSAT access and determine whether such a testing program could be justified under a Fourth Amendment analysis.** Pursuant to 18 U.S.C. § 175b(d)(2)(D), a person who is an unlawful user of a controlled substance is a restricted person for purposes of access to BSAT.

2. **Consider amending the SAR such that persons with duties associated with the highest risk BSAT and based on the activities performed with the agent are required to be in an occupational health program.** The occupational health program should at a minimum include an initial screening that assesses an individual's general health and also reviews medications for any possible conflicts with BSAT work. Description of the occupational health program will be required in the biosafety or security plan of the entity. The cost of implementing this recommendation should be weighed against the number of laboratories it will affect and the benefit that will be gained. It should be noted that this type of a change to the SAR could require a legislative amendment.

3. **The DOC, CDC, and APHIS should determine how to best implement deemed export regulations with respect to the Select Agent Program-regulated community and should subsequently establish training for IOs, ROs, and funding agencies on deemed export regulation requirements for BSAT work.**

**3. Continual Monitoring of Personnel**

a. **Amend the SAR to require that a Security Risk Assessment be performed every three years for all individuals with access to BSAT.**

b. **Assess the feasibility of random drug testing (urinalysis) for continued BSAT access to ensure that an individual does not fall into a restricted category.**

# Working Group Report (cont'd)

APPENDIX 6

**c. Amend the SAR to include a requirement that entities provide training for ROs, principal investigators, researchers, and technicians on suitability criteria as determined by the WG above; mechanisms for supervisor-, self- and peer-reporting of issues relating to the suitability criteria; and a process for temporary suspension or permanent removal of access in their security plans.** Leadership, supervisors, medical personnel, peers, and individuals themselves should be aware of personal, professional, and medical (physical and mental) criteria that may impact perception or performance associated with working with or around BSAT. This may require a legislative change.

**d. Ensure that all individuals who work with BSAT have access to an occupational health professional for referral of physical or mental health issues that arise after BSAT access is granted.** Ensure that entities include contact information and procedures for referring individuals in the description of their occupational health programs.

**4. Termination of BSAT Access and Granting New Access**

**a. Provide guidance to the RO regarding their role in removing individuals from BSAT access who display behaviors indicating they are at risk of doing harm to themselves or to others.** Ensure that entities include procedures for referring individuals who display these behaviors in the description of their occupational health programs.

**b. Ensure that entities describe procedures for temporary or permanent removal from access due to physical, occupational, or mental health concerns or other issues potentially impacting fitness for duty with respect to BSAT possession and use.**

**c. Ensure that procedures are in place for the RO to immediately notify the local FBI Weapons of Mass Destruction Coordinator in order to initiate a threat assessment process in the event that he/she becomes aware of an incident or action that may indicate possible criminal activity regarding BSAT.**

**5. Other Recommendations**

**a. Perform a study of Chemical and Nuclear Personal Reliability Programs to examine the cost of individual PRP measures and the value of eligibility/ineligibility criteria, significance of the personal interview, and effectiveness of continual review/monitoring to identify potentially disqualifying information or reliability issues that would result in an individual's permanent disqualification.**

*C. Recommendations for Improving Physical Security Regulations*

**Develop minimum physical security standards based on the risk of the agent or toxin and characteristics of facilities and type of work being done.**

Appendix 4-B, provided by the physical security subgroup shows an example of how physical security standards could be applied to a stratified list of BSAT taking into consideration the type of facility and

# Working Group Report (cont'd)



the work that is done. Using a standard security risk assessment will allow a facility to build upon the baseline or minimum physical security requirements and will ensure a standard approach while allowing for additional security requirements under current regulations.

*D. Recommendations for Improving BSAT Transport*

The SAR have been adequate in ensuring secure transportation of BSAT. There is currently no evidence to substantiate an increase in transportation security for BSAT. Furthermore, BSAT represent a tiny fraction of the hazardous materials that are routinely handled in daily commerce. Therefore, the key recommendation of the WG is to:

**Task the TSA, in partnership with other USG agencies, to conduct a risk assessment to determine the risk posed by air and ground transportation of BSAT.**

**The risk assessment should consider:**

**1. The risk of the BSAT,** the threat of an unintentional release of the BSAT during transportation (to include likelihood that insider or external threats may compromise a BSAT shipment) and the vulnerabilities in physical, personnel, or operational security during transportation and at stopping points along the shipping routes.

**2. The risk posed by having the technical name of BSAT on the shipping paper, balanced by the need to provide enough information to meet the information needs of the emergency responder.**

**The results of the risk assessment can be used to determine:**

**1. If high risk BSAT should be shipped using more stringent security controls (*e.g.*, use of restricted service) or an enhanced tracking system (*i.e.*, global positioning systems (GPS)) device in shipments.** The baseline security plan requirements contained in the HMR may be sufficient for most BSAT, however, more stringent security controls may be deemed appropriate for BSAT identified by TSA as posing a more serious security risk.

**2. If additional background checks should be performed** on personnel who handle BSAT, to include couriers and others in the transport chain.

**3. If tighter chain of custody requirements and tracking should be implemented.**

**Other recommendations by the WG include the following:**

**1. Establish a communication plan to ensure effective communication among entities, couriers, DOT, and CDC/APHIS.** This plan may involve creating agreements on security-based communications practices, or a secure web portal that would enhance tracking capabilities or the provision of the tracking number to CDC or APHIS (APHIS/CDC Form 2, line 37 requests this information) in order to give those agencies the ability to track shipment of the package(s) through the courier's system.

**2. Require CDC/APHIS to maintain a list of BSAT couriers.** This will facilitate DOT inspections of BSAT couriers so that compliance with current hazmat security plan requirements can be

## Working Group Report (cont'd)



determined. In turn, DOT, CDC, and APHIS should ensure that information on BSAT couriers is protected from disclosure that could compromise security.

**3. Consider inclusion of plant BSAT in the HMR.**

# Appendix G

## Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

The scope of activities considered by the Task Force included those that occur in all high and maximum containment research laboratories in all sectors (government [Federal, State, Tribal, and municipal], academia, privately funded research institutions, and private industry) using potentially hazardous biological agents. The activities covered included research with disease-causing agents (pathogens) that can infect humans, zoonotic agents that can infect both animals and humans, biologic toxins, and agricultural pathogens and pests. Also included were activities related to research, such as the maintenance of facilities and equipment needed for effective biosafety and biocontainment, incident-reporting, and public outreach and communication efforts.

The Task Force was co-chaired by HHS and USDA, and consisted of representatives from the Departments of Commerce, Defense, Energy, Homeland Security, Labor, State, Transportation, Veterans' Affairs, and the Environmental Protection Agency and National Science Foundation.

The Task Force analyzed current framework for biosafety and biocontainment oversight, identified eight areas in which oversight could be improved, and defined eight objectives to address these areas.

In the short term, many recommendations require compliance and implementation by institutions that are federally owned or funded by the Federal Government; and encourage compliance by individuals and institutions not federally owned or receiving Federal support.

In the long term, these recommendations should lead to a comprehensive national strategy for biosafety and biocontainment oversight, and compliance and implementation by all individuals and institutions in all sectors. The Task Force recognized that its recommendations also could be applied to entities outside the scope of their report, and that legislation or rule-making might be required to implement the recommendations in all sectors. The Task Force recommendations were developed without consideration of potential competing priorities across the Federal Government, and their implementation would be subject to the availability of funds.

The Task Force explained that acting on the objectives and recommendations in the report required enhanced communication and collaboration among Federal entities and their non-Federal partners, and, in some cases, addition or redirection of resources as well as further analysis.

The Task Force concluded that there was a robust system for laboratory biosafety and biocontainment oversight in place. The objectives and recommendations of the Task Force reports were designed to:

- optimize local biosafety and biocontainment oversight at individual high and maximum containment research facilities,
- improve and better coordinate Federal oversight of these facilities and their activities, and
- help increase public confidence and trust that high and maximum containment research laboratories in the United States are being operated as safely as possible.

The following is a summary of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (July 2009 Report) objectives and recommendations.

## *Objective 1*

Enhance the overarching framework for biosafety and biocontainment oversight of high and maximum containment research through improved coordination of oversight activities.

### *Recommendations*

1.1: Identify or establish a Federal entity to coordinate biosafety and biocontainment oversight activities, and to ensure comprehensive and effective Federal oversight for all high and maximum containment research facilities and activities in all sectors.

1.2: Develop a registry of all high and maximum containment research facilities in the United States.

1.3: Require that all institutions conducting high and maximum containment research designate:

- A senior official with the appropriate knowledge, authority, and accountability who is responsible for institutional compliance with biosafety and biocontainment regulations and guidelines.
- A credentialed biosafety professional (see Recommendation 3.3) who is responsible for oversight of biosafety and biocontainment programs.

1.4: Require that, at all institutions conducting high or maximum containment research, an appropriately constituted review body performs a thorough risk assessment of all laboratory protocols potentially requiring high or maximum containment.

## *Objective 2*

Encourage a robust culture of accountability characterized by individual and institutional compliance with biosafety and biocontainment regulations, guidelines, standards, and policies.

### *Recommendations*

2.1: Mandate compliance with Federal biosafety and biocontainment guidelines, including the Biosafety in Microbiological and Biomedical Laboratories and the National Institutes of Health guidelines, for all high and maximum containment research institutions in all sectors.

2.2: Support the development of an accreditation system for biosafety/ biocontainment management programs at high and maximum containment research institutions.

## *Objective 3*

Develop a national strategy to enable and ensure the appropriate training and technical competence of all individuals who work in, oversee, support, or manage high or maximum containment research laboratories.

### *Recommendations*

3.1: Establish national, position-specific training standards and core competencies in biosafety and biocontainment for all research, managerial, and support personnel at high and maximum containment research laboratories in all sectors.

3.2: Require institutions to ensure that all individuals who work in, oversee, support, or manage high or maximum containment research laboratories are appropriately trained and competent in biosafety and biocontainment.

3.3: Implement a phased-in requirement that the designated biosafety professional (Biological Safety Officer or equivalent) at all high and maximum containment research facilities be credentialed.

## Objective 4

Obtain and analyze information about laboratory incidents to enable trend analysis, minimize the number of future incidents, and share lessons learned with the overall goals of optimizing laboratory safety and oversight.

### *Recommendation*

4.1: Establish:

- A new voluntary, non-punitive incident-reporting system for high and maximum containment research laboratories that would ensure the protection of sensitive and private information, as necessary.
- A centralized, integrated mechanism for analyzing incidents and sharing information and lessons learned from both current mandatory reports and the new voluntary reporting system.

## Objective 5

Ensure that biosafety and biocontainment regulations and guidelines cover current and emerging hazardous biological agents, and develop an agricultural equivalent of the Biosafety in Microbiological and Biomedical Laboratories guidelines.

### *Recommendations*

5.1: Develop comprehensive biocontainment guidelines comparable to those of the Biosafety in Microbiological and Biomedical Laboratories to cover research, including high and maximum containment research, on plant, livestock, and other agriculturally significant pests and pathogens.

5.2: Maintain rigorous and comprehensive processes for the review and updating of biosafety and biocontainment regulations and guidelines, and ensure that these processes include broad-based participation by all relevant stakeholders.

## Objective 6

Ensure that the infrastructure and equipment necessary for biosafety and biocontainment at high and maximum containment research facilities are in place and properly maintained.

### *Recommendations*

6.1: Require that all institutions with high or maximum containment laboratories ensure proper installation of and preventive and ongoing maintenance programs for biosafety and biocontainment infrastructure and equipment.

6.2: Develop a mechanism for sharing information and best practices about infrastructure and equipment design, operations, and maintenance among all high and maximum containment research facilities.

## *Objective 7*

Develop and support a national research agenda for applied biosafety and biocontainment to improve the management of biohazard risks.

### *Recommendation*

7.1: Develop and maintain a robust program of applied biosafety and biocontainment research to create additional and update existing evidence-based practices and technologies.

## *Objective 8*

Improve and share strategies to ensure effective public communication, outreach, and transparency about biosafety and biocontainment issues.

### *Recommendation*

8.1: Develop comprehensive strategies to improve public communication, outreach, and transparency about biosafety and biocontainment issues and activities at high and maximum containment research facilities.

# Appendix H

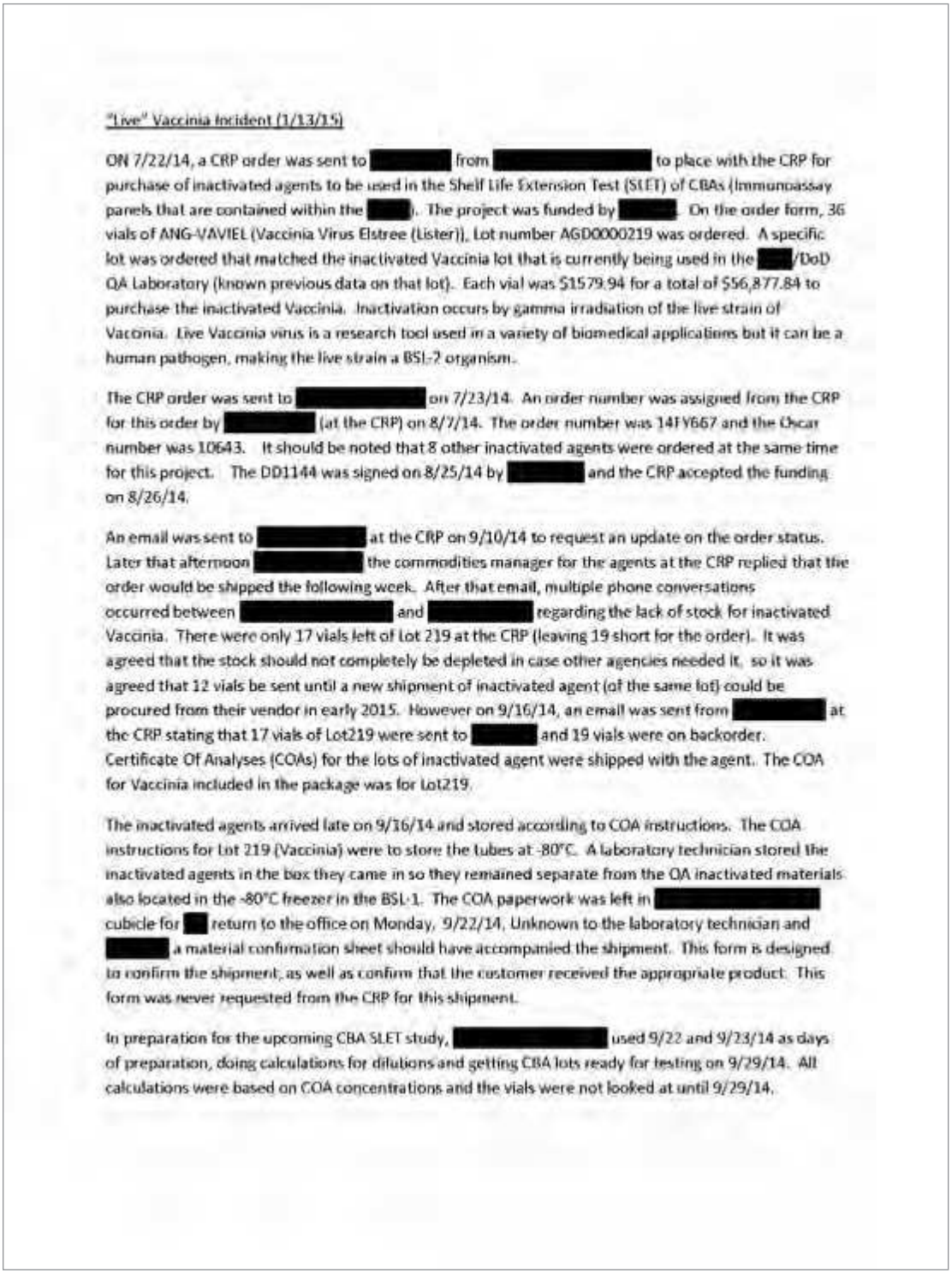
## Dugway Proving Grounds Shipping Incidents

The following documents describe two errant pathogen shipping incidents we identified during our evaluation.

In the first incident described on pages 67-72, incorrectly labeled *Vaccinia* virus was shipped from Dugway Proving Grounds to another laboratory. *Vaccinia* virus is managed in a BSL-2 laboratory when alive, and in a BSL-1 laboratory when dead. In this shipping incident, dead virus was mislabeled as live and was shipped to the ordering laboratory.

In the second incident described on page 72, a package of Venezuelan Equine Encephalitis virus (a BSAT agent managed in a BSL-3 laboratory) was apparently mislabeled as dead *Bacillis anthracis* Sterne strain. When the shipment was opened by the ordering laboratory and the incorrect contents were identified, the shipment was secured.

# Dugway Proving Grounds Shipping Incidents (*Vaccinia* virus)



"Live" Vaccinia Incident (1/13/15)

ON 7/22/14, a CRP order was sent to [redacted] from [redacted] to place with the CRP for purchase of inactivated agents to be used in the Shelf Life Extension Test (SLET) of CBAs (Immunoassay panels that are contained within the [redacted]). The project was funded by [redacted]. On the order form, 36 vials of ANG-VAVIEL (Vaccinia Virus Elstree (Lister)), Lot number AGD0000219 was ordered. A specific lot was ordered that matched the inactivated Vaccinia lot that is currently being used in the [redacted]/DoD QA Laboratory (known previous data on that lot). Each vial was $1579.94 for a total of $56,877.84 to purchase the inactivated Vaccinia. Inactivation occurs by gamma irradiation of the live strain of Vaccinia. Live Vaccinia virus is a research tool used in a variety of biomedical applications but it can be a human pathogen, making the live strain a BSL-2 organism.

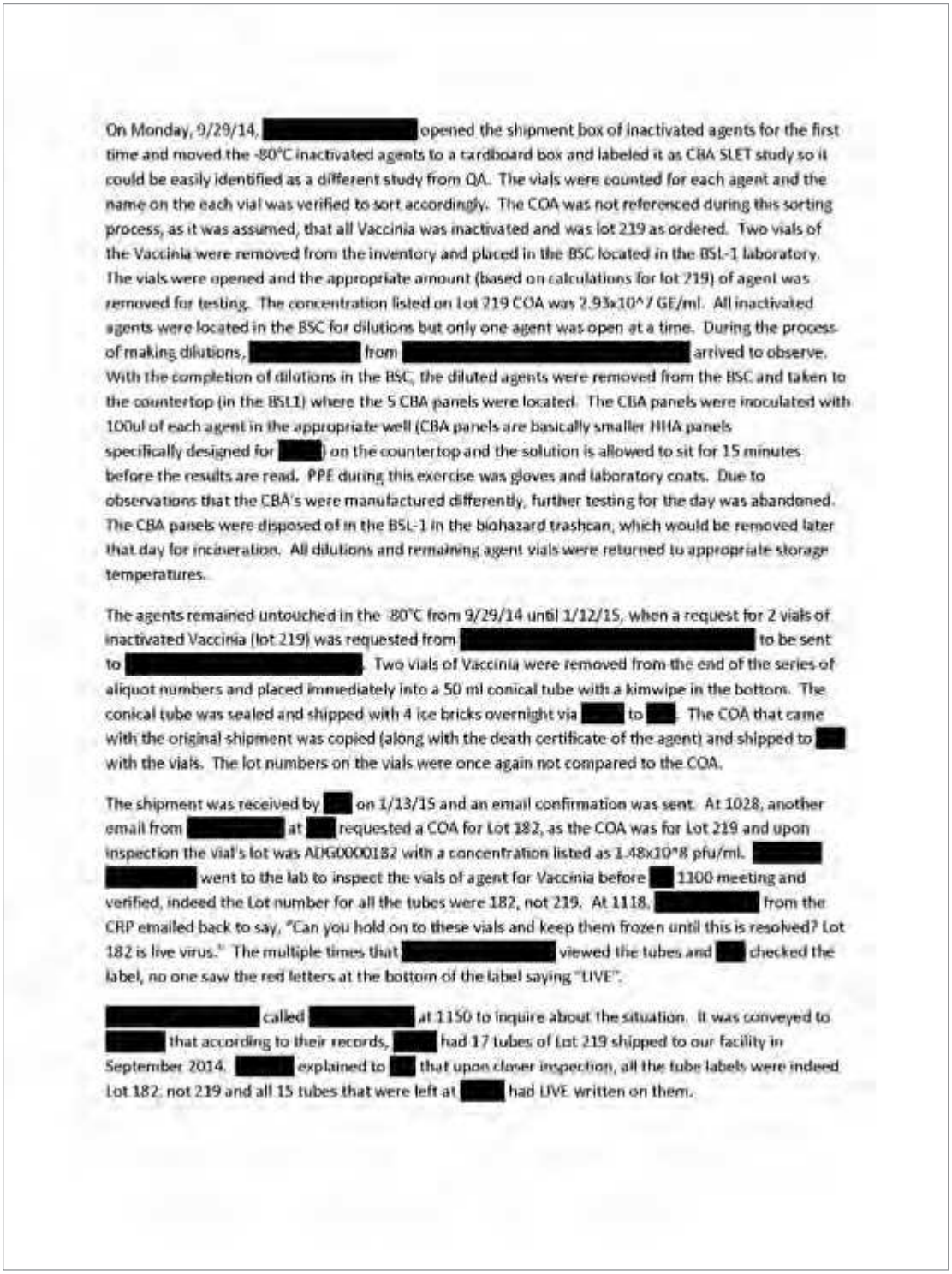
The CRP order was sent to [redacted] on 7/23/14. An order number was assigned from the CRP for this order by [redacted] (at the CRP) on 8/7/14. The order number was 14FY667 and the Oscar number was 10643. It should be noted that 8 other inactivated agents were ordered at the same time for this project. The DD1144 was signed on 8/25/14 by [redacted] and the CRP accepted the funding on 8/26/14.

An email was sent to [redacted] at the CRP on 9/10/14 to request an update on the order status. Later that afternoon [redacted] the commodities manager for the agents at the CRP replied that the order would be shipped the following week. After that email, multiple phone conversations occurred between [redacted] and [redacted] regarding the lack of stock for inactivated Vaccinia. There were only 17 vials left of Lot 219 at the CRP (leaving 19 short for the order). It was agreed that the stock should not completely be depleted in case other agencies needed it, so it was agreed that 12 vials be sent until a new shipment of inactivated agent (of the same lot) could be procured from their vendor in early 2015. However on 9/16/14, an email was sent from [redacted] at the CRP stating that 17 vials of Lot219 were sent to [redacted] and 19 vials were on backorder. Certificate Of Analyses (COAs) for the lots of inactivated agent were shipped with the agent. The COA for Vaccinia included in the package was for Lot219.

The inactivated agents arrived late on 9/16/14 and stored according to COA instructions. The COA instructions for Lot 219 (Vaccinia) were to store the tubes at -80°C. A laboratory technician stored the inactivated agents in the box they came in so they remained separate from the QA inactivated materials also located in the -80°C freezer in the BSL-1. The COA paperwork was left in [redacted] cubicle for [redacted] return to the office on Monday, 9/22/14. Unknown to the laboratory technician and [redacted] a material confirmation sheet should have accompanied the shipment. This form is designed to confirm the shipment, as well as confirm that the customer received the appropriate product. This form was never requested from the CRP for this shipment.

In preparation for the upcoming CBA SLET study, [redacted] used 9/22 and 9/23/14 as days of preparation, doing calculations for dilutions and getting CBA lots ready for testing on 9/29/14. All calculations were based on COA concentrations and the vials were not looked at until 9/29/14.

# Dugway Proving Grounds Shipping Incidents (*Vaccinia* virus) (cont'd)



On Monday, 9/29/14, [redacted] opened the shipment box of inactivated agents for the first time and moved the -80°C inactivated agents to a cardboard box and labeled it as CBA SLET study so it could be easily identified as a different study from QA. The vials were counted for each agent and the name on the each vial was verified to sort accordingly. The COA was not referenced during this sorting process, as it was assumed, that all Vaccinia was inactivated and was lot 219 as ordered. Two vials of the Vaccinia were removed from the inventory and placed in the BSC located in the BSL-1 laboratory. The vials were opened and the appropriate amount (based on calculations for lot 219) of agent was removed for testing. The concentration listed on Lot 219 COA was 2.93x10^7 GE/ml. All inactivated agents were located in the BSC for dilutions but only one agent was open at a time. During the process of making dilutions, [redacted] from [redacted] arrived to observe. With the completion of dilutions in the BSC, the diluted agents were removed from the BSC and taken to the countertop (in the BSL1) where the 5 CBA panels were located. The CBA panels were inoculated with 100ul of each agent in the appropriate well (CBA panels are basically smaller HHA panels specifically designed for [redacted]) on the countertop and the solution is allowed to sit for 15 minutes before the results are read. PPE during this exercise was gloves and laboratory coats. Due to observations that the CBA's were manufactured differently, further testing for the day was abandoned. The CBA panels were disposed of in the BSL-1 in the biohazard trashcan, which would be removed later that day for incineration. All dilutions and remaining agent vials were returned to appropriate storage temperatures.

The agents remained untouched in the -80°C from 9/29/14 until 1/12/15, when a request for 2 vials of inactivated Vaccinia (lot 219) was requested from [redacted] to be sent to [redacted]. Two vials of Vaccinia were removed from the end of the series of aliquot numbers and placed immediately into a 50 ml conical tube with a kimwipe in the bottom. The conical tube was sealed and shipped with 4 ice bricks overnight via [redacted] to [redacted]. The COA that came with the original shipment was copied (along with the death certificate of the agent) and shipped to [redacted] with the vials. The lot numbers on the vials were once again not compared to the COA.

The shipment was received by [redacted] on 1/13/15 and an email confirmation was sent. At 1028, another email from [redacted] at [redacted] requested a COA for Lot 182, as the COA was for Lot 219 and upon inspection the vial's lot was ADG0000182 with a concentration listed as 1.48x10^8 pfu/ml. [redacted] went to the lab to inspect the vials of agent for Vaccinia before [redacted] 1100 meeting and verified, indeed the Lot number for all the tubes were 182, not 219. At 1118, [redacted] from the CRP emailed back to say, "Can you hold on to these vials and keep them frozen until this is resolved? Lot 182 is live virus." The multiple times that [redacted] viewed the tubes and [redacted] checked the label, no one saw the red letters at the bottom of the label saying "LIVE".

[redacted] called [redacted] at 1150 to inquire about the situation. It was conveyed to [redacted] that according to their records, [redacted] had 17 tubes of Lot 219 shipped to our facility in September 2014. [redacted] explained to [redacted] that upon closer inspection, all the tube labels were indeed Lot 182, not 219 and all 15 tubes that were left at [redacted] had LIVE written on them.

# Dugway Proving Grounds Shipping Incidents (*Vaccinia* virus) (cont'd)

[redacted] notified the Laboratory Director, Branch head and in turn, [redacted] notified the RO. There were 13 full 1 ml vials left of Vaccinia Lot 182, one vial containing about 500µl and one empty vial that was used (but not disposed of). All 15 vials were removed from the BSL-1 -80°C and moved into a separate container labeled Vaccinia and placed in the BSL2 -80°C freezer. After moving the agent to an appropriate location, [redacted] called [redacted] for an update on their investigation. There were no updates at 1300 and [redacted] was asked if [redacted] could just use the stock tubes that were sent of Vaccinia for [redacted] testing in January. [redacted] response was no, inactivated agent needed to be used.

An email was sent by the [redacted] on 1/13/15 at 1650 stating, "I want to update you all on this shipment. The material shipped is indeed killed virus but was labelled with incorrect LIVE labels, so the material you have is inactivated. I will let you know how we will best address this by COB tomorrow."

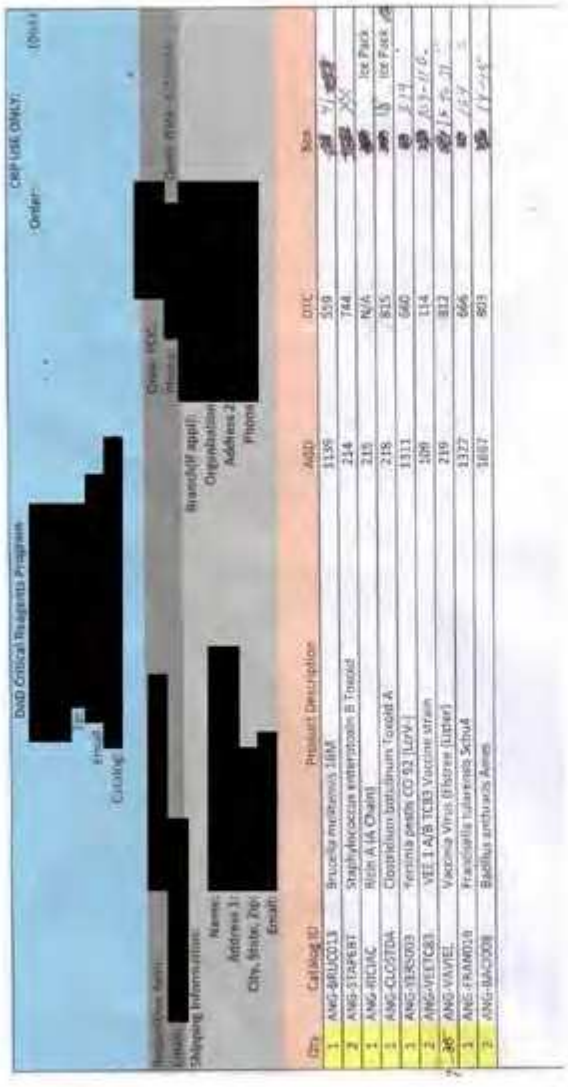
Further information was provided on 1/14/15 at 1711 from the CRP. The email stated, "The shipping issues have been resolved and as stated yesterday the vials were indeed dead antigen. Per procedures I will like all 16 unopened vials to be returned to DPG to be correctly labelled and then we will reship. The shipping cost will be charged to the CRP. I will let you know the charging code and I am sorry for this inconvenience."

A telecom was held on 1/15/15 with [redacted] and [redacted] to discuss details of the root cause analysis performed at CRP. The findings were as follows:

1. All paperwork documentation correctly specifies 17 tubes of AGD219 leaving Dugway.
2. 17 dead ABI Vaccinia tubes were removed from the Freezer. ABI Lot#9C0012 labels were removed and placed on the back of the order form.

# Dugway Proving Grounds Shipping Incidents (*Vaccinia* virus) (cont'd)

3. Aliquot 15-31 was hand-written on back of the original OSCAR form.



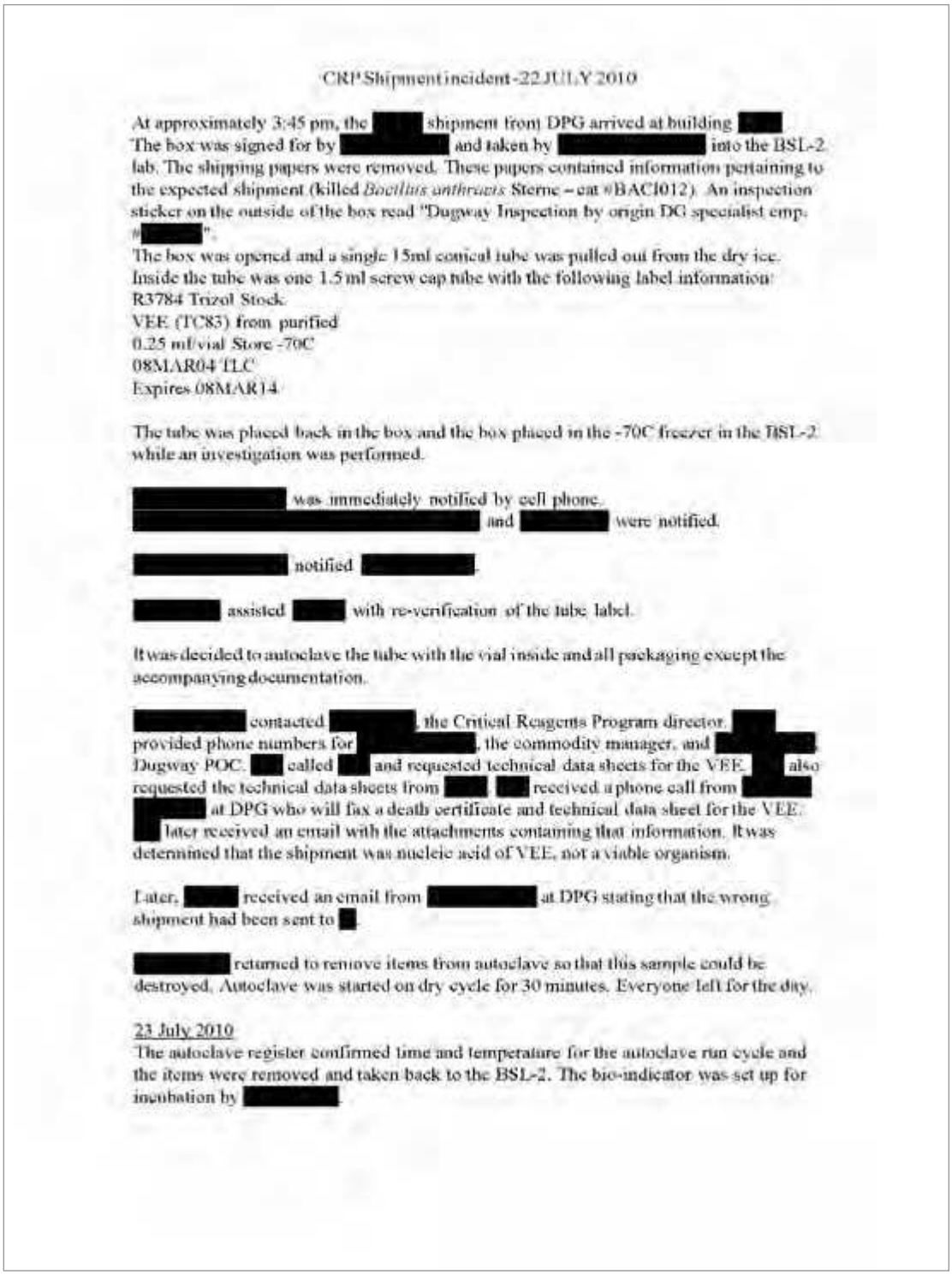

4. A CRP Technician accidently grabbed the WRONG labels and relabeled the tubes with the "Live AGD182" stickers.

# Dugway Proving Grounds Shipping Incidents (*Vaccinia* virus) (cont'd)

5. The correct stickers (which the CRP still has) should have been Aliquot 49-65, AGD219.
6. The staff actually shipped the tubes only verified that 17 tubes of Vaccinia were shipped - they did not verify the lot number with 2 different DPG staff.
7. All "LIVE" tubes leaving DPG have a RED cap on the actual vial. These 17 tubes that were shipped have clear caps, which verifies they are "Dead".
The customer is safe.
CRP recommended the easiest/best course of action will be to "RECALL" all tubes, if possible.

It has been determined that the vials of Vaccinia will be shipped back to Dugway on Tuesday, January 20, 2015. The vials will be re-labeled with the correct label and sent back to [redacted]. The material confirmation sheet will be filled out upon arrival and sent back to the CRP immediately.

# Dugway Proving Grounds Shipping Incident (Venezuelan Equine Encephalitis virus)



CRP Shipment incident -22 JULY 2010

At approximately 3:45 pm, the [redacted] shipment from DPG arrived at building [redacted]. The box was signed for by [redacted] and taken by [redacted] into the BSL-2 lab. The shipping papers were removed. These papers contained information pertaining to the expected shipment (killed *Bacillus anthracis* Sterne – cat #BAC1012). An inspection sticker on the outside of the box read "Dugway Inspection by origin DG specialist emp. #[redacted]".
The box was opened and a single 15ml conical tube was pulled out from the dry ice. Inside the tube was one 1.5 ml screw cap tube with the following label information:
R3784 Trizol Stock
VEE (TC83) from purified
0.25 ml/vial Store -70C
08MAR04 TLC
Expires 08MAR14

The tube was placed back in the box and the box placed in the -70C freezer in the BSL-2 while an investigation was performed.

[redacted] was immediately notified by cell phone.
[redacted] and [redacted] were notified.

[redacted] notified [redacted].

[redacted] assisted [redacted] with re-verification of the tube label.

It was decided to autoclave the tube with the vial inside and all packaging except the accompanying documentation.

[redacted] contacted [redacted], the Critical Reagents Program director, [redacted] provided phone numbers for [redacted], the commodity manager, and [redacted], Dugway POC. [redacted] called [redacted] and requested technical data sheets for the VEE. [redacted] also requested the technical data sheets from [redacted]. [redacted] received a phone call from [redacted] at DPG who will fax a death certificate and technical data sheet for the VEE. [redacted] later received an email with the attachments containing that information. It was determined that the shipment was nucleic acid of VEE, not a viable organism.

Later, [redacted] received an email from [redacted] at DPG stating that the wrong shipment had been sent to [redacted].

[redacted] returned to remove items from autoclave so that this sample could be destroyed. Autoclave was started on dry cycle for 30 minutes. Everyone left for the day.

23 July 2010
The autoclave register confirmed time and temperature for the autoclave run cycle and the items were removed and taken back to the BSL-2. The bio-indicator was set up for incubation by [redacted].

# Appendix I

## Committee for Comprehensive Review of DoD Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* Spores Findings and Recommendations

### *Findings*

#### *The root cause for the incomplete inactivation of* Bacillus anthracis *samples at DoD laboratories*

A single root cause for shipping viable *Bacillus anthracis* could not be identified. DoD personnel appear to have followed their own protocols correctly. However, the committee found inherent deficiencies in protocols for three phases in the production of inactive spores that could lead to nonsterile products:

- radiation dosing,
- viability testing, and
- aseptic operations (contamination prevention).

These deficiencies and other factors contributed to the establishment of protocols that do not completely or permanently sterilize these samples.

#### *Why post inactivation viability testing did not detect the presence of live* Bacillus anthracis

There is no single root cause to explain why the *Bacillus anthracis* samples were incompletely inactivated, or why viability testing did not detect live *Bacillus anthracis* spores. Contributing factors that may have resulted in undetected live *Bacillus anthracis* spores during viability testing in U.S. Army Dugway Proving Ground's samples include deficiencies in sample sizes and inadequate incubation periods after irradiation.

#### *Existing DoD laboratory biological safety protocols and procedures*

The committee identified existing DoD laboratory safety protocols and procedures in each location. However, these procedures are not standardized among the laboratories.

### *DoD laboratory adherence to established procedures and protocols*

In most cases, the committee observed that DoD laboratories followed their own established procedures and protocols.

### *Identification of systemic problems and what steps should be taken to fix those problems*

The primary systemic issue responsible for failures in the preparation of inactivated Bacillus anthracis spores is the lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures.

## *Recommendations (abridged)*

**Quality assurance**. Enhance quality control programs at DoD laboratories working with hazardous select agents and other pathogens.

**Standardize *Bacillus anthracis* inactivation protocols across laboratories**. All DoD laboratories should follow a common standard operating procedure for such practices as irradiation and viability testing.

**Institute more rigorous quality procedures**. Establish quality assurance and quality control procedures for inactivation and viability testing of *Bacillus anthracis* spores.

**Clarify the conditions of the material transfer agreement**. Material transfer agreements enable DoD laboratories to communicate potential hazards to the customers and maintain a positive inventory tracking for potential recalls on all select agent inactivated materials.

**Perform preventive maintenance**. All reusable mechanical equipment employed throughout the process should be routinely maintained and calibrated, from mechanical pipettes to the irradiator.

**Establish and manage an environmental surface sampling program**. Some laboratories lack written procedures to document, investigate, and report contamination found outside primary containment areas during environmental persistent agent sampling.

**Establish validated dose curves**. Radiation dose curves should be generated for each *Bacillus anthracis* strain used for production at the same concentrations used in production, and performed on the same irradiator as used for inactivation of spore preparations.

**Understand the end users' needs**. The Chief Science Officer of the laboratory, Army or Command, should work with individual customers to understand sample requirements and determine the appropriate strains and material needed to support the objectives.

**Quantitate spores before irradiation**. Spore preparations intended for irradiation should be quantified as precisely as possible to maximize the likelihood of achieving the inactivation levels predicted by kill curves produced with the same strain in the same irradiator.

**Peer review**. Establish *Bacillus anthracis* spore inactivation and viability testing protocols that are based on relevant scientific data, standards, and studies conducted to fill knowledge gaps. All protocols and subsequent protocol modifications should be subject to a peer review process, validated, and implemented uniformly across similar operations.

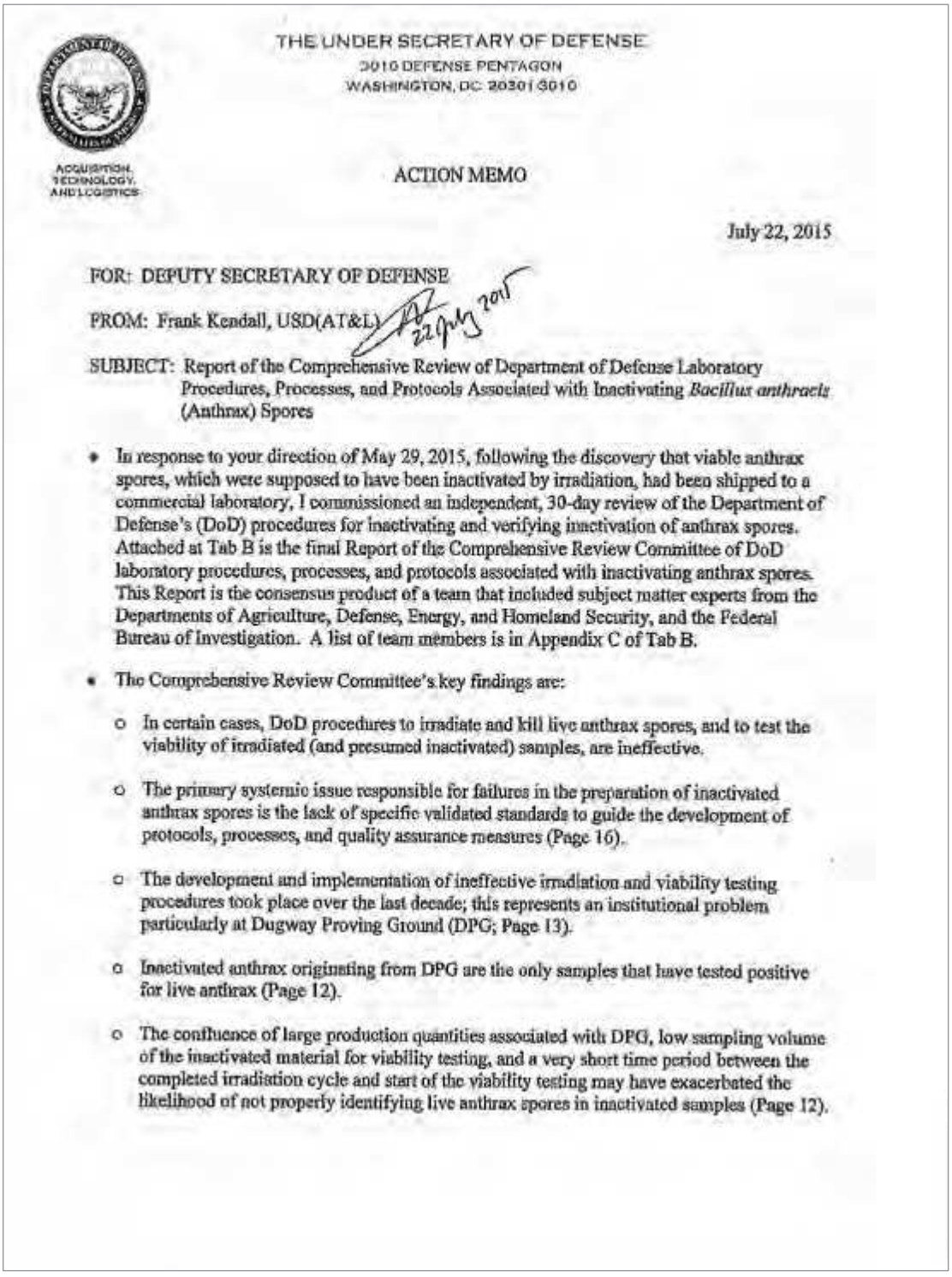
**Program management**. Program managers should provide adequate laboratory space, equipment, and time to conduct relevant safety and surety research for select agents and other pathogens. Program managers should develop a plan to track and document the implementation and long-term sustainability of the recommended corrective actions identified through this review panel as well as all internal and external audits.

# Appendix J

## USD(AT&L) Action Memorandum, July 22, 2015

Refer to page three and four of the action memorandum (pages 77-80) for the recommendations that USD(AT&L) advocated that the Deputy Secretary of Defense direct.

# USD(AT&L) Action Memorandum



THE UNDER SECRETARY OF DEFENSE
3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

ACQUISITION, TECHNOLOGY, AND LOGISTICS

ACTION MEMO

July 22, 2015

FOR: DEPUTY SECRETARY OF DEFENSE

FROM: Frank Kendall, USD(AT&L) 22 July 2015

SUBJECT: Report of the Comprehensive Review of Department of Defense Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* (Anthrax) Spores

- In response to your direction of May 29, 2015, following the discovery that viable anthrax spores, which were supposed to have been inactivated by irradiation, had been shipped to a commercial laboratory, I commissioned an independent, 30-day review of the Department of Defense's (DoD) procedures for inactivating and verifying inactivation of anthrax spores. Attached at Tab B is the final Report of the Comprehensive Review Committee of DoD laboratory procedures, processes, and protocols associated with inactivating anthrax spores. This Report is the consensus product of a team that included subject matter experts from the Departments of Agriculture, Defense, Energy, and Homeland Security, and the Federal Bureau of Investigation. A list of team members is in Appendix C of Tab B.
- The Comprehensive Review Committee's key findings are:
  - In certain cases, DoD procedures to irradiate and kill live anthrax spores, and to test the viability of irradiated (and presumed inactivated) samples, are ineffective.
  - The primary systemic issue responsible for failures in the preparation of inactivated anthrax spores is the lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures (Page 16).
  - The development and implementation of ineffective irradiation and viability testing procedures took place over the last decade; this represents an institutional problem particularly at Dugway Proving Ground (DPG; Page 13).
  - Inactivated anthrax originating from DPG are the only samples that have tested positive for live anthrax (Page 12).
  - The confluence of large production quantities associated with DPG, low sampling volume of the inactivated material for viability testing, and a very short time period between the completed irradiation cycle and start of the viability testing may have exacerbated the likelihood of not properly identifying live anthrax spores in inactivated samples (Page 12).

# USD(AT&L) Action Memorandum (cont'd)

- Laboratory biosafety protocols and procedures are not standardized amongst the DoD laboratories (Page 16); this is potentially due to the fact that the laboratories are managed under multiple chains of command (Page 18, TAB C).

- The Comprehensive Review Committee's recommendations are grouped into three broad areas. The Review Committee recommends DoD laboratories that work with hazardous select agents and other pathogens:
  - Enhance quality control programs, particularly regarding inactivation and viability testing protocols.
  - Establish anthrax spore inactivation and viability testing protocols that are based on relevant scientific data, standards, and studies conducted to fill knowledge gaps.
  - Improve program management to ensure adequate laboratory space, equipment, and time to conduct relevant research for select agents and other pathogens.

- After a careful reading of the Comprehensive Review Report and discussion with subject matter experts, my conclusion is that while this is an institutional failure that spanned more than a decade and involved multiple organizations and multiple leadership changes, there is nevertheless significant evidence from previous incidents that steps should have been taken to address the problems identified by the Review Committee, particularly at DPG. The Review Committee's findings and the viability testing conducted since the discovery that viable anthrax spores had mistakenly been shipped, confirms that the only institution known to have experienced a failure to inactivate and detect failed inactivation was the Army's DPG. I agree with the Review Committee that the combination of unique characteristics at DPG, to include high volume production, low sampling size, intentionally impure products, and more immediate post-inactivation viability testing are possible contributing factors. However, the Report also indicates that in recent years DPG has had a relatively high incidence (20%) of post-inactivation viability tests that showed unsuccessful inactivation, but failed to address all the root causes of this high incidence.

- In my opinion, the technical leadership at DPG, particularly the individuals who are responsible for the safe processing and shipping of inactivated anthrax spores, should have been well aware of the statistical natures of both anthrax spore inactivation by irradiation and post-inactivation viability testing, as well as of the degree to which DPG was operating outside the parameters of the available scientific data on anthrax inactivation, specifically with respect to spore concentration. In addition, there are indications in the Report that the Microbiology Office of the Life Sciences Division at DPG was not keeping adequate records, failing to ensure current procedures were documented correctly, or following laboratory best practices. Although the Review Committee found that the problems at DPG did "not necessarily reflect on any one individual," I believe that individual accountability should be investigated more completely. As a result, I recommend that in addition to implementation of the Review Committee recommendations, you direct the Army to conduct a thorough formal investigation of the institutions and individuals at DPG, including the chain of command, that are responsible for the widespread, unintended viable anthrax spore shipments.

# USD(AT&L) Action Memorandum (cont'd)

- I agree with the Review Committee's conclusion that the science of anthrax inactivation is not adequately understood and that additional work is needed to establish effective standards and protocols for inactivation and viability testing; this is an institutional problem that involves organizations outside the Department. The problem has existed for ten years, and the Review Committee's observations and recommendations apply to all DoD labs that conduct inactivation of anthrax. It is clear that the situation must be corrected per the recommendations of the Review Committee, with particular focus on a re-evaluation of both the underlying science and the structure of the DoD biological laboratory system.
- To ensure that the recommendations of the Report are effectively implemented and that a similar incident does not occur in the future, I recommend you sign the Memorandum at TAB A that directs:
  - The Secretary of the Army, in coordination with the Secretary of the Navy, to develop an implementation plan for addressing the specific recommendations in the Report on quality assurance, peer review, and program management; provide the implementation plan to you for review in 30 days, with periodic updates on progress quarterly thereafter; review laboratory missions and chains of command and provide policy and organizational recommendations to ensure consistent application of biosafety and biosecurity policies across the laboratories; and assess the optimal distribution of research, development, and production activities at the laboratories in support of the Chemical and Biological Defense Program mission to develop countermeasures for the warfighter against chemical and biological threats.
  - The Secretary of the Army initiate a formal investigation, by an appropriate investigative organization, of the specific actions at DPG that contributed to the unintended and unacknowledged shipment of viable anthrax spores to a large number of recipients.
  - Designation of the Secretary of the Army as the DoD Executive Agent for the DoD Biological Select Agent and Toxin (BSAT) Biosafety Program. As the DoD Executive Agent for the DoD BSAT Biosafety Program, the Secretary of the Army shall be responsible for the technical review, inspection, and harmonization of biosafety protocols and procedures across DoD laboratories that handle BSAT and shall have tasking authority of all DoD components for this purpose. The Army shall designate a certified biological safety officer to execute this responsibility.
  - My office to work with DoD stakeholders, the Centers for Disease Control and Prevention (CDC), and other relevant departments and agencies to develop a plan for research related to the development of standardized irradiation and viability testing protocols; establish standards, in coordination with DoD stakeholders, the CDC, and other relevant departments and agencies, for irradiation and viability testing using the results of research conducted; ensure sufficient funding is available through the Chemical and Biological Defense Program for research related to the development of standardized irradiation and viability testing protocols; review, and revise as necessary, DoD biosafety and biosecurity policy and ensure consistent application across DoD laboratories; and oversee Military Department and Service implementation of the Review Committee's recommendations.

3

## USD(AT&L) Action Memorandum (cont'd)

- Continuation of the moratorium on the production, work with, and shipment of inactivated anthrax until all recommendations are addressed, except as required for the development of standardized, peer-reviewed, and validated protocols for inactivation and viability testing.

COORDINATION: OGC

RECOMMENDATION: Sign memorandum at TAB A.

Attachments:
TAB A: DSD Implementation of the Recommendations in the Comprehensive Review Report: Inadvertent Shipment of Live *Bacillus anthracis* (Anthrax) Spores by Department of Defense
TAB B: Comprehensive Review Report
TAB C: DoD Laboratory Chains of Command

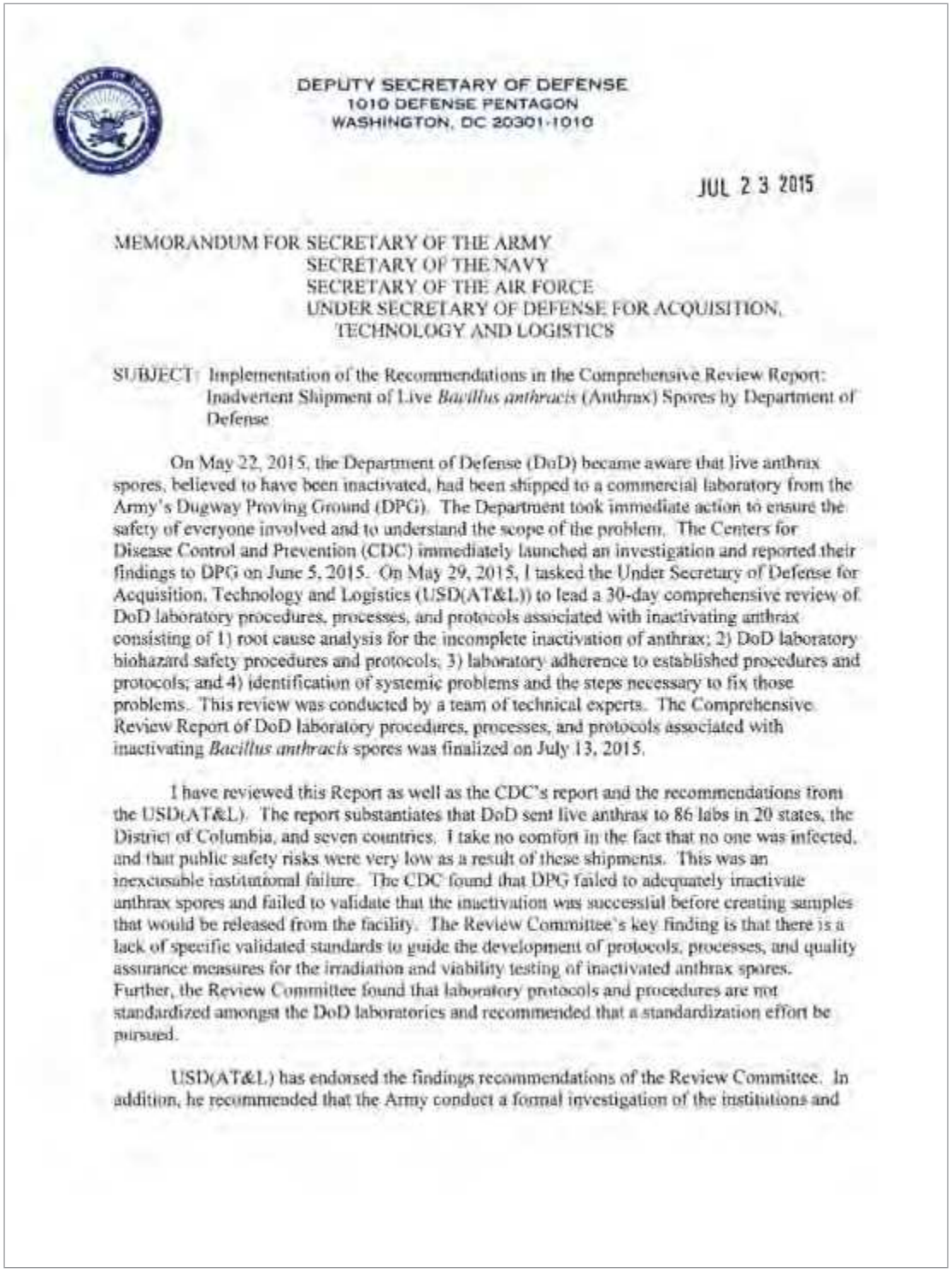
4

# Appendix K

## Deputy Secretary of Defense Memorandum, July 23, 2015

The five Deputy Secretary of Defense directives to USD(AT&L) are listed on page two of the following memorandum (pages 82-84). The five Deputy Secretary of Defense directives to the Secretary of the Army, as well as the designation of the Secretary of the Army as DoD Executive Agent for the DoD BSAT Biosafety Program are also listed on page two of the memorandum.

# Deputy Secretary of Defense Memorandum



DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

JUL 23 2015

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE
UNDER SECRETARY OF DEFENSE FOR ACQUISITION, TECHNOLOGY AND LOGISTICS

SUBJECT: Implementation of the Recommendations in the Comprehensive Review Report: Inadvertent Shipment of Live *Bacillus anthracis* (Anthrax) Spores by Department of Defense

On May 22, 2015, the Department of Defense (DoD) became aware that live anthrax spores, believed to have been inactivated, had been shipped to a commercial laboratory from the Army's Dugway Proving Ground (DPG). The Department took immediate action to ensure the safety of everyone involved and to understand the scope of the problem. The Centers for Disease Control and Prevention (CDC) immediately launched an investigation and reported their findings to DPG on June 5, 2015. On May 29, 2015, I tasked the Under Secretary of Defense for Acquisition, Technology and Logistics (USD(AT&L)) to lead a 30-day comprehensive review of DoD laboratory procedures, processes, and protocols associated with inactivating anthrax consisting of 1) root cause analysis for the incomplete inactivation of anthrax; 2) DoD laboratory biohazard safety procedures and protocols; 3) laboratory adherence to established procedures and protocols; and 4) identification of systemic problems and the steps necessary to fix those problems. This review was conducted by a team of technical experts. The Comprehensive Review Report of DoD laboratory procedures, processes, and protocols associated with inactivating *Bacillus anthracis* spores was finalized on July 13, 2015.

I have reviewed this Report as well as the CDC's report and the recommendations from the USD(AT&L). The report substantiates that DoD sent live anthrax to 86 labs in 20 states, the District of Columbia, and seven countries. I take no comfort in the fact that no one was infected, and that public safety risks were very low as a result of these shipments. This was an inexcusable institutional failure. The CDC found that DPG failed to adequately inactivate anthrax spores and failed to validate that the inactivation was successful before creating samples that would be released from the facility. The Review Committee's key finding is that there is a lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures for the irradiation and viability testing of inactivated anthrax spores. Further, the Review Committee found that laboratory protocols and procedures are not standardized amongst the DoD laboratories and recommended that a standardization effort be pursued.

USD(AT&L) has endorsed the findings recommendations of the Review Committee. In addition, he recommended that the Army conduct a formal investigation of the institutions and

# Deputy Secretary of Defense Memorandum (cont'd)

individuals at DPG, including the chain of command, as well as the actions of DPG that led to the inadvertent widespread shipments of viable anthrax spores.

To ensure that the recommendations of the Report are effectively implemented and that a similar incident does not occur in the future, I direct the following:

The USD(AT&L) will:

- Work with DoD stakeholders, the CDC, and other relevant departments and agencies to develop a plan for research related to the development of standardized irradiation and viability testing protocols;
- Establish standards, in coordination with DoD stakeholders, the CDC, and other relevant departments and agencies, for irradiation and viability testing using the results of research conducted;
- Ensure sufficient funding is available through the Chemical and Biological Defense Program for research related to the development of standardized irradiation and viability testing protocols;
- Review, and revise as necessary, DoD biosafety and biosecurity policy and ensure consistent application across DoD laboratories; and
- Oversee Military Department and Service implementation of the Review Committee's recommendations.

The Secretary of the Army will:

- Conduct a full accountability assessment of the responsible institutions and individuals at DPG, including the chain of command, to include initiating a formal investigation by an appropriate investigative organization, of the specific actions at DPG that contributed to the unintended and unacknowledged shipment of viable anthrax spores to a large number of recipients;
- In coordination with the Secretary of the Navy, develop an implementation plan for addressing the specific recommendations in the Report on quality assurance, peer review, and program management;
- Provide the implementation plan to me for review in 30 days, with quarterly updates on progress thereafter;
- Review laboratory missions and chains of command and provide policy and organizational recommendations to ensure consistent application of biosafety and biosecurity policies across the laboratories; and
- Assess the optimal distribution of research, development, and production activities at the laboratories that support the Chemical and Biological Defense Program mission to develop countermeasures for the warfighter against chemical and biological threats.

In addition, I am designating the Secretary of the Army as the DoD Executive Agent for the DoD Biological Select Agent and Toxin (BSAT) Biosafety Program. As the DoD Executive Agent for the DoD BSAT Biosafety Program, the Secretary of the Army shall be responsible for the technical review, inspection, and harmonization of biosafety protocols and procedures across DoD laboratories that handle BSAT and shall have tasking authority of all DoD components for

2

## Deputy Secretary of Defense Memorandum (cont'd)

this purpose. The Army shall designate a certified biological safety officer to execute this responsibility.

Until all the recommendations in the Report are addressed, I direct the moratorium on the production, handling, testing, and shipment of inactivated anthrax, except as required for the development of standardized, peer-reviewed, validated protocols for inactivation and viability testing. USD(AT&L) will work with all DoD and interagency stakeholders to mitigate the impacts of the continuing moratorium on important research, development, and production activities related to the development of countermeasures to protect the warfighter and the Nation from biological threats.

cc:
Chairman of the Joint Chiefs of Staff
Under Secretary of Defense for Policy
Under Secretary of Defense for Personnel and Readiness

3

# Appendix L

## The Centers for Disease Control and Prevention Division of Select Agent and Toxins cited requirements from 42 CFR, Part 73 and Report Observations Based on the Cited Requirements

(Refer to pages 87-89 for the full report)

**Requirement**: The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidently exposed to, or infected with a select agent. 42 CFR, Part 73 [Section 12(a)]

**Observation**: The standard operating procedures for the irradiation of *Bacillus anthracis* spore suspensions did not account for the variable amounts of spores treated in the gamma cell irradiator. This resulted in inactivation failures that led to the transfer of viable Bacillus anthracis to nonregistered entities.

Provide an updated standard operating procedure, as part of or referenced in the U.S. Army Dugway Proving Grounds Life Science Test Facility (LSTF) biosafety plan, in which all steps in the preparation of the spore suspensions have been verified to not inhibit their inactivation.

**Requirement**: The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). 42 C.F.R., Part 73 [Section 12(b)]

**Observation**: The method used for inactivation of the *Bacillus anthracis* spore suspensions, Cobalt 60 gamma irradiation, was not validated using standardized control spore samples at varying concentrations, volumes, and levels of irradiation before creating spore suspensions that would be released from the facility. As a result, viable *Bacillus anthracis* spore suspensions were shipped from LSTF as inactivated samples in April 2015, December 2014, October 2014, and March 2014.

Provide documentation validating the method of inactivation to ensure that each preparation does not contain viable spores or cells after irradiation. Please include, but not limited to, the following:

- How LSTF will determine that the parameters of the irradiation are adequate.
- How LSTF will determine that post-irradiation sample preparations are completely sterile.

**Requirement**: Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by CDC or APHIS prior to the transfer. 42 C.F.R., Part 73 [Section 16(a)]

**Observation**: As of June 5, 2015, LSTF has sent unauthorized shipments of live *Bacillus anthracis* to 52 laboratories located across 19 U.S. states (including the District of Columbia), from January 2005 to May 2015, totaling 74 unauthorized shipments.

Effective immediately (presumably at the date of the report) all shipments of "inactivated" *Bacillus anthracis* preparations were suspended. Any "inactivated" *Bacillus anthracis* preparations were to be considered a select agent until proven otherwise. Before any shipments of inactivated preparations could occur, LSTF had to submit definitive proof that the procedures implemented ensured that no viable organisms were present in the preparations.

# Centers for Disease Control and Prevention Report

Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Atlanta, Georgia

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Agriculture Select Agent Services
Riverdale, Maryland

June 05, 2015

[redacted] (Responsible Official)
Life Science Test Facility
2029 Burns Road
Dugway, UT 84022-5006
[redacted]
cc: [redacted]

**RE: Entity Inspection Report; Life Science Test Facility (LSTF)**

Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have established regulatory requirements for the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal and plant health, and animal and plant products. These requirements can be found at 42 CFR Part 73 (HHS), 7 CFR Part 331 (USDA-PPQ), and 9 CFR Part 121 (USDA-VS). The Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) inspects entities to evaluate whether they meet the regulatory requirements set forth in 42 CFR Part 73, and the Animal and Plant Health Inspection Service (APHIS) Agriculture Select Agent Services (AgSAS) inspects entities to evaluate whether they meet the regulatory requirements set forth in 7 CFR Part 331 and 9 CFR Part 121. The above referenced regulations and supporting guidance information may be found at http://www.selectagents.gov/

DSAT inspectors visited your facility located at 2029 Burns Road Dugway, UT 84022-5006 from May 26, 2015 to May 28, 2015. A list of laboratories inspected on these dates is on file with this letter at CDC.

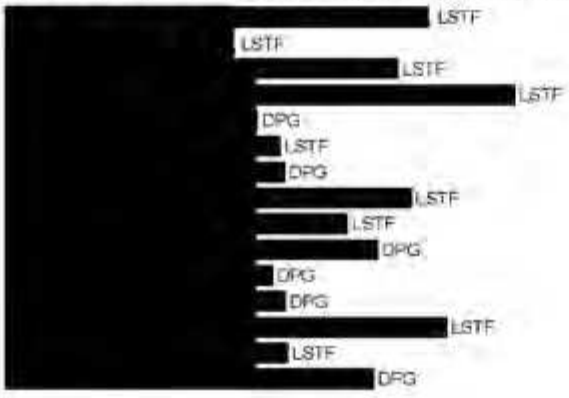
The following personnel from the CDC Select Agent Program inspected the facility:

[redacted]

The following person from the Federal Bureau of Investigation inspected the facility:

[redacted] Special Agent

Individuals from Life Science Test Facility present during the inspection included:



# Centers for Disease Control and Prevention Report (cont'd)

[redacted] LSTF
[redacted] LSTF
[redacted] LSTF
[redacted] DPC
[redacted] DPS
ATEC Headquarters G-2
[redacted] LSTF

During the inspection, departures from regulatory requirements cited above were noted. Please address each of the items described in Attachment 1 (List of Entity Departures) and include in your response the specific actions or changes to be adopted to correct these departures. A detailed response should be received by this office not later than 14 calendar days from receipt of this letter. An electronic copy of your response should be sent to the lead inspector. Failure to fully respond may result in the initiation of proceedings for the withdrawal of your facility registration to possess, use, or transfer select agents and toxins.

**Effective immediately, all shipments of "inactivated" *B. anthracis* preparations are to be suspended, except in support of the ongoing investigation. Any "inactivated" *B. anthracis* preparations are to be considered a select agent until proven otherwise. Before any shipments of inactivated preparations can occur, LSTF must submit definitive proof that the procedures implemented ensure that no viable organisms are present in the preparations.**

**Please be advised that all newly discovered spore preparations determined to be viable must be added to LSTF's inventory as required in Section 17 of the Select Agent Regulations.**

If you have any questions concerning this correspondence please contact [redacted] at [redacted]

Sincerely,

Robin S. Weyant, PhD, RBP (ABSA)
Captain, USPHS (Ret.)
Director, Division of Select Agents and Toxins
Department of Health and Human Services
Centers for Disease Control and Prevention

Attachment: 1
List of Entity Departures

# Centers for Disease Control and Prevention Report (cont'd)

**Entity Inspection Report**
Life Science Test Facility
**Attachment 1: Entity Departures**

Attachment 1
Page 3

Departures noted during the period of May 26, 2015 to May 26, 2015 at Life Science Test Facility (LSTF) (citations from 42 CFR Part 73 specifying each requirement are given in brackets)

1 **Requirement:** The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. [Section 12(a)]

**Observation:** The Standard Operating Procedures for the irradiation of *B. anthracis* spore suspensions did not account for the variable amounts of spores treated in the gamma cell irradiator. This resulted in inactivation failures that led to the transfer of viable *B. anthracis* to non-registered entities.

Please provide an updated standard operating procedure, as part of or referenced in LSTF's biosafety plan, in which all steps in the preparation of the spore suspensions have been verified to not inhibit their inactivation.

2 **Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [Section 12(b)]

**Observation:** The method used for inactivation of the *B. anthracis* spore suspensions, Cobalt 60 gamma irradiation, was not validated using standardized control spore samples at varying concentrations, volumes, and levels of irradiation before creating spore suspensions that would be released from the facility. As a result, viable *B. anthracis* spore suspensions were shipped from LSTF as inactivated samples in April 2015, December 2014, October 2014, and March 2014.

Please provide documentation validating the method of inactivation to ensure that each preparation does not contain viable spores or cells after irradiation. Please include, but not limited to, the following: (1) How LSTF will determine that the parameters of the irradiation protocols are adequate; and (2) How LSTF will determine that post-irradiation sample preparations are completely sterile.

3 **Requirement:** Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by CDC or APHIS prior to the transfer. [Section 16(a)]

**Observation:** As of June 5, 2015, Life Science Test Facility has sent unauthorized shipments of live *B. anthracis* to 52 laboratories located across 19 U.S. states (including the District of Columbia), from January 2005 to May 2015, totaling 74 unauthorized shipments. The *B. anthracis* preparations that are currently known to contain viable organisms after gamma irradiation inactivation include: Ames lot 1667, Ames lot 70, Ames lot 516, Canadian Bison lot 822, Jamaican lot 810, Scotland lot 806, and Zimbabwe lot 794.

**Effective immediately, all shipments of "inactivated" *B. anthracis* preparations are to be suspended. Any "inactivated" *B. anthracis* preparations are to be considered a select agent until proven otherwise. Before any shipments of inactivated preparations can occur, LSTF must submit definitive proof that the procedures implemented ensure that no viable organisms are present in the preparations.**

# Appendix M

## BSAT Laboratory Inspection Requirements (Vulnerability Assessments)

### *Army*

According to Army Regulation 190-17, *Military Police*, Biological Select Agents and Toxins Security Program, 3 December 2009, Chapter 4 states:

> All biological select agents and toxins facilities: A vulnerability assessment (VA) will be conducted at each BSAT facility and laboratory (Laboratory Response Network facilities that do not store BSAT are exempt) to:
>
> a. Determine the facility's vulnerability to sabotage, theft, loss, seizure, or unauthorized access, use, or diversion of BSAT materiels from both external and internal threats.
>
> b. Counter the identified vulnerabilities.
>
> Department of the Army (DA) Implementing Instructions to the DoD Postulated Threat: The VA team will utilize the DA implementing instructions on threats to BSAT based on the DA Implementing Instructions to the DoD Postulated Threat when assessing the facility's vulnerabilities.
>
> Conducting vulnerability assessments and reviews
>
> a. The VA will be conducted—
>
> (1) When a BSAT facility is activated.
>
> (2) When no record exists of a prior VA.
>
> (3) When significant changes/modifications to the facility have taken place since the last VA that may have an impact on the site security posture. (that is, the construction of facilities, loss of intrusion detection system, and so forth)
>
> (4) When significant changes have been made to the DA Implementing Instructions to the DoD Postulated Threat that would affect security forces.
>
> (5) When the commander determines greater frequency is required.

b. The VA will be formally reviewed annually (every 12 months) and forwarded through command channels for review.

c. The Senior Commander (SC) will ensure BSAT facilities complete the required VA, updates, and annual reviews and submit them through command channels in a timely manner. A courtesy copy will be provided to the garrison commander. The SC is the approval authority for all VAs and VA updates.

## *Navy*

According to Office of the Chief of Naval Instruction 5530.16A, Minimum Security Standards for Safeguarding Biological Select Agents and Toxins, 11 May 2011, 3. Responsibilities states:

> The Commander, Navy Installations Command shall submit program objective memorandum requirements. The review will use a risk-based decision-making process that incorporates threat and vulnerability, representative loss estimates, and cost of implementation to provide a meaningful benefit and cost index for relative ranking in order to substantiate requested physical security upgrades. Upgrade reviews may include physical security of facilities, secured storage equipment, secured transportation of BSAT materials, surveillance systems, personal security processes, or other substantiated requests to assure that only the most reliable and skilled personnel have access to the materials necessary to conduct research appropriate to the mission.

## *Air Force*

According to Air Force Directive 10-39, Operations, Safeguarding Biological Select agents and Toxins, 19 August 2011, 3. Responsibilities and Authorities:

> The Deputy Chief of Staff for Logistics, Installations, and Mission Support (AF/A4/7) will ensure a security baseline vulnerability assessment is conducted annually and reviewed or updated as necessary when new threats or vulnerabilities become apparent.

# Management Comments

## Under Secretary of Defense for Acquisition, Technology, and Logistics response on behalf of the Deputy Secretary of Defense (Pages 92 – 96)

THE UNDER SECRETARY OF DEFENSE
3010 DEFENSE PENTAGON
WASHINGTON, DC 20301-3010

ACQUISITION, TECHNOLOGY, AND LOGISTICS

APR 01 2016

MEMORANDUM FOR DEPUTY INSPECTOR GENERAL, SPECIAL PLANS AND OPERATIONS, OFFICE OF INSPECTOR GENERAL

SUBJECT: Evaluation of DoD Biological Safety and Security Implementation (Project No. D2015-D00SPO-0054.000)

This is in response to your March 4, 2016, memorandum requesting comments on recommendations made in the Department of Defense Office of the Inspector General (DoDIG) report on the "Evaluation of DoD Biological Safety and Security Implementation." I am responding on behalf of the Deputy Secretary of Defense; the attachment responds to all of the recommendations requesting comment. The Department appreciates the opportunity to review the report and agrees with the DoDIG recommendations.

If additional information is required, please contact [redacted]

/ Frank Kendall

Attachment:
As stated

# Management Comments (cont'd)

**DODIG DRAFT REPORT DATED MARCH 4, 2016**
**PROJECT NO. D2015-D000SPO-0054.000**

**"EVALUATION OF DOD BIOLOGICAL SAFETY AND SECURITY IMPLEMENTATION"**

**DEPARTMENT OF DEFENSE RESPONSES TO THE DODIG RECOMMENDATIONS**

**RECOMMENDATION 1.a: Deputy Secretary of Defense appoint a single Executive Agent responsible for biosafety and biosecurity.**

**DoD RESPONSE:** Agree. The Secretary of the Army was designated as the Executive Agent (EA) for the Department of Defense (DoD) Biological Select Agent and Toxins (BSAT) Biosafety Program in a July 23, 2015, memorandum. That designation was included as a responsibility for the Secretary of the Army in the DoD Instruction 5210.88, "Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)," published on January 19, 2016. The DoD Instruction specifically states that the Secretary of the Army "serves as DoD Executive Agent for the DoD BSAT Biosafety Program…with responsibility for the technical review, inspection, and harmonization of biosafety protocols and procedures across DoD laboratories that handle BSAT and tasking authority of all DoD Components for this purpose."

The Army Biosafety Task Force, established in July 2015 to comprehensively address the issues identified as a result of the inadvertent shipment of live anthrax, came to the conclusion that biosafety and biosecurity are inextricably linked. The Task Force work highlighted that the separation of these programs creates gaps that make the consistent application and oversight of biosafety and biosecurity policies across the Services and labs difficult. To make the program more effective and reduce the risk to DoD, the EA authority will be expanded to oversee both the biosafety and biosecurity programs for the Department. The Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics (OUSD(AT&L)) has been directed to draft and coordinate a DoD Directive outlining the roles and responsibilities of the Army EA.

**RECOMMENDATION 1.b.a: Deputy Secretary of Defense direct the Executive Agent for biosafety and biosecurity to conduct standardized oversight and inspections in accordance with applicable Federal regulations of Department of Defense Biological Select Agent and Toxins laboratories.**

**DoD RESPONSE:** Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 1.b.b: Deputy Secretary of Defense direct the Executive Agent for biosafety and biosecurity to track all internal and external inspection results and report status of all findings, recommendations, and actions taken to address deficiencies to the appropriate Department of Defense management level.**

# Management Comments (cont'd)

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 1.b.c: Deputy Secretary of Defense direct the Executive Agent for biosafety and biosecurity to develop and implement training for Biological Select Agent and Toxins laboratory inspectors and subject matter expert inspection team augmentees.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 1.b.d: Deputy Secretary of Defense direct the Executive Agent for biosafety and biosecurity to ensure that all personnel included in inspection teams have sufficient scientific expertise and experience.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 2.a: Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity (Recommendation 1.a) to implement an external technical and scientific peer review function that addresses both biosafety and biosecurity issues to support all Department of Defense Biological Select Agent and Toxins laboratories.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 2.b: Under Secretary of Defense for Acquisitions, Technology, and Logistics issue guidance that all Department of Defense Biological Select Agent and Toxins laboratories implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity issues.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 3.a: Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity to serve as the single Department of Defense point of contact with the Centers for Disease Control and**

2

# Management Comments (cont'd)

**Prevention and the Animal and Plant Health Inspection Service for coordinating and participating in inspections of Department of Defense Biological Select Agents and Toxins laboratories.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 3.b: Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity to develop and implement an agreement with the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service for scheduling combined inspections of Department of Defense Biological Select Agents and Toxins laboratories.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 3.c: Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity to define combined inspection criteria and guidance with the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service for Department of Defense Biological Select Agents and Toxins laboratories.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 3.d: Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity to serve as the formal communication entity with the Federal Select Agent Program regarding findings and lessons learned from the Centers for Disease Control and Prevention and the Animal and Plant Health Inspection Service relevant to the Department of Defense Biological Select Agents and Toxins program.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 4.a: Deputy Secretary of Defense direct the Department of Defense Executive Agent for Biosafety and Biosecurity to implement criteria for inclusion of site-specific security vulnerability assessment findings into Department of Defense Biological Select Agent and Toxins laboratory biosafety and biosecurity inspections.**

3

## Management Comments (cont'd)

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The role identified in this recommendation is listed in the draft directive.

**RECOMMENDATION 4.b: Under Secretary of Defense for Acquisitions, Technology, and Logistics develop implementing guidance that requires site-specific laboratory security vulnerability assessment findings be included during Biological Select Agent and Toxins laboratory inspections.**

**DoD RESPONSE**: Agree. The OUSD(AT&L) is drafting a DoD Directive for the DoD BSAT Biosafety and Biosecurity Program that establishes policy and designates and defines the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Program. The EA role includes harmonization across sites to ensure site-specific vulnerability assessments are considered during security inspections. The Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs is also reviewing the DoD Instruction 5210.88 to reinforce this issue.

# Acronyms and Abbreviations

| | |
|---|---|
| **APHIS** | Animal and Plant Health Inspection Service (USDA) |
| **AT&L** | Acquisition, Technology & Logistics |
| **BSAT** | Biological Select Agents and Toxins |
| **BSL** | Biological Safety Level |
| **BSL-4** | Biosafety level 4 which is the maximum level |
| **BUMED** | Bureau of Medicine and Surgery |
| **CDC** | Centers for Disease Control and Prevention |
| **CFR** | Code of Federal Regulations |
| **DAIG** | Department of the Army Inspector General |
| **DPG** | Dugway Proving Ground |
| **DSD** | Deputy Secretary of Defense |
| **ECBC** | Edgewood Chemical and Biological Center |
| **FESAP** | Federal Experts Security Advisory Panel, |
| **FTAC** | Fast Track Action Committee |
| **HHS** | Department of Health and Human Services |
| **JP** | Joint Publication |
| **LSTF** | Life Science Test Facility |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DEPARTMENT OF DEFENSE

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