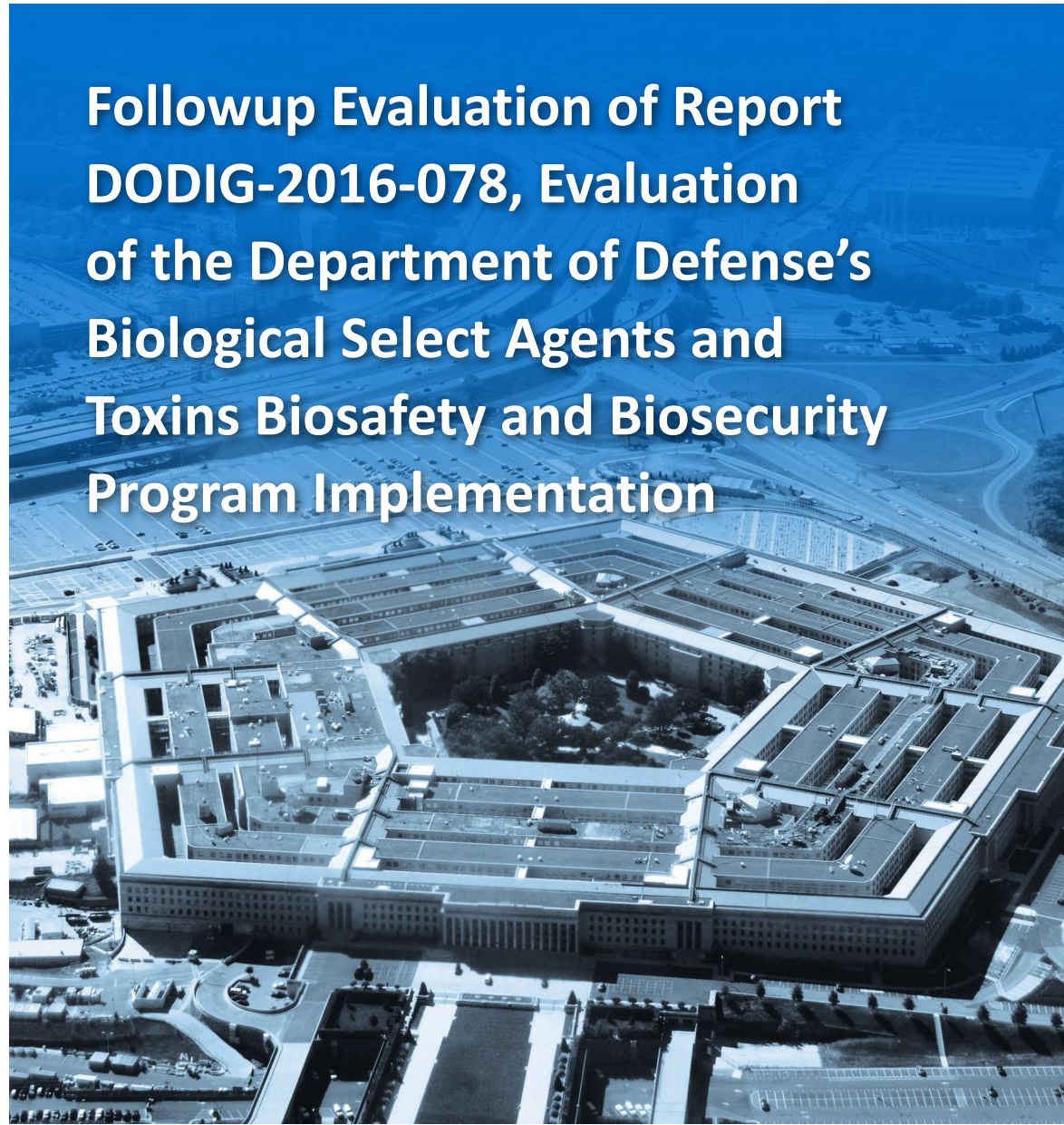




INSPECTOR GENERAL

U.S. Department of Defense

JULY 16, 2020



Followup Evaluation of Report DODIG-2016-078, Evaluation of the Department of Defense's Biological Select Agents and Toxins Biosafety and Biosecurity Program Implementation

INTEGRITY ★ INDEPENDENCE ★ EXCELLENCE





Results in Brief

Followup Evaluation of Report DODIG-2016-078, Evaluation of the Department of Defense's Biological Select Agents and Toxins Biosafety and Biosecurity Program Implementation

July 16, 2020

Objective

The objective of this followup evaluation was to validate implementation of recommendations from report DODIG-2016-078, "Evaluation of DoD Biological Safety and Security Implementation," April 27, 2016, and determine whether the actions taken by the Office of the Under Secretary of Defense for Acquisition and Sustainment and the Secretary of the Army as the DoD Executive Agent for the DoD Biological Select Agents and Toxins Biosafety and Biosecurity Programs met the intent of the recommendations.

Background

Biological defense encompasses measures taken to protect and recover from the effects of biological select agents and toxins or emerging biological threats. Biological select agents and toxins (BSAT) are the microorganisms and poisonous substances that have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products. Common examples of BSAT are microorganisms that cause anthrax, bubonic plague, and smallpox, as well as the toxin ricin.

The Army and Navy maintain BSAT Biosafety and Biosecurity Programs to accomplish the biological defense vision to address biological threats and minimize their effects. The Army maintains

Background (cont'd)

three BSAT-registered laboratories and the Navy has two BSAT-registered laboratories.

- U.S. Army Combat Capabilities Development Command Chemical Biological Center, Dugway Proving Ground, Utah
- U.S. Army Combat Capabilities Development Command Chemical Biological Center, Aberdeen Proving Ground, Maryland
- U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland
- Naval Surface Warfare Center Dahlgren Division, Dahlgren, Virginia
- Naval Medical Research Center Biological Defense Research Directorate, Fort Detrick, Maryland

In April 2016, the DoD Office of Inspector General published report DODIG-2016-078, "Evaluation of DoD Biological Safety and Security Implementation," (our 2016 report) which included 13 recommendations concerning the execution of the DoD BSAT Biosafety and Biosecurity Programs. In January 2019, the Office of the Under Secretary of Defense for Acquisition and Sustainment issued a new directive, DoD Directive (DoDD) 5101.20E, to address the 13 recommendations.

The Secretary of Defense designated the roles and responsibilities for the DoD BSAT Biosafety and Biosecurity Programs to several DoD components, including the Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD[A&S]), the Secretary of the Army, the Department of the Army Inspector General (DAIG) Technical Inspections Division, and the BSAT Biorisk Program Office (BBPO).



Results in Brief

Followup Evaluation of Report DODIG-2016-078, Evaluation of the Department of Defense's Biological Select Agents and Toxins Biosafety and Biosecurity Program Implementation

Finding

The OUSD(A&S) and the Secretary of the Army as the DoD Executive Agent (EA) for the DoD BSAT Biosafety and Biosecurity Programs implemented actions that met the intent of 9 of the 13 recommendations from our 2016 report. For example, the Deputy Secretary of Defense designated the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Programs, which addressed the recommendation regarding appointing a single EA responsible for biosafety and biosecurity. However, 4 of the 13 recommendations from our 2016 report had not fully been implemented.

- The OUSD(A&S) did not issue policy requiring all DoD BSAT-registered laboratories to implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity. This occurred because an OUSD(A&S) Chemical and Biological Security Policy official stated that the language in DoDD 5101.20E requires both external and internal technical and scientific peer reviews. However, the directive only requires an external peer review.
- The EA did not conduct standardized oversight of the BSAT-registered laboratories or track all internal and external inspection results. This occurred because the BBPO officials, as directed by the former Executive Agent Responsible Official (EARO), focused more on support efforts to advise, assist, and advocate for the BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratories, without establishing themselves as an oversight body in accordance with DoDD 5101.20E.
- The DAIG did not develop and implement training for BSAT laboratory inspectors and subject matter expert inspection team augmentees. This occurred because the DAIG Technical Inspections Division relied on training obtained from the Department of the Army Inspector General course, non-DoD BSAT-registered laboratory specific technical courses, and the inspectors' experience.

As a result, incomplete and inconsistent oversight of the DoD BSAT Biosafety and Biosecurity Programs remain, which increases the risk of exposing DoD BSAT entities, personnel, and the public to the hazards associated with BSAT.

Recommendations

In February 2019, the DoD Office of Inspector General closed the recommendations from our 2016 report. However, in this followup evaluation, we determined that 4 of the 13 recommendations from our 2016 report should not have been closed. Therefore, we are making 3 new recommendations (we combined two of the recommendations from our 2016 report into one new recommendation). Specifically, we recommend that the Office of the Under Secretary of Defense for Acquisition and Sustainment issue policy requiring all DoD biological select agents and toxins-registered laboratories to implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity.

We recommend that the DoD Executive Agent for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs, in coordination with the Biological Select Agents and Toxins Biorisk Program Office, develop a plan to conduct standardized oversight of the DoD Biological Select Agents and Toxins Biosafety and Biosecurity Programs and biological select agents and toxins-registered laboratories, including tracking all internal and external inspection results.

We recommend that the Department of the Army Inspector General Technical Inspections Division, in coordination with the Executive Agent for the DoD Biological Select Agents and Toxins Biosafety and Biosecurity Programs, develop and implement training requirements for biological select agents and toxins laboratory inspectors and inspection team subject matter expert augmentees.



Results in Brief

Followup Evaluation of Report DODIG-2016-078, Evaluation of the Department of Defense's Biological Select Agents and Toxins Biosafety and Biosecurity Program Implementation

Management Comments and Our Responses

The Acting Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, responding on behalf of the Under Secretary of Defense for Acquisition and Sustainment, agreed with the recommendation. Specifically, the Acting Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs will include a requirement for all DoD BSAT laboratories to establish internal technical and scientific peer review panels to review biosafety protocols and biosecurity policies in Change 1 to Department of Defense Directive 5101.20E, "DoD Biological Select Agents and Toxins (BSAT) Biosafety and Biosecurity Program." Therefore, the recommendation is considered resolved, but will remain open.

The Department of the Army Surgeon General, as the Executive Agent Responsible Official, responding on behalf of the DoD Executive Agent for the BSAT Biosafety and Biosecurity Programs, agreed with the recommendation. The Surgeon General has developed a plan to conduct standardized oversight of the DoD BSAT Biosafety and Biosecurity Programs and DoD BSAT-registered laboratories, including tracking all internal and external inspection results. Specifically, the EARO and a BBPO official have begun site visits to each BSAT-registered laboratory and will provide formal communication to the BSAT biosafety and biosecurity community to clarify their oversight role with expected completion by August 31, 2020. Additionally, the BBPO

developed and implemented a formal BSAT Executive Agent Responsible Official Program for Biosafety and Biosecurity Related Staff Assistance Visits Program, signed by the EARO on May 27, 2020. According to management comments and a review of program documentation, this Staff Assistance Visits Program will provide direct oversight of the DoD BSAT-registered laboratories' compliance status with Federal, DoD, Service-specific, state, and local regulations to ensure the laboratories are inspection ready at all times. Additionally, the BBPO has moved from tracking the inspection results from the initial spreadsheet to the Quality Management System Inspections Database within the Joint Interagency Biorisk System. The BBPO has completed entry of inspection results from the Department of the Army Inspector General Technical Inspections Division and the Centers for Disease Control and Prevention Division of Select Agents and Toxins back to 2016, and has begun entering results from the Department of the Army Safety pre-operational surveys with planned database entry completion by July 1, 2020. Therefore, we consider this recommendation closed.

The Department of the Army Inspector General, responding on behalf of the DAIG Technical Inspections Division, agreed with the recommendation. Specifically, the Department of the Army Inspector General agreed to require technical inspectors and external subject matter expert inspectors to participate in training specific to DoD and Service-specific BSAT standards. Therefore, the recommendation is resolved, but will remain open.

Please see the Recommendations Table on the next page for the status of the recommendations.

Recommendations Table

Management	Recommendations Unresolved	Recommendations Resolved	Recommendations Closed
Office of the Under Secretary of Defense for Acquisition and Sustainment	None	1	None
Department of Defense Executive Agent for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs	None	None	2
Department of the Army Inspector General Technical Inspections Division	None	3	None

Note: The following categories are used to describe agency management’s comments to individual recommendations.

- **Unresolved** – Management has not agreed to implement the recommendation or has not proposed actions that will address the recommendation.
- **Resolved** – Management agreed to implement the recommendation or has proposed actions that will address the underlying finding that generated the recommendation.
- **Closed** – OIG verified that the agreed upon corrective actions were implemented.



**INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
4800 MARK CENTER DRIVE
ALEXANDRIA, VIRGINIA 22350-1500**

July 16, 2020

**MEMORANDUM FOR SECRETARY OF THE ARMY
OFFICE OF THE UNDER SECRETARY OF DEFENSE FOR
ACQUISITION AND SUSTAINMENT
SURGEON GENERAL OF THE UNITED STATES ARMY
AUDITOR GENERAL, DEPARTMENT OF THE ARMY**

SUBJECT: Followup Evaluation of Report DODIG-2016-078, Evaluation of the DoD's Biological Select Agents and Toxins Biosafety and Biosecurity Program Implementation (Report No. DODIG-2020-105)

This final report provides the results of the DoD Office of Inspector General's evaluation. We previously provided copies of the draft report and requested written comments on the recommendations. We considered managements' comments on the draft report when preparing the final report. All comments received are included in the report.

Management comments and associated actions from the Department of Defense Executive Agent for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs addressed the recommendation in this report and we consider the recommendation closed. The Office of the Under Secretary of Defense for Acquisition and Sustainment and the Department of the Army Inspector General Technical Inspections Division agreed to address all the recommendations presented in the report; therefore, the recommendations are considered resolved and open. As described in the Recommendations, Management Comments, and Our Response section of this report, the recommendations may be closed when we receive adequate documentation showing that all agreed upon actions to implement the recommendations have been completed. Therefore, please provide us your response, within 90 days, concerning specific actions in process or completed on the recommendations. Your response should be sent to [REDACTED]

If you have any questions, please contact [REDACTED]

A handwritten signature in cursive script, reading "Carolyn R. Hantz", is positioned above the printed name.

Carolyn Ramona Hantz
Assistant Inspector General for Evaluations
Programs, Combatant Commands,
and Overseas Contingency Operations

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Introduction

Objective

The objective of this followup evaluation was to validate implementation of recommendations from report DODIG-2016-078, “Evaluation of DoD Biological Safety and Security Implementation,” April 27, 2016, and determine whether the actions taken by the Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD[A&S]) and the Secretary of the Army as the Executive Agent (EA) for the DoD Biological Select Agents and Toxins Biosafety and Biosecurity Programs met the intent of the recommendations.

Background

Biological defense encompasses measures taken to protect and recover from the effects of biological agents or emerging biological threats. Biological Select Agents and Toxins (BSAT) is the term used to designate microorganisms and poisonous substances that have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products. Common examples of BSAT are microorganisms that cause anthrax, bubonic plague, and smallpox, as well as the toxin ricin.

The Army and Navy maintain BSAT Biosafety and Biosecurity Programs to accomplish the biological defense vision to address biological threats and minimize their effects.¹ According to OUSD(A&S) and the BSAT Biorisk Program Office (BBPO), the Army maintains three BSAT-registered laboratories and the Navy has two BSAT-registered laboratories.²

- U.S. Army Combat Capabilities Development Command Chemical Biological Center, Dugway Proving Ground, Utah
- U.S. Army Combat Capabilities Development Command Chemical Biological Center, Aberdeen Proving Ground, Maryland
- U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland
- Naval Surface Warfare Center Dahlgren Division, Dahlgren, Virginia
- Naval Medical Research Center Biological Defense Research Directorate, Fort Detrick, Maryland

¹ The Air Force does not currently have a BSAT Biosafety and Biosecurity Program.

² Criteria for laboratory biosafety levels, ranging in ascending order from biosafety level-1 to biosafety level-4, outline suitability for work with designated infectious microorganisms and animals to ensure the necessary degree of protection provided to personnel, the environment, and the community. Standard microbiological practices apply to all biosafety level laboratories with additional special protocols required to address the risk of handling BSAT needing increased levels of containment.

Each DoD entity registers its BSAT laboratories with the Federal Select Agent Program of the Centers for Disease Control and Prevention (CDC)-Division of Select Agents and Toxins (DSAT).³ The CDC-DSAT oversees the possession, use, and transfer of the BSAT used to accomplish the DoD biological defense mission.⁴ Scientists assigned to the Army and Navy's BSAT Biosafety and Biosecurity Programs conduct critical research, development, and testing and evaluation in BSAT-registered laboratories to advance protocols for detection, sterilization, decontamination, and medical countermeasures.

In May 2015, personnel at the U.S. Army BSAT-registered laboratory in Dugway Proving Ground, Utah, inadvertently shipped live *Bacillus anthracis* (anthrax) spore samples. At the time, four DoD BSAT-registered laboratories produced inactivated anthrax spores in support of defensive research and development. The DoD took precautionary measures following the shipment of live anthrax spores that included notification of all DoD BSAT-registered laboratories, instruction to stop working with all anthrax samples, and administration of post-exposure prophylaxis. In July 2015, the Deputy Secretary of Defense placed a moratorium on all DoD BSAT-registered laboratories prohibiting the laboratories from producing, handling, testing, and shipping any anthrax samples. In July 2017, the Deputy Secretary of Defense approved the rescission of the moratorium, with the exception of the BSAT-registered laboratories at Dugway Proving Ground.⁵ On June 12, 2020, the DoD BSAT Executive Agent's Responsible Official issued a memorandum rescinding the moratorium on operations at Dugway Proving Ground.

Evaluation of DoD Biological Safety and Security Implementation

In April 2016, the DoD Office of Inspector General published report DODIG-2016-078, "Evaluation of DoD Biological Safety and Security Implementation," (our 2016 report) which included 13 recommendations concerning the execution of the DoD Biosafety and Biosecurity Programs.⁶ In January 2019, the Office of the Under Secretary of Defense for Acquisition and Sustainment issued a new directive, DoD Directive (DoDD) 5101.20E, to address the 13 recommendations. Officials from the OUSD(A&S) stated that the publication of DoDD 5101.20E closes all but one recommendation (Recommendation 2.B) from our 2016 report.

³ The CDC-DSAT, jointly with the Animal and Plant Health Inspection Service, Agriculture Select Agent Services, serves as the Federal oversight agency for the safety and security of BSAT.

⁴ The DoD biological defense mission is to enable the warfighter to deter, prevent, protect, mitigate, respond, and recover from acts of bioterrorism, the deliberate release of viruses, bacteria, or other biological agents used to cause illness or death in people, animals, or plants.

⁵ During the duration of this followup evaluation, there was still a moratorium on BSAT research and operations at Dugway Proving Ground. However, on June 12, 2020, the Department of the Army Office of the Surgeon General Executive Agent's Responsible Official issued a memorandum rescinding the Secretary of the Army's restrictions on the possession, use, production, storage, handling, transportation, transfer, or destruction of BSAT by the Combat Capability Development Command Chemical Biological Center Biotesting Division at Dugway Proving Ground, Utah.

⁶ DODIG-2016-078, "Evaluation of DoD Biological Safety and Security Implementation," April 27, 2016.

In February 2019, the DoD Office of Inspector General reviewed the issued policy and closed the recommendations from our 2016 report. On August 12, 2019, the DoD Office of Inspector General announced this followup evaluation to validate the implementation of the recommendations from our 2016 report and determine whether the actions taken by the OUSD(A&S) and the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Programs met the intent of the recommendations. We determined that 4 of the 13 recommendations from our 2016 report should not have been closed.

Roles and Responsibilities for the DoD Biological Select Agents and Toxins Biosafety and Biosecurity Programs

The Secretary of Defense designated roles and responsibilities for the DoD BSAT Biosafety and Biosecurity Programs to several DoD components.

The Office of the Under Secretary of Defense's Responsibilities for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs

The FY 2017 National Defense Authorization Act abolished the position of the Under Secretary of Defense for Acquisition, Technology, and Logistics and divided the responsibilities between the OUSD(A&S) and the Office of the Under Secretary of Defense for Research & Engineering. As a result, the OUSD(A&S) serves as the Principal Staff Assistant to oversee activities of the DoD EA for the DoD BSAT Biosafety and Biosecurity Programs. On January 25, 2019, the OUSD(A&S) published DoDD 5101.20E, establishing policy and assigning roles and responsibilities for the DoD BSAT Biosafety and Biosecurity Programs and for meeting the safety standards for microbiological and biomedical laboratories.⁷ On February 1, 2018, the Deputy Secretary of Defense directed the realignment of operational safety and occupational health from the OUSD(A&S) to the Office of the Under Secretary of Defense for Personnel and Readiness (OUSD[P&R]). The OUSD(P&R) serves as the Principal Staff Assistant for biosafety. Therefore, the OUSD(A&S) is responsible for DoD policy for biosecurity and the OUSD(P&R) is responsible for DoD policy for biosafety.

⁷ Safety standards for microbiological and biomedical laboratories are prescribed in DoD Manual 6055.18-M, "Safety Standards for Microbiological and Biomedical Laboratories," July 16, 2019.

The Secretary of the Army's Responsibilities for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs

On July 23, 2015, the Deputy Secretary of Defense issued a memorandum that designated the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety Program. Additionally, on January 3, 2017, the Deputy Secretary of Defense tasked the Secretary of the Army with the responsibility to increase harmonization for the DoD BSAT Biosafety and Biosecurity Programs by aligning biosecurity and biosafety into one execution office to create mission efficiencies and reduce the potential for information gaps. As the EA, the Secretary of the Army is responsible for the technical review, inspection, and harmonization of biosafety and biosecurity protocols and procedures across DoD BSAT-registered laboratories that handle BSAT and has the tasking authority over all DoD components for this mission.

On October 26, 2015, the Secretary of the Army delegated responsibility for the DoD BSAT Biosafety and Biosecurity Programs to the Surgeon General of the Army. The Secretary of the Army issued Army Directive 2016-24 in July 2016, making this delegation permanent.⁸ On August 25, 2016, the Secretary of the Army approved further delegation of authority to the DoD Executive Agent Responsible Official (EARO), in support of the DoD EA for the BSAT Biosafety and Biosecurity Programs, to the Commander of the U.S. Army Medical Research and Development Command.⁹

The Department of the Army Inspector General Technical Inspections Division's Responsibilities for Biological Select Agents and Toxins-Registered Laboratories

The Secretary of the Army directed the Department of the Army Inspector General (DAIG) to establish and maintain a joint DoD BSAT Biosafety and Biosecurity Inspection Program composed of subject matter experts from the Army, Air Force, and Navy to harmonize BSAT biosafety inspections across the DoD. The Secretary of the Army designated the DAIG Technical Inspections Division to form the core of the team, and to organize and develop the inspection processes. The DAIG Technical Inspections Division is responsible for assessing the implementation of Federal, DoD, and Service-specific biosafety and biosecurity measures for all DoD BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratories. The DAIG's oversight operates independently of the EARO and the BBPO, and ensures compliance with BSAT biosafety and biosecurity policies across the DoD.

⁸ Army Directive 2016-24, "Department of Defense Biological Select Agents and Toxins Biosafety Program," July 25, 2016.

⁹ U.S. Army Medical Research and Development Command, formerly the U.S. Army Medical Research and Materiel Command.

The joint DoD BSAT Biosafety and Biosecurity Inspection Program focuses on, but is not limited to, biosafety, biosecurity, occupational health, emergency response, facility policies, and approved protocols. Army Directive 2016-24 requires the DAIG to report to the EARO and the DoD BSAT-registered laboratories quarterly on the trending common deficiencies identified across all the DoD BSAT-registered laboratories and to monitor deficiencies until corrected, and share best practices and lessons learned.

The Biological Select Agents and Toxins Biorisk Program Office and Executive Agent Responsible Official's Responsibilities

The Surgeon General of the Army established the BBPO in March 2016 to support the EARO in the oversight of the DoD's BSAT Biosafety and Biosecurity Programs.¹⁰ The BBPO directly reports to the EARO on DoD BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratory matters. Furthermore, the BBPO communicates to DoD leadership, Congress, and other oversight agencies, such as the CDC-DSAT, through regular updates to enhance awareness and transparency of the DoD BSAT Biosafety and Biosecurity Programs. The BBPO advises the EARO for the DoD BSAT Biosafety and Biosecurity Programs on all matters pertaining to risks associated with DoD BSAT operations.

The BBPO's responsibilities include developing a comprehensive BSAT Biorisk Program that follows the guidelines for harmonization, as outlined in Executive Order 13546.¹¹ Additionally, DoDD 5101.20E assigns roles and responsibilities for the BBPO, including:

- working with the Federal Select Agent Program to create a mechanism for coordinated and reciprocal inspection of DoD BSAT facilities;
- harmonizing administrative practices for DoD BSAT facilities, where possible;
- ensuring consistent and timely identification and resolution of BSAT compliance issues;
- assisting information sharing among DoD BSAT facilities and with other departments and agencies regarding oversight activities;
- establishing a Government-only scientific peer review panel to conduct an initial technical review of biosafety protocols and procedures, and biosecurity policies and procedures across DoD BSAT-registered laboratories that handle BSAT;

¹⁰ The BSAT Biorisk Program Office, formerly the BSAT Biosafety Program Office.

¹¹ Biorisk encompasses biosafety and biosecurity.

Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," July 8, 2010.

- tracking all internal and external inspection results and reporting status of findings, recommendations, and actions taken to address deficiencies and trends to the appropriate DoD manager; and
- developing and implementing an agreement with the CDC-DSAT and Animal and Plant Health Inspection Service, Agriculture Select Agent Services for scheduling combined inspections of DoD BSAT-registered laboratories and establishing joint inspection criteria.

Finding

The DoD Did Not Fully Implement Recommendations for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs

The OUSD(A&S) and the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Programs implemented and met the intent for 9 of the 13 recommendations from our April 27, 2016 issued report. However, 4 of the 13 recommendations from our 2016 report had not fully been implemented.

- Regarding the first recommendation, the OUSD(A&S) did not issue policy requiring all DoD BSAT-registered laboratories to implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity. This occurred because an OUSD(A&S) Chemical and Biological Security Policy official stated that the language in DoDD 5101.20E requires both external and internal technical and scientific peer reviews. However, the directive only requires an external peer review.
- Regarding the second and third recommendations, the EA did not conduct standardized oversight of the BSAT-registered laboratories or track all internal and external inspection results. This occurred because the BBPO officials, as directed by the former EARO, focused more on support efforts to advise, assist, and advocate for the BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratories, without establishing themselves as an oversight body in accordance with DoDD 5101.20E.
- Regarding the fourth recommendation, the DAIG did not develop and implement training for BSAT laboratory inspectors and subject matter expert inspection team augmentees. This occurred because the DAIG Technical Inspections Division relied on training obtained from the Department of the Army Inspector General course, non-DoD BSAT-registered laboratory specific technical courses, and the inspectors' experience.

As a result, incomplete and inconsistent oversight of the DoD BSAT Biosafety and Biosecurity Programs remains, which increases the risk of exposing DoD BSAT entities, personnel, and the public to the hazards associated with BSAT.

The OUSD(A&S) and Executive Agent Implemented Nine Report Recommendations

The OUSD(A&S) and the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Programs implemented and met the intent for 9 of the 13 recommendations from our 2016 report. In July 2015, the Deputy Secretary of Defense designated the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Programs. Additionally, the BBPO established the BSAT Biorisk and Scientific Review Panel (BSRP), which is composed of members from DoD components as well as members from external agencies, including the CDC-DSAT and the United States Department of Agriculture Animal and Plant Health Inspection Service, Agriculture Select Agent Services. Finally, the OUSD(A&S) published DoDD 5101.20E, assigning responsibility and directing management actions regarding oversight of the BSAT Biosafety and Biosecurity Programs. See Appendix B for a list of the closed recommendations and a summary of management actions taken to implement them.

The OUSD(A&S) and the Executive Agent Did Not Implement Four Report Recommendations

The OUSD(A&S) and the DoD EA did not take action to fully implement the remaining four recommendations from our 2016 report. Specifically:

- The OUSD(A&S) did not issue policy requiring all DoD BSAT-registered laboratories to implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity issues, as recommended in our 2016 report.
- Our 2016 report recommended that the Deputy Secretary of Defense direct the EA for Biosafety and Biosecurity to conduct standardized oversight and inspections. The recommendation was partially implemented through the delegation to the DAIG to conduct standardized inspections, but the EA did not conduct standardized oversight of DoD BSAT-registered laboratories. Additionally, as part of the EA's standardized oversight responsibilities, the EA did not track all internal and external inspection results, as recommended by our 2016 report and directed by the DoDD 5101.20E.
- The DAIG, on behalf of the EA, did not develop and implement training for BSAT laboratory inspectors and subject matter experts who augment inspection teams, as recommended by our 2016 report.

DoD Directive 5101.20E Did Not Require Implementation of an Internal Technical and Scientific Peer Review Function

The OUSD(A&S) did not issue policy requiring all DoD BSAT-registered laboratories to implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity. Our 2016 report identified the lack of peer review forums to review scientific protocols as a contributing factor to the 2015 inadvertent shipment of live anthrax from Dugway Proving Ground. The 2016 report recommended implementation of internal and external technical and scientific peer reviews to address biosafety and biosecurity. Management agreed with and planned on establishing policy with the intent to address all of the 2016 report recommendations. The OUSD(A&S) intended to publish DoDD 5101.20E with policy to address the recommendation to issue guidance that the DoD BSAT Biosafety and Biosecurity Programs implement internal and external technical and scientific peer review functions that address both biosafety and biosecurity issues. However, DoDD 5101.20E only addressed the external technical and scientific peer review recommendation; it does not include policy to address the internal technical and scientific peer review function recommendation.

DoDD 5101.20E requires the BBPO Director to “[e]stablish a government-only scientific peer review panel to conduct an initial technical review, and subsequent periodic reviews, of biosafety protocols and procedures and biosecurity policies and procedures across DoD laboratories that handle BSAT.” DoDD 5101.20E further states, “[t]his scientific peer review should include DoD and non-DoD representation whenever possible.”

To meet this directive requirement, the BBPO Director established the BSAT Biorisk and Scientific Review Panel (BSRP) comprised of representatives from the DoD BSAT-registered laboratories, the CDC-DSAT, and the Animal and Plant Health Inspection Service, Agriculture Select Agent Services.¹² However, this scientific review panel only satisfies the external technical and scientific peer review recommendation. The DoDD 5101.20E does not include policy to implement an internal technical and scientific peer review function. In February 2019, the OUSD(A&S) officials responded to a DoD Office of Inspector General status request of completed actions on the recommendations issued in our 2016 report acknowledging that the internal technical and scientific peer review function recommendation was not addressed in the DoDD 5101.20E publication.

¹² The Animal and Plant Health Inspection Service, Agriculture Select Agent Services is part of the United States Department of Agriculture.

The OUSD(A&S) Should Update DoD Directive 5101.20E to Include Policy for an Internal Technical and Scientific Peer Review Function

The OUSD(A&S) did not issue a policy requiring that all DoD BSAT-registered laboratories implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity because an OUSD(A&S) Chemical and Biological Security Policy official stated that the DoDD 5101.20E, as written, requires both external and internal technical and scientific peer reviews. Specifically, the official cited the DoDD 5101.20E guideline directing the BBPO Director to “[e]stablish a government-only scientific peer review panel to conduct an initial technical review, and subsequent periodic reviews, of biosafety protocols and procedures and biosecurity policies and procedures across DoD laboratories that handle BSAT,” as issued guidance addressing both external and internal technical and scientific peer review functions. However, in a written response to us in February 2019, the OUSD(A&S) officials acknowledged that the DoDD 5101.20E did not address the internal technical and scientific peer review function recommended in our 2016 report.

In accordance with DoDD 5101.20E, the BBPO Director established the BSRP. Internal technical and scientific peer review panels were not established at all DoD BSAT-registered laboratories because the DoDD 5101.20E guidelines did not include this requirement. The BSRP reviews all BSAT laboratory protocols to determine technical and scientific sufficiency on a rotational basis. The internal technical and scientific peer review functions at each BSAT-registered laboratory would ensure that all BSAT laboratory protocols are reviewed and updated for technical and scientific sufficiency regularly to help mitigate BSAT risks. The internal technical and scientific peer reviews would help reduce immediate BSAT risks at the laboratory-level while the external technical and scientific peer review function serves as an additional layer of assessment at the department-level with additional outside Government insight. The DoDD 5101.20E directed the establishment of the BSRP, an external technical and scientific peer review panel, but the directive did not address the internal technical and scientific peer review recommendation from our 2016 report.

BSAT Biorisk Program Office Officials Did Not Fully Conduct Standardized Oversight of the DoD BSAT Biosafety and Biosecurity Programs

The EA did not fully conduct standardized oversight of the BSAT-registered laboratories, including tracking all internal and external inspection results and reporting the results to management, as recommended in our 2016 report.

The DoDD 5101.20E requires the BBPO to track inspection results across the DoD BSAT enterprise in order to perform its oversight responsibilities. The lack of complete data in the tracking system prevents the BBPO from identifying trends or observing, forecasting, or taking action on DoD BSAT biosafety and biosecurity issues.

BBPO officials maintained an internal spreadsheet tracking BSAT-registered laboratory inspection results, but the spreadsheet was incomplete. We found that the BBPO officials were only tracking 125 of 226 deficiencies when we compared the number of deficiencies contained in the BBPO's internal spreadsheet to the number of total deficiencies from the DAIG and the CDC-DSAT inspection results across the DoD BSAT enterprise. For example, the BBPO's database did not include any CDC-DSAT inspection results from September 2017 to September 2019, during which the CDC-DSAT reported a total of 97 discrepancies at the DoD BSAT-registered laboratories.

BSAT Biorisk Program Office Officials Focused on Support Functions Instead of Oversight

The EA did not fully conduct standardized oversight because the BBPO officials, as directed by the former EARO, focused more efforts on supporting, advising, assisting, and advocating for the BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratories, without establishing themselves as an oversight body. Interviews with multiple BSAT Biosafety and Biosecurity Programs personnel highlighted that the BSAT community is not clear on the BBPO's roles.

- A BBPO official acknowledged that there is confusion as to the BBPO's role and stated that some laboratories perceive the BBPO as being an inspection or regulatory agency.
- The physical security manager and biosafety laboratory managers from an Army BSAT-registered laboratory stated that the BBPO's roles and responsibilities were not clear.
- An Army BSAT-registered laboratory manager and a Navy biosafety officer stated that they understood the BBPO's role to be oversight, but in practice saw the BBPO more as an advisory body.

In 2019, the EARO directed the BBPO to conduct staff assistance visits.¹³ These visits are required to include observing BSAT-registered laboratory functions, and preparing and sharing an observation report with the EARO and the laboratory. Personnel from multiple BSAT-registered laboratories stated that the BBPO officials

¹³ The BBPO officials stated that the office is in the process of developing an implementation plan for the staff assistance visits.

focused more on their advise and assist role, and that the BBPO's oversight role was not evident. However, DoDD 5101.20E issued guidance in response to the recommendation in our 2016 report that directs the BBPO to conduct standardized oversight, including tracking all internal and external inspection results.

The current model for BBPO to conduct standardized oversight is not fully developed. The BSAT-registered laboratory officials stated that the BBPO's oversight role is not clear and that the results of the internal and external inspections from the DAIG and the CDC-DSAT are not all tracked by the BBPO.¹⁴ Standardizing oversight roles and responsibilities and tracking internal and external inspection results were recommendations from our 2016 DoD OIG report; however, neither recommendation has been fully implemented.

The Department of the Army Inspector General Did Not Develop and Implement Training for Biological Select Agent and Toxins Laboratory Inspectors

The DAIG did not develop and implement training for BSAT laboratory inspectors and subject matter expert augmentees. The intent of recommending BSAT laboratory inspector training in our 2016 report was to reduce the risk of inspectors not having the expertise required for the technical inspections and to ensure that the inspectors consistently examined laboratories' compliance with applicable Service-specific BSAT policies. The development and implementation of training requirements for DoD BSAT inspectors and subject matter experts who augment teams would ensure consistency in understanding and inspecting for compliance with Service-specific BSAT regulations.

In response to the recommendation from our 2016 report, the OUSD(A&S) published DoDD 5101.20E on January 25, 2019. While DoDD 5101.20E assigns the BBPO Director responsibility to "develop a comprehensive inspection program," and Army Directive 2016-24 requires the DAIG to "establish and maintain a joint DoD inspection team," neither document requires or assigns responsibility for the development and implementation of training for BSAT laboratory inspectors and subject matter experts that augment inspection teams. Therefore, the intent of the recommendation has not been met and the recommendation has not been implemented.

¹⁴ Internal inspection refers to those conducted by the DoD, such as the DAIG and the Department of the Army Safety. External inspections refers to those conducted by non-DoD agencies, such as the CDC-DSAT.

The Department of the Army Inspector General Relied on Inspector Experience and Expertise and Various Trainings

The DAIG did not develop and implement training for BSAT laboratory inspectors and subject matter experts who augment inspection teams because the DAIG Technical Inspections Division relied on a combination of inspector experience and expertise as well as on-the-job and various other training, including internally- and externally-provided training courses related to specific functional areas, such as CDC-DSAT laboratory inspections. According to a DAIG Technical Inspections Division official, DoD BSAT laboratory inspectors are required to complete institutional, on-the-job, and internally- and externally-provided training. However, these trainings are not specific to DoD BSAT-registered laboratory inspections. Specifically, there is no training encompassing DoD and Service-specific BSAT policy, as recommended in our 2016 report.

DAIG Technical Inspections Division BSAT-Registered Laboratory Inspectors Did Not Always Inspect in Accordance With Service-Specific Requirements

DoD BSAT-registered laboratory personnel at multiple installations stated that the DAIG Technical Inspections Division inspectors did not always inspect DoD BSAT-registered laboratories in accordance with Service-specific BSAT policies. Specifically many of the BSAT-registered laboratory officials stated that there have been instances in which the DAIG technical inspectors cited deficiencies or observations based on best practices instead of DoD or Service-specific criteria.¹⁵ The DAIG Technical Inspections personnel stated that observations were different from deficiencies which require corrective actions, and BSAT-registered laboratories were not required to address the observations. However, a representative from a DoD BSAT-registered laboratory stated that, although an issue was reported as an observation, the representative treated the observation similarly to a failing deficiency that required action. Several other BSAT-registered laboratory personnel across the DoD BSAT enterprise echoed this sentiment.

Another BSAT-registered laboratory official stated that some of the DAIG technical inspection results were based more on best practices than requirements, which has a financial impact when it comes to addressing certain deficiencies or observations that are not solely based on criteria. A DoD BSAT-registered laboratory official stated that the DAIG technical inspectors were proponents of citing best practices

¹⁵ Criteria refers to DoD policies, such as the DoDD 5101.20E, and Service-specific regulations, such as Army Directive 2016-24.

as deficiencies or observations in their inspection reports. However, the best practices could not be referenced back to criteria. Another BSAT-registered laboratory official stated that the best practices-based observations depended on the inspector. The official further stated that the inspectors reported best practices based on their experience, rather than the DoD policy or Service-specific regulation requirement, without considering justification for the inspected BSAT-registered laboratory having different practices.

One BSAT-registered laboratory official described an instance where a DAIG Technical Inspections inspector identified a deficiency not supported by a DoD requirement. In this particular instance, a BBPO official observing the DAIG's inspection processes intervened to inform the DAIG technical inspector that the identified deficiency was not supported by a requirement. The gap in inspector training, as demonstrated by the testimony provided by laboratory personnel, shows that DAIG technical inspections of DoD BSAT-registered laboratories were not always conducted in accordance with DoD and Service-specific BSAT requirements.

DAIG Technical Inspections Inspectors Do Not Receive DoD-Specific BSAT Training

According to a DAIG Technical Inspections Division official, inspectors are required to complete the Department of the Army Inspector General course. The Army Inspector General course covers inspection fundamentals, including the development of findings and effective writing techniques to all personnel assigned to the Inspector General throughout the Army. However, the training course does not include any BSAT laboratory-related topics. Additionally, a DAIG Technical Inspections Division official stated that inspectors attend training courses provided by other, non-DoD Federal agencies, such as the inspections course sponsored by the CDC-DSAT. However, the CDC-DSAT course prepares inspectors for evaluating compliance with standards in the Code of Federal Regulations, not DoD or Service-specific policy.

A DAIG Technical Inspections Division official stated that inspectors also attend specialized training for their functional area expertise. These technical courses do not address inspection techniques nor policy and standards specific to DoD BSAT-registered laboratories. For example, a DAIG technical inspector with a background in occupational health will be sent to training specific to occupational health. However, there is no evidence to suggest that DAIG Technical Inspections inspectors attend cross-functional training that prepares them to inspect for compliance with Service-specific requirements.

The DAIG Technical Inspectors' Combination of Experience and Expertise Should Be Supplemented With DoD Policy-Specific Training

A DAIG Technical Inspections Division official explained that new inspectors are required to shadow an experienced inspector before they are permitted to be the primary inspector in a functional area. This on-the-job training is the only training that is specific to DoD BSAT-registered laboratory inspections. However, experienced inspectors may not possess the requisite knowledge required to train the new inspector because DoD policy and Service-specific regulations training is not offered. Additionally, the various training courses, such as the Army Inspector General course, are not made available to the subject matter expert inspection team augmentees. A DAIG Technical Inspections Division official stated that he selected subject matter experts for their depth of knowledge in their field, such as microbiology and occupational health. Nevertheless, this expertise, without DoD BSAT-specific training, may leave knowledge gaps regarding DoD BSAT policies and Service-specific protocols.

Training specific to DoD BSAT laboratory inspections and Service-specific BSAT policies would ensure that DoD BSAT inspectors and supporting subject matter experts apply DoD policies and inspect for compliance with respective Service-specific regulations across all DoD BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratories.

Incomplete and Inconsistent BSAT Biosafety and Biosecurity Programs Policy and Oversight Decreases Program and Mission Integrity and Increases Risks

The lack of comprehensive DoD BSAT Biosafety and Biosecurity Programs policy and incomplete and inconsistent oversight decreases the integrity of the program and mission and increases the risk of exposing DoD BSAT entities, personnel, and the public to BSAT hazards. Nearly 4 years after the issuance of our 2016 report recommendations, the DoD BSAT Biosafety and Biosecurity Programs remain vulnerable to potential hazards associated with the mishandling of infectious biological pathogens. Without a comprehensive oversight program that ensures corrective actions are sustained over time, which includes tracking all inspection findings, the DoD BSAT Biosafety and Biosecurity Programs lack the ability to create harmonization of administrative practices for registered entities in the Federal Select Agent Program, as required by Executive Order 13546.

While the BSRP is working to ensure the scientific adequacy of and harmonize biosafety and biosecurity processes across all DoD BSAT-registered laboratories, the lack of a requirement for an internal technical and scientific peer review of laboratory policies and protocols contributed to continued preventable and avoidable biosafety and biosecurity incidents such as reports of improperly putting on and removing personal protective equipment. A DoD policy instituting an internal technical and scientific peer review function at each of the DoD BSAT-registered laboratories would add a layer of oversight to deter biosafety and biosecurity issues from going undetected. Furthermore, the internal technical and scientific peer review would likely improve program management, identify biosafety and biosecurity vulnerabilities, and mitigate the risk of biosafety and biosecurity incidents.

Additionally, responsible oversight officials did not track all biosafety and biosecurity inspection results, nor did policy exist to ensure that BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratory management addressed identified deficiencies. Tracking deficiencies and corrective actions is a critical component of program management, allowing management to identify trends and vulnerabilities, and take corrective actions to eliminate risks to health and safety.

Although the DAIG Technical Inspections inspectors were experienced and received institutional, external, and on-the-job training, the lack of standardized DoD BSAT-specific inspection training caused inspectors to misidentify acceptable processes as deficiencies, requiring laboratories to implement corrective actions that expend mission essential resources unnecessarily. The lack of DoD BSAT-specific inspection training leaves a gap in acceptable and appropriate inspector practices. Service BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratories are required to comply with Service-specific regulations; therefore, the DAIG Technical Inspections inspectors should not require compliance with a different Service's regulations. Correcting deficiencies inapplicable to the laboratory or based on best practices instead of relevant criteria may require BSAT Biosafety and Biosecurity Programs management to unnecessarily expend resources, which could impact the essential mission.

In February 2019, the DoD OIG closed the recommendations from our 2016 report. However, we determined that 4 of the 13 recommendations from our 2016 report should have not been closed. Therefore, we are making three new recommendations to address the deficiencies discussed in this report.

Management Comments on the Finding and Our Response

Department of the Army Inspector General's Comments

The Department of the Army Inspector General did not agree with the deficiency and specifically did not agree with a statement in the report stating that DAIG Technical Inspections Division BSAT-registered laboratory inspectors did not always inspect in accordance with Service-specific requirements. The Department of the Army Inspector General stated that it provided 3 years of inspection reports as support to the DoD OIG, which included over 100 findings, and that all deficiencies identified a written Federal, DoD, Service, or local standard that was applicable to the entity inspected.

Our Response

The Department of the Army Inspector General did not agree that DAIG Technical Inspections Division BSAT-registered laboratory inspectors did not always inspect in accordance with Service-specific requirements. However, several Army and Navy BSAT Biosafety and Biosecurity Program senior officials, many Army and Navy BSAT-registered laboratory management officials, BSAT scientists, and laboratory technicians all stated DAIG Technical Inspections Division BSAT-registered laboratory inspectors did not always inspect in accordance with Service-specific requirements. According to DAIG-TI Report No. 1903, dated December 13, 2018, there were multiple findings (observations) that were not cited to a standard but included a recommendation with a deliverable. During the evaluation, DoD BSAT-registered laboratory officials stated that, although an issue was reported as an observation, the representative treated the observation similarly to a failing deficiency that required action. Additionally, during the evaluation, a DAIG official agreed with the statement that described an instance where a DAIG Technical Inspections inspector identified a deficiency not supported by a DoD requirement, in which a BBPO official intervened to inform the DAIG technical inspector that the identified deficiency was not supported by a requirement. Based on our review of DAIG inspection reports and testimonial evidence, we concluded that the DAIG inspectors did not always inspect in accordance with Service-specific requirements.

Recommendations, Management Comments, and Our Response

Recommendation 1

We recommend that the Office of the Under Secretary of Defense for Acquisition and Sustainment issue policy requiring all DoD biological select agents and toxins-registered laboratories to implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity.

The Acting Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs' Comments

The Acting Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, responding on behalf of the Under Secretary of Defense for Acquisition and Sustainment, agreed with the recommendation. Specifically, the Acting Assistant Secretary of Defense agreed to include a requirement for all DoD BSAT laboratories to establish internal technical and scientific peer review panels to review biosafety protocols and biosecurity policies in Change 1 to Department of Defense Directive 5101.20E, "DoD Biological Select Agents and Toxins (BSAT) Biosafety and Biosecurity Program."

Our Response

Comments from the Acting Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs addressed the specifics of the recommendation; therefore, the recommendation is resolved, but will remain open. We will close the recommendation once the DoD updates DoD Directive 5101.20E to include a requirement for all DoD BSAT-registered laboratories to establish internal technical and scientific peer review panels to review biosafety protocols and biosecurity policies.¹⁶

Recommendation 2

We recommend that the DoD Executive Agent for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs, in coordination with the Biological Select Agents and Toxins Biorisk Program Office, develop a plan to conduct standardized oversight of the DoD Biological Select Agents and Toxins Biosafety and Biosecurity Programs and biological select agents and toxins-registered laboratories, including tracking all internal and external inspection results.

¹⁶ Comments from the Acting Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs referenced the incorrect DoD Directive number, but did reference the correct DoD Directive title. Therefore, we modified their response to cite the correct DoD Directive number, 5101.20E.

Executive Agent Responsible Office's Comments

The Surgeon General of the Army, as the Executive Agent's Responsible Official, responding on behalf of the DoD Executive Agent for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs, agreed with the recommendation. The Surgeon General has developed a plan to conduct standardized oversight of the DoD Biosafety and Biosecurity Programs and DoD biological select agents and toxins-registered laboratories, including tracking all internal and external inspections results. Specifically, the EARO and a BBPO official have begun site visits to each BSAT-registered laboratory and will provide formal communication to the BSAT biosafety and biosecurity community to clarify their oversight role with expected completion by August 31, 2020. Additionally, the Biological Select Agents and Toxins Biorisk Program Office developed and implemented a formal Biological Select Agents and Toxins Executive Agent Responsible Official Program for Biosafety and Biosecurity Related Staff Assistance Visit Program, signed by the EARO on May 27, 2020. According to the management comments and a review of the program documentation, this Staff Assistance Visit program will provide direct oversight of the DoD BSAT laboratories compliance status with Federal, DoD, Service-specific, state, and local regulations to ensure the laboratories are inspection ready at all times.

Additionally, the BBPO has moved from tracking the inspection results from the initial spreadsheet to the Quality Management System Inspections Database within the Joint Interagency Biorisk System. The BBPO has completed entry of inspection results from the Department of Army Inspector General Technical Inspections Division and the Centers for Disease Control and Prevention's Division of Select Agents and Toxins back to 2016. The BBPO has begun entering results from the Department of Army Safety pre-operational surveys and plan to have all results, corrective actions, and final outcome information entered into the database by July 1, 2020.

Our Response

Comments from the Surgeon General addressed the specifics of the recommendation. Specifically, BBPO issued a memorandum establishing policy for the roles and responsibilities of the BSAT BBPO during DoD Joint Inspections, Centers for Disease Control and Prevention Division of Select Agents and Toxins/Animal and Plant Health Inspection Service, Agriculture Select Agent Services inspections, and any additional outside agency inspections focused on BSAT conducted at DoD BSAT laboratories. Additionally, the Surgeon General issued instruction that establishes policy and procedures for recurring Department of Defense BSAT BBPO Staff Assistance Visits to aid laboratory staff

in achieving biosafety and biosecurity program compliance with all Federal, DoD, state, and local regulatory and operational requirements. Therefore, the recommendation is closed.

Recommendation 3

We recommend that the Department of the Army Inspector General Technical Inspections Division, in coordination with the DoD Executive Agent for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs, develop and implement training requirements for biological select agents and toxins laboratory inspectors and inspection team subject matter expert augmentees.

The Department of the Army Inspector General's Comments

The Department of the Army Inspector General, responding on behalf of the Department of the Army Inspector General Technical Inspections Division, agreed with the recommendation. Specifically, the Department of the Army Inspector General agreed to require technical inspectors and external subject matter expert inspectors to participate in training specific to DoD and Service-specific BSAT standards. The training will include an overview of the BSAT program, roles of DoD and other Federal entities, and a review of applicable DoD and Service regulations with an estimated completion in the 2nd quarter of FY 2021.

Our Response

Comments from the Department of the Army Inspector General addressed the specifics of the recommendation; therefore, the recommendation is resolved, but will remain open. We will close the recommendation once the Department of the Army Inspector General develops and implements training specific to DoD and Service-specific BSAT standards for BSAT laboratory inspectors and inspection team subject matter expert augmentees.

Appendix A

Scope and Methodology

We conducted this evaluation from August 2019 through April 2020 in accordance with the “Quality Standards for Inspection and Evaluation” published by the Council of the Inspectors General on Integrity and Efficiency in January 2012. Those standards require that we plan and perform the evaluation to obtain sufficient and appropriate evidence to provide a reasonable basis for our findings, conclusions, and recommendations based on our evaluation objectives. We believe that the evidence obtained provides a reasonable basis for our findings, conclusions, and recommendations based on our followup evaluation.

The objective and scope of this followup evaluation was to validate implementation of recommendations from our previous report, “Evaluation of DoD Biological Safety and Security Implementation,” April 27, 2016, and ensure the measures taken by the OUSD(A&S) and the Secretary of Army as the EA for the DoD BSAT Biosafety and Biosecurity Programs met the intent of the recommendations. Specifically, we focused on the DoD BSAT Biosafety and Biosecurity Programs and BSAT laboratories registered in the Federal Select Agent Program. DoD Laboratory Response Networks with a biological safety and security component were outside the scope of this evaluation.

To address and achieve the objective for this report, we reviewed the following.

- Executive Order 13456 – Optimizing the Security of Biological Select Agents and Toxins in the United States, July 8, 2010
- Public Law 107-188 – Public Health Security and Bioterrorism Preparedness and Response Act, June 12, 2002
- Title 50, section 1527, United States Code – Improved biosafety for handling of select agents and toxins, May 5, 2019
- 7 CFR part 331 – Possession, Use, and Transfer of Select Agents and Toxins (Agriculture), June 27, 2019
- 9 CFR part 121 – Possession, Use, and Transfer of Select Agents and Toxins (Animals and Animal Products), June 27, 2019
- 42 CFR part 73 – Select Agents and Toxins (Public Health), June 27, 2019
- The National Defense Authorization Acts for FYs 2017, 2018, and 2019
- DoD policies and guidance related to BSAT, including DoDD 5101.1, “DoD Executive Agent,” November 21, 2003; DoDD 5101.20E, “DoD Biological Select Agents and Toxins (BSAT) Biosafety and Biosecurity Program,” January 25, 2019; DoD Instruction 5210.88, “Security Standards

for Safeguarding Biological Select Agents and Toxins,” May 26, 2020; and DoD 6055.18-M, “Safety Standards for Microbiological and Biomedical Laboratories,” July 16, 2019

We visited the following DoD BSAT-registered laboratories.

- U.S. Army Combat Capabilities Development Command – Chemical Biological Center, Dugway Proving Ground, Utah
- U.S. Army Combat Capabilities Development Command – Chemical Biological Center, Aberdeen Proving Ground, Maryland
- U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland
- Naval Surface Warfare Center – Dahlgren Division, Dahlgren, Virginia
- Naval Medical Research Center – Biological Defense Research Directorate, Fort Detrick, Maryland

Additionally, we interviewed the Executive Agent responsible official, BSAT oversight officials, BSAT Biosafety and Biosecurity Program management officials, BSAT registered laboratory management officials, biosafety and biosecurity officials, competent medical authorities, laboratory research scientists and technicians, and BSAT laboratory inspectors responsible for the DoD BSAT Biosafety and Biosecurity Programs and BSAT-registered laboratories. Additionally, we conducted interviews with representatives from the following offices and organizations.

- Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense
- Office of the Deputy Assistant Secretary of Defense for Acquisition and Sustainment-Chemical and Biological Defense
- Office of the Deputy Assistant Secretary of Defense for Personnel and Readiness-Safety and Occupational Health
- Centers for Disease Control and Prevention-Division of Select Agents and Toxins
- BSAT Biorisk Program Office
- Department of the Army Inspector General-Technical Inspections Division

To validate the implementation of recommendations from our 2016 report and ensure that the actions met the intent of the recommendations, we obtained and reviewed various documents, including signed memorandums, DoD issuances, appointment and delegation orders, strategic and implementation plans, inspection operating procedures, inspection criteria checklists, DAIG and CDC-DSAT inspection

findings, e-mail correspondences, and other documentation. We also obtained DAIG and CDC DSAT BSAT-registered laboratory inspection reports from September 2017 to September 2019 to determine if the BBPO was tracking all inspection results.

Use of Computer-Processed Data

We used computer-processed data for this followup evaluation. Specifically, we used an internal spreadsheet for tracking DoD laboratory inspection results, provided by BBPO officials. According to a BBPO official, the BBPO Deputy Director for Biosecurity is responsible for the consolidation of the internal spreadsheet for tracking inspection results. The spreadsheet was sent to us as an encrypted e-mail and password protected to maintain the integrity of the data. We compared each data point to scanned electronic copies of the source data for inspection results provided by a DAIG Technical Inspections Division official to determine whether the BBPO was tracking all internal and external laboratory inspection results. We determined that the internal spreadsheet provided by the BBPO for tracking laboratory inspection results data that we used for our analysis of recommendation implementation was sufficiently reliable.

Prior Coverage

During the last 5 years, the Government Accountability Office (GAO) issued three reports discussing actions needed to enhance the select agent program, improving management of the DoD's Biosafety and Biosecurity Program, and the DoD's use of Executive Agents. The Department of Defense Office of Inspector General (DoD OIG) issued one report discussing DoD Biological Security Implementation, and the uniform application of biosafety and biosecurity policy and directives, plans, orders, and guidance across DoD Component laboratories.

Unrestricted GAO reports can be accessed at <http://www.gao.gov>.

Unrestricted DoD OIG reports can be accessed at www.dodig.mil/reports.

GAO

Report GAO-18-145, "High Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens," October 2017

The report focused on the oversight of the Federal Select Agent Program and made 11 recommendations, including 1) assess the effectiveness of risks within its current structure to reduce conflicts of interest, 2) assess the risk of activities it oversees and target those reviews to high-risk activities, and

3) develop a joint workforce plan. While elements within the GAO report identified important program management components of oversight, this GAO report did not have an impact on the followup evaluation.

Report GAO 18-422, “Biological Select Agents and Toxins: Actions Needed to Improve Management of DoD’s Biosafety and Biosecurity Program,” September 2018

The report included four recommendations for the DoD: 1) develop an approach to assess the effectiveness of the recommendations, 2) develop a strategy and implementation plan for its BSAT Biosafety and Biosecurity Programs, 3) develop measures to ensure independence, and 4) develop time frames to complete a study. The DoD concurred with the recommendations. This GAO report was useful because it contained reference material in support of the followup evaluation.

Report GAO 17-601, “Defense Management: DOD Needs to Improve Its Oversight of Executive Agents,” September 2017

The GAO was required to review the DoD’s Executive Agents in response to a provision under the National Defense Authorization Act for FY 2017. The GAO recommended that the Office of the Deputy Chief Management Officer strengthen its approach to tracking DoD Executive Agents, maintain a list of Executive Agent designations, and oversee the Executive Agent assessments. This GAO report did not have an impact on the followup evaluation.

DoD OIG

Report No. DODIG-2016-078, “Evaluation of DoD Biological Safety and Security Implementation,” April 27, 2016

The report assessed the uniform application of biosafety and biosecurity policy, directives, plans, orders, and guidance across DoD component laboratories that were conducting research using biological select agents and toxins. The report was an evaluation of the 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 the recommendations from previous Government Accountability Office, Defense Science Board, and Defense Health Board reports.

Appendix B

Status of Recommendations From Report No. DODIG-2016-078

The USD(A&S) and the DoD Executive Agent for the BSAT Biosafety and Biosecurity Programs implemented and met the intent for 9 of the 13 recommendations from our 2016 report. However, 4 of the 13 recommendations from our 2016 report had not been fully implemented. We are closing the four recommendations that had not been fully implemented from our 2016 report and making three new recommendations. The table below provides a status of the 13 recommendations from our 2016 report.

The Under Secretary of Defense for Acquisition, Technology, and Logistics, responding for the Deputy Secretary of Defense, agreed with our 2016 report recommendations and stated that the Under Secretary of Defense for Acquisition, Technology, and Logistics was drafting a directive, DoDD 5101.20E, for the DoD BSAT Biosafety and Biosecurity Programs. Specifically, the response stated that the Directive will establish policy and designate and define the role of the Secretary of the Army as the DoD EA for the DoD BSAT Biosafety and Biosecurity Programs and that the roles identified in the recommendations, with one exception, were listed in the draft directive.¹⁷

Table. Follow Up of the 2016 Recommendations

Recommendation	Status at the Start of This Followup Evaluation	Status of Recommendation Implementation
1.a. Deputy Secretary of Defense appoint a single Executive Agent responsible for biosafety and biosecurity.	Closed	Implemented
1.b (1) Deputy Secretary of Defense direct the EA for Biosafety and Biosecurity to conduct standardized oversight and inspections in accordance with applicable Federal regulations of DoD BSAT laboratories.	Closed	Partially Implemented

¹⁷ In February 2019, personnel from the USD(A&S) stated that the publication of 5101.20E "closes all but one Recommendation (Recommendation 2.B) from the report."

Table. Follow Up of the 2016 Recommendations (cont'd)

Recommendation	Status at the Start of This Followup Evaluation	Status of Recommendation Implementation
1.b (2) Deputy Secretary of Defense direct the EA 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 DoD management level.	Closed	Not Implemented
1.b (3) Deputy Secretary of Defense direct the EA for Biosafety and Biosecurity to develop and implement training for BSAT laboratory inspectors and subject matter expert inspection team augmentees.	Closed	Not Implemented
1.b (4) Deputy Secretary of Defense direct the EA for Biosafety and Biosecurity to ensure that all personnel included in inspection teams have sufficient scientific expertise and experience.	Closed	Implemented
2.a Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to implement an external technical and scientific peer review function that addresses both biosafety and biosecurity issues to support all DoD BSAT laboratories.	Closed	Implemented
2.b Under Secretary of Defense for Acquisition, Technology, and Logistics issue guidance that all DoD BSAT laboratories implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity issues.	Closed	Not Implemented
3.a Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to serve as the single DoD POC with the CDC and Animal and Plant Health Inspection Service for coordinating and participating in inspections of DoD BSAT laboratories.	Closed	Implemented

Table. Follow Up of the 2016 Recommendations (cont'd)

Recommendation	Status at the Start of This Followup Evaluation	Status of Recommendation Implementation
3.b Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to develop and implement an agreement with the CDC and Animal and Plant Health Inspection Service for scheduling combined inspections of DoD BSAT laboratories.	Closed	Implemented
3.c Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to define combined inspection criteria and guidance with the CDC and Animal and Plant Health Inspection Service for DoD BSAT laboratories.	Closed	Implemented
3.d Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to serve as the formal communication entity with the FSAP regarding findings and lessons learned from the CDC and Animal and Plant Health Inspection Service relevant to the DoD BSAT Program.	Closed	Implemented
4.a Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to implement criteria for inclusion of site-specific security vulnerability assessment findings into DoD BSAT laboratory biosafety and biosecurity inspections.	Closed	Implemented
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 BSAT laboratory inspections.	Closed	Implemented

Source: DoD OIG.

Recommendation 1.A Deputy Secretary of Defense appoint a single Executive Agent responsible for biosafety and biosecurity.

As of January 2017, the Deputy Secretary of Defense designated the Secretary of the Army as the single DoD EA for the DoD BSAT Biosafety and Biosecurity Programs. The designation of the Secretary of the Army as the single DoD EA for the DoD BSAT Biosafety and Biosecurity Programs met the intent of Recommendation 1.A. Therefore, Recommendation 1.A is resolved and closed.

Recommendation 1.B (1) Deputy Secretary of Defense direct the EA for Biosafety and Biosecurity to conduct standardized oversight and inspections in accordance with applicable Federal regulations of DoD BSAT laboratories.

The Department of the Army published a Directive which designated the DAIG, specifically the DAIG Technical Inspections, as the responsible inspection body. Per the Army Directive, the DAIG personnel established and maintained a joint DoD inspection team composed of trained subject matter experts from the Army, and Navy as appropriate and needed, to harmonize BSAT inspections across DoD laboratories. The DAIG Technical Inspections personnel issued a detailed inspection plan outlining the inspection program, including team composition, and general and specific inspection SOPs. Personnel from the DAIG Technical Inspections also implemented the detailed inspection plan by conducting solo inspections as well as multiple joint inspections with the CDC-DSAT. However, we found that personnel from the BBPO did not fully provide oversight for the DoD BSAT Program and BSAT-registered laboratory operations. Therefore, Recommendation 1.B (1) has been partially implemented.

See the Finding for a detailed discussion.

Recommendation 1.B (2) Deputy Secretary of Defense direct the EA 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 DoD management level.

DoDD 5101.20E directed the BBPO Director to track all internal and external inspection results and report the status of findings, recommendations, and actions taken to address deficiencies and trends to the appropriate DoD manager. Personnel from the BBPO regularly reported updates to appropriate management. However, personnel from the BBPO were not tracking all internal and external inspection results, thus not meeting the intent of our 2016 report Recommendation 1.B(2). Furthermore, because all inspection results were not

tracked, the BBPO Director could not report all results to appropriate management. Therefore, the BBPO was not tracking all inspection report deficiencies, and Recommendation 1.B(2) has not been implemented.

See the Finding for a detailed discussion.

Recommendation 1.B (3) Deputy Secretary of Defense direct the EA for Biosafety and Biosecurity to develop and implement training for BSAT laboratory inspectors and subject matter expert inspection team augmentees.

DoDD 5101.20E does not require the development and implementation of training for personnel on BSAT laboratory inspection teams. According to the DAIG, BSAT laboratory inspectors attend institutional, externally-provided, and on-the-job training. However, the EA did not require, develop, or implement DoD-specific BSAT training for BSAT laboratory inspectors and subject matter expert who augment inspection teams. Therefore, Recommendation 1.B(3) has not been implemented.

See the Finding for a detailed discussion.

Recommendation 1.B (4) Deputy Secretary of Defense direct the EA for Biosafety and Biosecurity to ensure that all personnel included in inspection teams have sufficient scientific expertise and experience.

DoDD 5101.20E directs the BBPO Director to ensure that all personnel included in inspection teams have scientific expertise, experience, and training. This guideline was completed by the BBPO Director who had several discussions with the DAIG Technical Inspections officials about what expertise and educational background, in addition to BSAT-registered laboratory experience, to consider when hiring to develop a comprehensive DoD BSAT biosafety and biosecurity inspection team. The DAIG Technical Inspection Division officials hired and created a well-rounded mixture of academic knowledge, including microbiology, molecular biology, and industrial hygiene, as well as Federal and DoD BSAT-registered laboratory experience, which comprises the core DAIG Technical Inspections BSAT team. Therefore, the actions taken by the BBPO and the DAIG personnel meets the intent of recommendation. Therefore, Recommendation 1B(4) is resolved and closed.

Recommendation 2.A. Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to implement an external technical and scientific peer review function that addresses both biosafety and biosecurity issues to support all DoD SAT laboratories

DoDD 5101.20E directs the BBPO Director to:

“[e]stablish a government-only scientific peer review panel to conduct an initial technical review, and subsequent periodic reviews, of biosafety protocols and procedures and biosecurity policies and procedures across DoD laboratories that handle BSAT. Implement changes to these protocols, procedures, and policies to enhance their effectiveness. This scientific peer review should include DoD and non-DoD representation whenever possible.”

In accordance with DoDD 5101.20E, the EARO, via the BBPO, established the BSRP. The BSRP convenes to review and assess biosafety and biosecurity concerns associated with currently established and new procedures conducted at DoD BSAT laboratories. The BSRP is composed of members from DoD components as well as members from external agencies, including the United States Department of Agriculture and the CDC-DSAT. The establishment of and the actions taken by the BBPO via the BSRP meet the intent of Recommendation 2.A. Therefore, Recommendation 2.A is resolved and closed.

Recommendation 2.B. Under Secretary of Defense for Acquisition, Technology, and Logistics issue guidance that all DoD BSAT laboratories implement an internal technical and scientific peer review function that addresses both biosafety and biosecurity issues.

During the close-out phase of our 2016 report, personnel from the USD(A&S) indicated that the publication of 5101.20E “close[d] all but one Recommendation (Recommendation 2.B) from the report.” However, the DoD OIG closed the recommendation. During this evaluation, the DoD OIG team inquired about the internal peer review process. A representative from the OASD(NCB/CBD) stated that the BSRP is comprised of military and civilian personnel and satisfied both the internal and external peer review requirement. Recommendation 2B stemmed from the need for internal committees, within the laboratories, to consider both biosafety and biosecurity issues. Although the BSRP consists of members from each laboratory, the BSRP exists outside of the laboratories and does not meet the purpose of or the need for an internal committee within each individual laboratory.

Furthermore, despite the response from the OASD(NCB/CBD) representative, per the USD(A&S), the language in 5101.20E does not meet the intent of Recommendation 2B and Recommendation 2B has not been implemented.

See the Finding for a detailed discussion.

Recommendation 3.A. Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to serve as the single DoD POC with the CDC and Animal and Plant Health Inspection Service for coordinating and participating in inspections of DoD BSAT laboratories.

A Memorandum of Understanding (see Recommendation 3.B.) between the CDC-DSAT; Animal and Plant Health Inspection Service, Agriculture Select Agent Services; and the DoD BSAT Biosafety and Biosecurity Programs established the relationship and responsibilities for each agency, including the designation of points of contact for coordination of inspections. Based on the Memorandum of Understanding and testimony provided by a DAIG-TI official, the DAIG-TI Chief serves as the single DoD point of contact with the CDC-DSAT and Animal and Plant Health Inspection Service, Agriculture Select Agent Services for coordinating and participating in inspections of DoD BSAT laboratories. The actions taken by the Animal and Plant Health Inspection Service, Agriculture Select Agent Services; the CDC-DSAT; and the DoD met the intent of Recommendation 3.B. Therefore, Recommendation 3.A is resolved and closed.

Recommendation 3.B. Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to develop and implement an agreement with the CDC and Animal and Plant Health Inspection Service for scheduling combined inspections of DoD BSAT laboratories.

On July 30, 2017, the CDC-DSAT; the Animal and Plant Health Inspection Service, Agriculture Select Agent Services; and the DoD signed a Memorandum of Understanding “to ensure effective oversight of biosafety and biosecurity, and where possible to reduce the burden on registered entities [and] agree to coordinate site visits of entities owned by DoD or conducting research sponsored or funded by DoD within the resources available to all Parties.” In addition to the Memorandum of Understanding, the DAIG provided testimonial and documentary evidence to support that the DAIG and the CDC-DSAT are coordinating inspections. The actions taken by the EA to develop and implement an agreement between

Animal and Plant Health Inspection Service, Agriculture Select Agent Services; the CDC-DSAT; and the DoD met the intent of Recommendation 3.B. Therefore, Recommendation 3.B is resolved and closed.

Recommendation 3.C. Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to define combined inspection criteria and guidance with the CDC and Animal and Plant Health Inspection Service for DoD BSAT laboratories.

DoDD 5101.20E requires the BBPO Director to: “[d]evelop and implement an agreement with the CDC and the Animal and Plant Health Inspection Service for scheduling inspections of DoD BSAT laboratories that are combined with any inspections required by DoD. This agreement should establish joint inspection criteria and guidance wherever possible.” Per 5101.20E and the MOU between the CDC-DSAT; the Animal and Plant Health Inspection Service, Agriculture Select Agent Services; and the DoD, personnel from the BBPO developed combined inspection criteria and guidance, including DoD and the CDC-DSAT inspection criteria, and provided it to DAIG Technical Inspections personnel. The actions taken by the BBPO personnel to develop, draft, and provide checklist to laboratories and the DAIG meets the intent of Recommendation 3.C. Therefore, Recommendation 3.C is resolved and closed.

Recommendation 3.D. Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to serve as the formal communication entity with the FSAP regarding findings and lessons learned from the CDC and Animal and Plant Health Inspection Service relevant to the DoD BSAT Program.

DoDD 5101.20E requires the BBPO Director to, “[s]erve as DoD’s primary point of contact for and liaison to the CDC and Animal and Plant Health Inspection Service, for BSAT biosafety and biosecurity matters to ensure departmental priorities or issues are clearly presented, addressed, and resolved.” As required by DoDD 5101.20E, the BBPO Director meets with a CDC-DSAT official on a quarterly basis to discuss biosafety and biosecurity issues. Based on the testimony provided by BBPO officials and a CDC-DSAT official, the BBPO Director and the BBPO serve as the formal communication entity with the Federal Select Agent Program regarding findings and lessons learned from the CDC-DSAT and the Animal and Plant Health Inspection Service, Agriculture Select Agent Services relevant to the Department of Defense Biological Select Agents and Toxins program. The actions taken, via the regular communication between the CDC-DSAT and the BBPO, meet the intent of Recommendation 3.D. Therefore, Recommendation 3.D. is resolved and closed.

Recommendation 4.A. Deputy Secretary of Defense direct the DoD EA for Biosafety and Biosecurity to implement criteria for inclusion of site-specific security vulnerability assessment findings into DoD BSAT laboratory biosafety and biosecurity inspections.

DoDD 5101.20E directs the BBPO Director to “[d]evelop a comprehensive inspection program that...[e]nsures inspections include a review of site-specific vulnerabilities.” The BBPO developed a criteria checklist for DoD BSAT laboratory inspections, including criteria for review of site-specific vulnerabilities. Because these standards are incorporated into the criteria checklist developed by the BBPO and DAIG inspections include a review of site specific vulnerability assessments, the actions taken meet the intent of Recommendation 4.A. Therefore, Recommendation 4.A is resolved and closed.

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 BSAT laboratory inspections.

The Office for the Under Secretary of Defense for Acquisition and Sustainment publication of DoDD 5101.20E requires that inspections include site-specific vulnerabilities. Therefore, the publication of DoDD 5101.20E, which requires that inspections include site specific vulnerabilities, meets the intent of Recommendation 4.B. Therefore, Recommendation 4.B is resolved and closed.

Management Comments

Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs



ASSISTANT SECRETARY OF DEFENSE
3050 DEFENSE PENTAGON
WASHINGTON, DC 20301-3050

NUCLEAR, CHEMICAL, AND
BIOLOGICAL DEFENSE PROGRAMS

JUN 11 2020

MEMORANDUM FOR THE DEPARTMENT OF DEFENSE OFFICE OF THE INSPECTOR
GENERAL, PROGRAM EVALUATIONS

SUBJECT: Response to DoDIG Final Report DODIG-2016-078, "Follow up Evaluation of
Biological Select Agents and Toxins Biosafety and Biosecurity Program
Implementation" (Project No. D2019-DEV0PA-0188.000)

As requested, I am providing responses to the general content and recommendations
contained in the subject report.


Recommendation 1:

The Office of the Under Secretary of Defense for Acquisition and Sustainment will issue a
policy requiring all DoD biological select agents and toxins (BSAT) laboratories to implement
an internal technical and scientific peer review function that addresses both biosafety and
biosecurity.

Response:

Concur. ASD(NCB) concurs with the DoD OIG's recommendation and will include a
requirement for all DoD BSAT laboratories to establish internal technical and scientific peer
review panels to review biosafety protocols and biosecurity policies in Change 1 to Department
of Defense Directive 5101.01E, "DoD Biological Select Agents and Toxins (BSAT) Biosafety
and Biosecurity Program."

Please contact [REDACTED] or
[REDACTED] if additional information is
required.


Alan R. Shaffer
Performing the Duties of the Assistant
Secretary of Defense for Nuclear, Chemical, and
Biological Defense Programs

Executive Agent Responsible Office



DEPARTMENT OF THE ARMY
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SAIG-ZA

23 June 2020

MEMORANDUM FOR Inspector General, Department of Defense, 4800 Mark Center Drive, Alexandria, VA 22350-1500

SUBJECT: Response to the Department of Defense Inspector General (DODIG) Follow-up Evaluation of the Department of Defense (DOD) Biological Select Agents and Toxins (BSAT) Biosafety and Biosecurity Program Implementation, Project No. D2019-DEV0PA-0188.000

1. Thank you for the opportunity to review the follow-up evaluation of the DOD BSAT Biosafety and Biosecurity Program implementation.
2. While I agree with recommendation 3, I do not agree with the deficiency highlighted in the body of this report. Specifically, the draft DODIG report states, "DAIG Technical Inspections Division BSAT-registered laboratory inspectors did not always inspect in accordance with Service-specific requirements." During this follow-up evaluation, DAIG provided three years of inspection reports as support to DoDIG. These reports included over 100 findings and all deficiencies identified a written Federal, DOD, Service, and or local standard that was applicable to the entity inspected.
3. In response to the recommendation, we will require technical inspectors and external subject matter expert inspectors to participate in training specific to DOD and Service-specific BSAT standards. The training will include an overview of the BSAT program, roles of DOD and other Federal entities, and a review of applicable DOD and Service regulations. Estimated completion is 2nd QTR, Fiscal Year 2021.
4. My point of contact is [REDACTED].

SMITH, LESLIE, CARLTON
TON [REDACTED]

LESLIE C. SMITH
Lieutenant General, USA
The Inspector General

Department of the Army Inspector General



DASG-CS

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042-5140

26 JUN 2020

MEMORANDUM FOR Department of Defense Inspector General, Assistant Inspector General for Evaluations Programs, Combatant Commands, and Overseas Contingency Operations, ATTN: Ms. Carolyn Hantz, [REDACTED]
[REDACTED]

SUBJECT: Follow-up Evaluation of Report DODIG-2016-078, Evaluation of the Department of Defense's Biological Select Agents and Toxins Biosafety and Biosecurity Program Implementation (Project No. D2019-DEV0PA-0188.000)

1. Thank you for the opportunity to review this draft report.
2. Our comments are enclosed for your consideration.
3. Our point of contact is [REDACTED]
[REDACTED] or email [REDACTED]

FOR THE SURGEON GENERAL:

Encls


RICHARD R. BEAUCHEMIN
Chief of Staff

Department of the Army Inspector General (cont'd)

Office of The Surgeon General (OTSG)

Comments on DODIG Draft Report Followup Evaluation of Report DODIG-2016-078, Evaluation of the Department of Defense's Biological Select Agents and Toxins Biosafety and Biosecurity Program Implementation (Project No. D2019-DEVOPA-0188.000)

RECOMMENDATION 2: We recommend that the DOD Executive Agent for the Biological Select Agents and Toxins Biosafety and Biosecurity Programs, in coordination with the Biological Select Agents and Toxins Biorisk Program Office, develop a plan to conduct standardized oversight of the DOD Biosafety and Biosecurity Programs and biological select agents and toxins-registered laboratories, including tracking all internal and external inspection results.

RESPONSE: The Surgeon General, as the Executive Agent's Responsible Official (EARO), concurs with this recommendation and has developed a plan to conduct standardized oversight of the DoD Biosafety and Biosecurity Programs and DOD biological select agents and toxins (BSAT)-registered laboratories, including tracking all internal and external inspection results. Specifically:

- To clarify the BBPO's oversight role of BSAT biosafety and biosecurity to the DOD BSAT-registered laboratories, the EARO and BBPO Director have begun site visits to each laboratory and will speak directly to leadership, biorisk, and laboratory personnel on this topic (see attachment 1 for discussion points related to BBPO role clarification; attachment 2 for the BBPO Inspection Program Roles and Responsibilities Policy; and attachment 3 for the BSAT EARO Program for Biosafety and Biosecurity Related Staff Assistance Visits documents). The EARO and BBPO will also provide formal communication to the BSAT biosafety and biosecurity community, such as inspection agencies, to clarify the oversight role. Visits to all laboratories are expected to be complete by 31 August 2020.
- The BBPO developed and implemented a formal BSAT EARO Program for Biosafety and Biosecurity Related Staff Assistance Visit (SAV) Program, signed by the EARO on 27 May 2020. This SAV program provides direct oversight of the DOD BSAT laboratories compliance status with Federal, DoD, Service-specific, state, and local regulations to ensure the laboratories are inspection ready at all times. The Laboratory Command has 90 days to address any deficiencies noted during the SAV, and BBPO conducts a follow-up on corrective actions taken. The BBPO also ensures corrective actions taken to close previous internal and external inspections and Department of Army Safety pre-operational survey results are complete and sustained over time. This program provides a comprehensive, standardized oversight program for all DOD BSAT-registered laboratories.

Encl

Department of the Army Inspector General (cont'd)

- The BBPO has moved from tracking the inspection results from the initial spreadsheet to the Quality Management System (QMS) Inspections Database within the Joint Interagency Biorisk System (JIBS). The BBPO has completed entry of inspection results from the Department of Army Inspectors General (DAIG) and the Centers for Disease Control and Prevention's Division of Select Agents and Toxins (DSAT) back to 2016. The BBPO has begun entering results from the Department of Army Safety pre-operational surveys. We plan to have all results, corrective actions, and final outcome information entered into the database by 1 July 2020 (see attachment 4 for database screenshots).

Acronyms and Abbreviations

BBPO	Biological Select Agents and Toxins Biorisk Program Office
BSAT	Biological Select Agents and Toxins
BSRP	Biorisk and Scientific Review Panel
CDC	Centers for Disease Control and Prevention
DAIG	Department of the Army Inspector General
DSAT	Division of Select Agents and Toxins
EA	Executive Agent
EARO	Executive Agent Responsible Official
OUSDA(S)	The Office of the Under Secretary of Defense for Acquisition and Sustainment
OUSDA(P&R)	The Office of the Under Secretary of Defense for Personnel and Readiness



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