United States Government Accountability Office

Report to Congressional Requesters

June 2015

CHEMICAL AND BIOLOGICAL DEFENSE

Designated Entity Needed to Identify, Align, and Manage DOD's Infrastructure

GAO-15-257

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GAO Highlights

Highlights of GAO-15-257, a report to congressional requesters

Why GAO Did This Study

The United States faces current and emerging chemical and biological threats, and defenses against these threats enable DOD to protect the force, preclude strategic gains by adversaries, and reduce risk to U.S. interests.

GAO was asked to review DOD efforts to manage its chemical and biological defense infrastructure capabilities. This report examines the extent to which the CBDP Enterprise has: (1) achieved its goal to identify required infrastructure capabilities to address current and emerging chemical and biological threats; (2) identified, addressed, and managed potential fragmentation, overlap, and duplication in its chemical and biological defense infrastructure; and (3) used and plans to use threat data and the results of risk assessments to support its investment planning for chemical and biological defense. GAO analyzed CBDP infrastructure policies, plans, and studies from organizations across the CBDP Enterprise from fiscal years 2008 through 2014.

What GAO Recommends

GAO recommends, among other things, that DOD (1) designate an entity to lead the effort to identify required infrastructure; (2) identify, request, and consider any information from chemical and biological infrastructure studies of other federal agencies to avoid potential duplication; and (3) update the CBDP Enterprise's guidance and planning process to fully institutionalize the use of risk assessments. DOD concurred with all five of GAO's recommendations and discussed actions it plans to take.

View GAO-15-257. For more information, contact Joseph Kirschbaum at (202) 512-9971 or kirschbaumj@gao.gov.

What GAO Found

A key component of the 26 Department of Defense (DOD) organizations that constitute the Chemical and Biological Defense Program (CBDP) Enterprise is the chemical and biological defense research and development and test and evaluation infrastructure. After nearly 7 years, the CBDP Enterprise has not fully achieved its goal to identify required infrastructure capabilities. The Joint Chemical, Biological, Radiological, and Nuclear Defense Program Analysis and Integration Office (PAIO), CBDP's analytical arm, recommended in 2008 that the CBDP Enterprise identify required infrastructure capabilities, such as laboratories to research chemical and biological agents, to ensure alignment of the infrastructure to its mission. CBDP Enterprise officials recognize the importance, validity, and necessity of addressing the 2008 recommendation. The CBDP Enterprise has made limited progress in achieving this infrastructure goal because CBDP Enterprise officials told GAO that they were focused on higher priorities and had no CBDP Enterprise-wide impetus to address the infrastructure recommendations. The Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs previously identified the need for an entity that has the responsibility and authority needed to ensure achievement of this goal, but DOD has not designated such an entity. By identifying and designating an entity with the responsibility and authority to lead infrastructure transformation, the CBDP Enterprise would be better positioned to achieve this goal.

The CBDP Enterprise has taken some actions at its laboratories to identify duplication in its chemical and biological defense infrastructure. DOD directives outline goals, such as to avoid duplication by using existing DOD and other federal agencies' facilities. As part of an ongoing study to identify required infrastructure, in July 2015 PAIO plans to inventory and analyze CBDP Enterprise infrastructure for potential duplication. However, study officials stated that they do not plan to identify, request, or consider information about infrastructure capabilities from existing studies of other federal agencies, such as the Department of Homeland Security, because their office does not have the authority or resources to require such information. By considering existing information, which would not necessarily require new authority, PAIO will have more information about existing infrastructure inventory across the federal government, such as its capability and potential availability for use.

The CBDP Enterprise used threat data and plans to use threat data and the results from risk assessments piloted in 2014 to support its future portfolio planning process to prioritize research and development investment. However, the CBDP Enterprise has not updated its guidance and planning process to fully institutionalize the use of risk assessments. Federal standards for internal control state that agencies should have written procedures to better ensure leadership directives are implemented. According to CBDP Enterprise officials, while updating the guidance would be beneficial, they had not committed to updating such guidance or established a time frame for doing so. By updating its guidance to fully institutionalize the use of risk assessments, the CBDP Enterprise would be better positioned to prioritize future research and development investments.

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Abbreviations

BSL	Biosafety Level
CBDP	Chemical and Biological Defense Program
CBRN	chemical, biological, radiological, and nuclear
CBRNE	chemical, biological, radiological, nuclear, and high-yield explosives
DOD	Department of Defense
DODD	Department of Defense Directive
OASD (NCB)	Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
ODASD (CBD)	Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense
PAIO	Program Analysis and Integration Office
USAMRICD	U.S. Army Medical Research Institute of Chemical Defense
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases

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June 25, 2015

The Honorable Mac Thornberry
Chairman
Committee on Armed Services
House of Representatives

The Honorable James R. Langevin
Ranking Member
Subcommittee on Emerging Threats and Capabilities
Committee on Armed Services
House of Representatives

The United States faces current and emerging chemical and biological threats. The *Quadrennial Defense Review 2014* states that North Korea's weapons of mass destruction program constitutes a significant threat to peace and stability on the Korean Peninsula and in Northeast Asia and is a growing and direct threat to the United States. In addition, the use of chemical weapons in Syria in 2013, the 2014 Ebola virus outbreak in West Africa, the emergence of nontraditional (chemical) agents, and the spread of scientific knowledge and capabilities by state and nonstate actors to produce effective chemical and biological weapons have each, among others, contributed to the nation's vulnerability to chemical and biological attacks and naturally occurring diseases.[1]

Defenses against these chemical and biological threats are intended to enable the Department of Defense (DOD) to protect the force, preclude strategic gains by adversaries, and reduce risks to U.S. interests. DOD's Chemical and Biological Defense Program (CBDP) leads the department's efforts to protect military personnel, particularly the warfighter, against a wide range of threats. The program's mission is "to enable the warfighter to deter, prevent, protect against, mitigate, respond to, and recover from chemical, biological, radiological, and nuclear (CBRN) threats and effects as part of a layered, integrated defense." The CBDP Enterprise—those 26 DOD organizations that determine warfighter

[1]Nontraditional (chemical) agents are chemicals reportedly researched or developed with potential application or intent for use as chemical warfare agents that do not fall into the category of traditional chemical warfare agents, toxic industrial chemicals, or toxic industrial materials.

requirements, provide science and technology expertise, conduct research and development and test and evaluation on capabilities needed to protect the warfighter, and provide oversight—implements the mission. (See app. I for a list of CBDP Enterprise organizations.) In fiscal year 2015, CBDP received $1.4 billion, and has requested $1.3 billion for fiscal year 2016, with the reduction coming in the Research, Development, Test, and Evaluation and Procurement accounts. A key component supporting this mission is DOD's chemical and biological defense research and development and test and evaluation infrastructure.

In 2008, the CBDP Enterprise's Joint Chemical, Biological, Radiological, and Nuclear Defense Program Analysis and Integration Office (hereinafter referred to as the Program Analysis and Integration Office—PAIO) , the analytical arm of the CBDP Enterprise, assessed the physical infrastructure capabilities that support the CBDP Enterprise's mission and recommended, among other things, that the CBDP Enterprise identify its required research and development and test and evaluation infrastructure capabilities to support its mission.[2] For the purpose of our review, we used the CBDP Enterprise's description of its infrastructure—both intellectual (also referred to as the knowledge and skill capabilities of its personnel) and physical (e.g., laboratories, testing facilities, and support facilities)[3]—needed to ensure that it addresses current and emerging chemical and biological threats.

You asked us to review DOD's efforts to manage its chemical and biological defense infrastructure capabilities to address current and emerging chemical and biological threats. This report examines the extent to which the CBDP Enterprise has (1) achieved its goal to identify required infrastructure capabilities to address current and emerging chemical and biological threats; (2) identified, addressed, and managed potential fragmentation, overlap, and duplication in its chemical and biological defense infrastructure; and (3) used threat data and plans to

[2]The Program Analysis and Integration Office (PAIO) provides independent analysis, review, and integration functions for the CBDP Enterprise as required by Department of Defense Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense (CBD) Program (CBDP)* (Oct. 9, 2008) (Hereinafter cited as DODD 5160.05E (Oct. 9, 2008)).

[3]According to Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (ODASD [CBD]) officials, specialized equipment in the facilities also is considered part of the physical infrastructure of the CBDP Enterprise.

use threat data and the results of risk assessments to support its investment planning in research and development for chemical and biological defense.

To determine the extent to which the CBDP Enterprise has achieved its goal to identify required infrastructure capabilities to address current and emerging chemical and biological threats, we reviewed PAIO's 2008 recommendations, including the recommendation that the CBDP Enterprise identify its required infrastructure capabilities.[4] We reviewed the recommendations with officials from the Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (ODASD [CBD]), who determined that the 2008 recommendations are still valid. We developed and administered a questionnaire to the CBDP Enterprise's four primary research and development and test and evaluation facilities on actions they have taken to identify required infrastructure capabilities. We included the four primary facilities in our review because they conduct the majority of the research and development and test and evaluation activities for the program. By including all of the primary facilities, we are obtaining information across the CBDP Enterprise, but this information is not generalizable to all facilities that may be used by the program to implement its mission. In addition, we interviewed and collected information from officials from other CBDP Enterprise organizations that have responsibilities for the program, such as ODASD (CBD), the Joint Science and Technology Office, and PAIO, on their actions and the CBDP Enterprise's progress to address its infrastructure. We compared PAIO's 2008 recommendation to the actions taken by the CBDP Enterprise since then through January 2015 to identify required infrastructure capabilities.

We analyzed relevant criteria from our work on the implementation of organizational transformation—such as the importance of establishing a dedicated authority responsible for day-to-day management for an organization's change initiatives with the necessary authority and resources to set priorities, make timely decisions, and move quickly to implement top leadership's decisions regarding organizational transformation; and a timeline and milestones to successfully implement

[4]The PAIO study made recommendations to address "physical" infrastructure capabilities, whereas the 2008 *Chemical and Biological Defense Program (CBDP) Strategic Plan* considers its infrastructure to be defined by both the physical and intellectual components required to implement its mission.

organizational change—and compared these criteria to actions that the CBDP Enterprise has taken to identify required infrastructure capabilities to address current and emerging chemical and biological threats. We used these criteria from our work[5] to analyze whether the CBDP Enterprise followed key implementation steps to successfully transform the way it manages its infrastructure to address its goals.

To determine the extent to which DOD's CBDP Enterprise has identified, addressed, and managed potential fragmentation, overlap, and duplication in its chemical and biological defense infrastructure, we reviewed policies on the program and related testing facility guidance and a 2011 study on infrastructure needs to support medical countermeasures, and a 2014 PAIO plan to identify infrastructure duplication and gain efficiencies. We developed and administered a questionnaire to the CBDP Enterprise's primary research and development and test and evaluation facilities to collect information on any processes or action to identify, address, and manage fragmentation, overlap, and duplication.[6] In addition, we interviewed ODASD (CBD)

[5]See GAO, *Results-Oriented Cultures: Implementation Steps to Assist Mergers and Organizational Transformations*, GAO-03-669 (Washington, D.C.: July 2, 2003). To identify the key practices and implementation steps for mergers and organizational transformation, the Comptroller General convened a forum in September 2002 of leaders who have had experience managing large-scale organizational mergers, acquisitions, and transformations, as well as academics and others who have studied these efforts to discuss and identify key practices and implementation steps for mergers and organizational transformation. We also interviewed selected forum participants and other experts about their experiences implementing mergers, acquisitions, and transformations. A new focus on infrastructure in recent years by the CBDP Enterprise, such as developing a new goal to identify required infrastructure and identifying the need for a dedicated authority to oversee infrastructure changes, demonstrates a paradigm shift in the way the CBDP Enterprise is transforming the way it manages infrastructure to ensure that it is aligned with its mission. Therefore, we determined that implementation of organizational transformation criteria was relevant because the elements of the criteria are applicable to the CBDP Enterprise's focus on infrastructure management. ODASD (CBD) officials agreed that these criteria were appropriate to use for our review of the CBDP Enterprise's actions to address its infrastructure goals.

[6]See GAO, *2014 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-14-343SP (Washington, D.C.: Apr. 8, 2014). GAO defines "fragmentation" to be those circumstances in which more than one federal agency (or more than one organization within an agency) is involved in the same broad area of national need, and opportunities exist to improve service delivery. "Overlap" occurs when multiple agencies or programs have similar goals, engage in similar activities or strategies to achieve them, or target similar beneficiaries. "Duplication" occurs when two or more agencies or programs are engaged in the same activities or provide the same services to the same beneficiaries.

officials about any plans to identify, address, and manage fragmentation, overlap, and duplication. Using DOD's guidance and responses to the questionnaire, we compared their processes and actions to DOD guidance to determine the extent to which the CBDP Enterprise reported that it avoided duplication and identified, addressed, and managed potential infrastructure duplication.[7]

To determine the extent to which the CBDP Enterprise has used threat data and plans to use threat data and the results of risk assessments to support future investment planning in research and development for chemical and biological defense, we received a threat briefing to understand the type of data provided to the CBDP Enterprise about chemical and biological threats. We reviewed a DOD Directive that includes information on risk assessments within the program.[8] We interviewed officials from the Joint Requirements Office within the Office of the Joint Chiefs of Staff and ODASD (CBD) about how they used the risk assessment guidance from the 2001 *Quadrennial Defense Review Report* to conduct their risk assessments.[9] We interviewed officials from ODASD (CBD), which develops CBDP Enterprise–wide policy and guidance to support various objectives to determine how threat data and the risk assessments are used—or will be used in the future—to support future research and development investment planning. We compared internal control standards on written procedures to those used by the CBDP Enterprise to conduct its risk assessments.[10] A more detailed explanation of our scope and methodology can be found in appendix II.

We conducted this performance audit from January 2014 to June 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our

[7]Department of Defense Directive 5134.08, *Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD (NCB))* (Feb. 14, 2013) (Hereinafter cited as DODD 5134.08 (Feb. 14, 2013)) and Department of Defense Directive 3200.11, *Major Range and Test Facility Base (MRTFB)* (Dec. 27, 2007) (Hereinafter cited as DODD 3200.11 (Dec. 27, 2007)).

[8]DODD 5160.05E (Oct. 9, 2008).

[9]See Department of Defense, *Quadrennial Defense Review Report* (Sept. 30, 2001).

[10]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

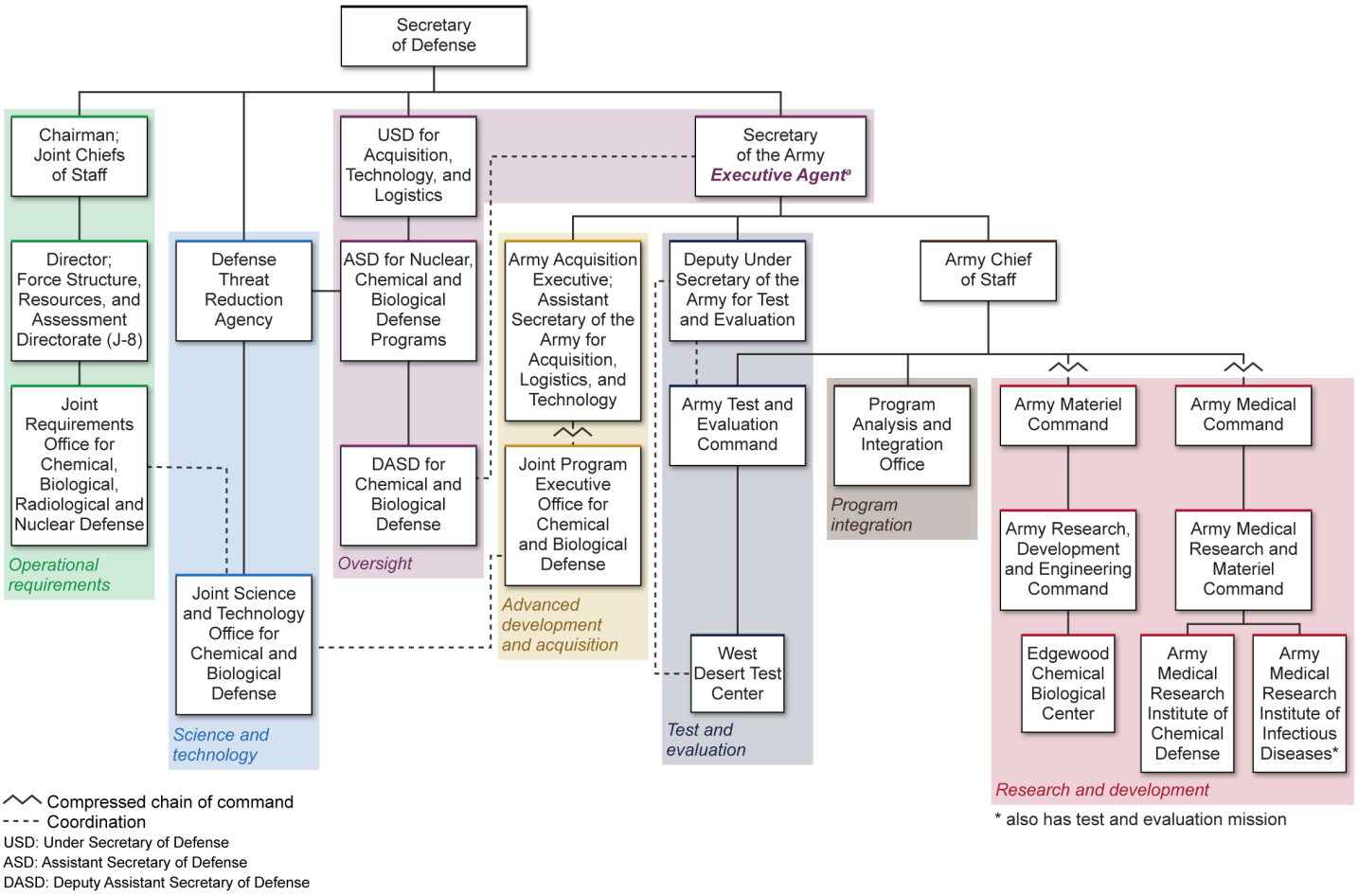
The CBDP Enterprise

The Chemical and Biological Defense Program was established in 1994 and develops defense capabilities to protect the warfighter from current and emerging chemical and biological threats.[11] Specifically, its mission is "to enable the warfighter to deter, prevent, protect against, mitigate, respond to, and recover from CBRN threats and effects as part of a layered, integrated defense." The CBDP Enterprise conducts research and develops defenses against chemical threats, such as cyanide and mustard gases, and biological threats, such as anthrax and Ebola, and tests and evaluates capabilities and products to protect military forces from them.

The CBDP Enterprise comprises 26 organizations across DOD that determine warfighter requirements, provide science and technology expertise, conduct research and development and test and evaluation on capabilities needed to protect the warfighter, and provide oversight. Figure 1 shows the CBDP Enterprise organizations included in our review and their roles.

[11]See National Defense Authorization Act for Fiscal Year 1994, Pub. L. No. 103-160, § 1703 (1993) (codified in relevant part at 50 U.S.C. §§ 1522 and 1523).

Figure 1: The Chemical Biological Defense Program (CBDP) Enterprise



Source: GAO analysis of Department of Defense (DOD) information. | GAO-15-257

[a]Army memorandums designate the Vice Chief of Staff of the Army and the Assistant Secretary of the Army for Acquisition, Logistics and Technology as cochairs of the Executive Agent Secretariat. According to Army officials, the Vice Chief of Staff of the Army delegated many of his executive agent responsibilities to the Office of the U.S. Army Deputy Chief of Staff, G-8.

Note: According to ODASD (CBD) officials, the CBDP Enterprise organizations in the figure and the three organizations cited in figure note "a" above, excluding the Office of the Secretary of Defense, constitute the 26 key organizations that make up the CBDP Enterprise.

The ability of the CBDP Enterprise to successfully implement its mission in a resource-constrained environment, according to the 2012 *CBDP Business Plan*,[12] relies on the integrated management of responsibilities performed by these organizations. The following CBDP Enterprise organizations have key roles and responsibilities:[13]

- **The Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs**, among other things, serves as the advisor to the Secretary of Defense for activities that combat current and emerging chemical and biological threats.
- **The Deputy Assistant Secretary of Defense for Chemical and Biological Defense** is responsible for Chemical and Biological Defense Program oversight activities, acquisition policy guidance, and interagency coordination.
- **The Secretary of the Army** is the Executive Agent for the Chemical and Biological Defense Program. Within the Army, the **Assistant Secretary of the Army for Acquisition, Logistics and Technology** and the **Office of the U.S. Army Deputy Chief of Staff, G-8** serve as cochairs of the Army Executive Agent Secretariat and are responsible for, among other duties, coordinating and integrating research, development, test, and evaluation, and acquisition requirements of the military departments for DOD chemical and biological warfare defense programs and reviewing all funding requirements for the CBDP Enterprise.[14]
- **The Deputy Under Secretary of the Army for Test and Evaluation** provides oversight, policy, governance and guidance to ensure timely, adequate, and credible test and evaluation for the Army and the

[12]Department of Defense, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, *Chemical and Biological Defense Program Business Plan* (Oct. 31, 2012).

[13]DODD 5160.05E (Oct. 9, 2008).

[14]Army memorandums designate the Vice Chief of Staff of the Army and the Assistant Secretary of the Army for Acquisition, Logistics, and Technology as cochairs of the Executive Agent Secretariat. See Department of the Army, *Deputy Chief of Staff, G-8, Army as Executive Agent of the Chemical and Biological Defense Program* (July 25, 2003) and Department of the Army, *Designation of an Executive Agent Secretariat for the Joint Chemical and Biological Defense Program* (July 26, 2004).

CBDP Enterprise. The Director, Army Test and Evaluation Office, serves as the Test and Evaluation Executive for the CBDP Enterprise.

- **The Program Analysis and Integration Office (PAIO)** is the analytical arm of the CBDP Enterprise and is responsible for monitoring the expenditures of research, development, test, and evaluation activities. It provides analysis, review, and integration functions for the CBDP Enterprise.

- **The Joint Program Executive Office for Chemical and Biological Defense** oversees the total life-cycle acquisition management for assigned chemical and biological programs, among others.

- **The Office of the Joint Chiefs of Staff, Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense** (hereinafter referred to as the Joint Requirements Office) serves as a focal point to the Chairman of the Joint Chiefs of Staff for all chemical and biological issues, among others, associated with combating weapons of mass destruction, and supports the development of recommendations to the Secretary of Defense regarding combatant commanders' chemical and biological requirements for operational capabilities, among others.

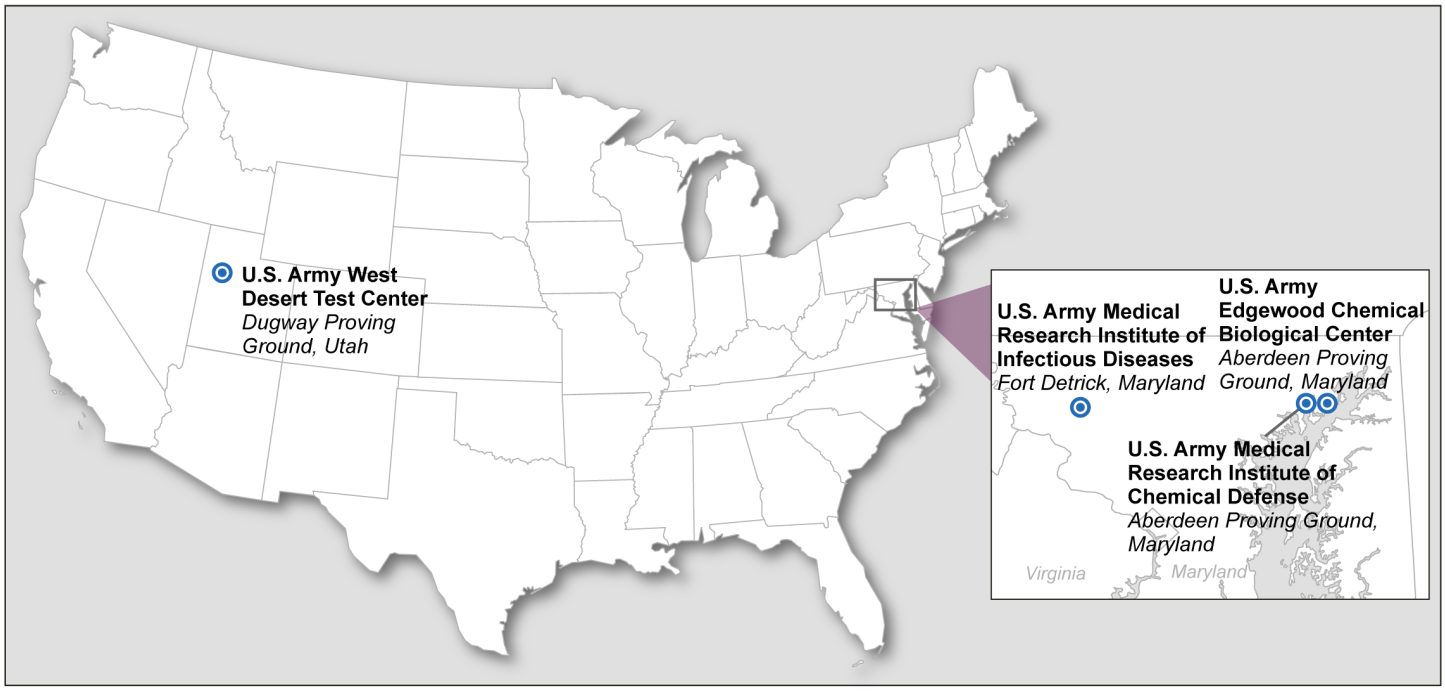
- **The Joint Science and Technology Office for Chemical and Biological Defense** (hereinafter referred to as Joint Science and Technology Office) oversees science and technology efforts in coordination with the military services' research and development laboratories, to include efforts with other agencies, laboratories, and organizations.

- The CBDP Enterprise's four primary research and development and test and evaluation facilities, as seen in figure 2, include the **U.S. Army Edgewood Chemical Biological Center** (hereinafter referred to as Edgewood), Aberdeen Proving Ground, Maryland; the **U.S. Army Medical Research Institute of Infectious Diseases** on the National Interagency Biodefense Campus, Ft. Detrick, Maryland; the **U.S. Army Medical Research Institute of Chemical Defense**, Aberdeen Proving Ground, Maryland; and the **West Desert Test Center** (hereinafter referred to as West Desert), Dugway Proving Ground, Utah. These facilities conduct research and development and test and evaluation of chemical and biological defense capabilities and are owned and operated by the U.S. Army and support the mission of the Chemical and Biological Defense Program. Additional information about DOD's chemical and biological defense primary

research and development and test and evaluation facilities can be found in appendix III.

Figure 2 shows the location of the CBDP Enterprise's primary research and development and test and evaluation facilities.

Figure 2: Chemical Biological Defense Program (CBDP) Enterprise's Primary Research and Development and Test and Evaluation Facilities



Source: Department of Defense (DOD) information; Map Resources (map). | GAO-15-257

CBDP Enterprise Infrastructure Plans and Assessment

The CBDP Enterprise's plans—which are used as guidance to meet its mission—articulate infrastructure goals and identify the ways (i.e., the functions, roles and responsibilities, and business practices) to achieve them. These plans include the following:

- The 2012 *Chemical Biological Defense Program Strategic Plan* is intended to map the direction and articulate the outcomes that the CBDP Enterprise aims to achieve.[15] The plan responds to evolving

[15]Department of Defense, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, *Chemical and Biological Defense Program (CBDP) Strategic Plan* (June 15, 2012).

threats and the fiscal environment by setting a vision to align resources to meet four strategic goals: (1) equip the force to protect and respond to CBRN threats and effects; (2) prevent surprise by anticipating threats and developing new capabilities for the warfighter to counter emerging threats; (3) maintain the infrastructure—both physical and intellectual—the department requires to meet and adapt to current and future needs for personnel, equipment, and facilities within funding constraints; and (4) lead CBDP Enterprise components in integrating and aligning activities.

- The 2012 *Chemical Biological Defense Program Business Plan* describes the ways in which the CBDP Enterprise intends to meet the four strategic goals identified in the 2012 *CBDP Strategic Plan*. The 2012 *CBDP Business Plan* assigns responsibility and provides the structures and processes to implement the 2012 *CBDP Strategic Plan*.

- PAIO's 2014 *CBDP Infrastructure Implementation Plan*, endorsed by the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, articulates the process by which the CBDP Enterprise intends to review its physical infrastructure to support the identification of required infrastructure and determine whether any potentially duplicative or redundant infrastructure capabilities exist within the CBDP Enterprise.[16]

- PAIO's 2008 *Non-Medical Physical Infrastructure Capabilities Assessment* was an assessment conducted by PAIO on the capabilities of the CBDP Enterprise's existing infrastructure to support critical mission areas.[17] The assessment was requested by the Special Assistant, Chemical and Biological Defense and Chemical Demilitarization Programs, to support critical mission areas. The study made four recommendations to the CBDP Enterprise:

[16]Department of Defense, *Chemical and Biological Defense Program Infrastructure Implementation Plan* (July 22, 2014).

[17]Department of Defense, *Chemical and Biological Defense Program Non-Medical Physical Infrastructure Capabilities Assessment* (May 15, 2008).

1. Identify its required research and development and test and evaluation infrastructure capabilities to support its mission.[18]
2. Create a joint strategic vision for military construction investment across all elements of the CBDP Enterprise.[19]
3. Establish a military construction program aligned with the joint strategy and processes integrating goals, objectives, and validation across the CBDP Enterprise.
4. Address the use of project validation, cost/benefit analysis, and investment business case issues for infrastructure decisions.

CBDP Enterprise's Research and Development Planning Process

The CBDP Enterprise annual planning process is designed to support decision making by program leadership regarding investments in research and development. This process is intended to incorporate chemical and biological threat information and chemical and biological defense warfighter requirements into the formulation of CBDP Enterprise strategic programming guidance for research and development investment decisions.

The CBDP Enterprise's 2014 risk assessments are based on DOD's 2001 *Quadrennial Defense Review Report* risk framework. The four dimensions of the risk framework are as follows:

- Force management—the ability to recruit, retain, train, and equip sufficient numbers of high-quality personnel and sustain the readiness of the force while accomplishing its many operational tasks.
- Operational—the ability to achieve military objectives in a near-term conflict or other contingency.

[18]The original language of this recommendation is "to establish a comprehensive set of core capabilities based upon the assessment's recommendations." In a discussion with ODASD (CBD) and PAIO officials, they confirmed that the CBDP Enterprise interprets this recommendation as a need to identify its required infrastructure capabilities. Therefore, for purposes of this report, we are using the recommendation language as interpreted by the CBDP Enterprise.

[19]ODASD (CBD) officials told us that, since the recommendations were made, they have expanded the recommendations to include all infrastructure investments, not just infrastructure funded by military construction appropriations.

- Future challenges—the ability to invest in new capabilities and develop new operational concepts needed to dissuade or defeat mid- to long-term military challenges.

- Institutional—the ability to develop management practices and controls that use resources efficiently and promote the effective operation of the defense establishment.

Together, the results from the four dimensions of the risk framework are expected to allow DOD to consider tradeoffs among fundamental resource constraints.

The CBDP Enterprise Has Taken Actions to Address Infrastructure Needs but Has Not Fully Achieved Its Goal to Identify Required Infrastructure Capabilities to Address Threats

The CBDP Enterprise has taken some actions, such as the development of infrastructure goals, to address its infrastructure needs; however, after nearly 7 years, the CBDP Enterprise has not fully achieved its goal to address the 2008 PAIO recommendation that it identify required infrastructure capabilities to ensure alignment of its infrastructure to its mission to address threats. At that time, the CBDP Enterprise made no plan and did not make infrastructure a priority to address the recommendation. CBDP Enterprise officials acknowledge the importance, validity, and necessity of addressing the 2008 recommendation and recognized these points in their 2012 *CBDP Business Plan*. However, the CBDP Enterprise has made limited progress in achieving this infrastructure goal because CBDP Enterprise officials told us that they were focused on higher priorities and had no CBDP Enterprise-wide impetus to address the infrastructure recommendations. OASD (NCB) previously identified the need for an entity that has the responsibility and level of authority needed to ensure achievement of this infrastructure goal, but DOD has not designated such an entity with CBDP Enterprise-wide responsibility and authority to lead this effort, nor has it established timelines and milestones for doing so.

The CBDP Enterprise Has Taken Actions to Address Its Infrastructure Needs but Has Not Fully Achieved Its Goal to Identify Its Required Infrastructure Capabilities

The CBDP Enterprise has taken actions, but has not fully achieved its goal to address the 2008 PAIO recommendation to identify required infrastructure (intellectual and physical) capabilities to address current and emerging chemical and biological threats. According to ODASD (CBD) officials, the CBDP Enterprise recognizes the importance, validity, and necessity of addressing this (and other) PAIO recommendations from the 2008 study, which would transform the way the CBDP Enterprise manages its infrastructure. However, at that time, CBDP Enterprise officials did not make a plan or set infrastructure as a priority to address the recommendation. In addition, CBDP Enterprise

officials told us that they have not addressed this recommendation because they were focused on higher priorities.

Since the 2008 PAIO recommendation, OASD (NCB) issued the 2012 *CBDP Strategic Plan*, which, for the first time, established maintaining infrastructure as a strategic goal. Additionally, OASD (NCB) issued the 2012 *CBDP Business Plan*, which proposed an assessment[20] of CBDP's required knowledge and skill capabilities of its personnel and physical infrastructure capabilities across the CBDP Enterprise to meet this strategic goal. In addition to these actions, the Deputy Assistant Secretary of Defense for Chemical and Biological Defense requested that the National Research Council of the National Academy of Sciences conduct a study to identify the science and technology capabilities needed for the CBDP Enterprise to meet its mission.[21] However, it was not until 2014 and 2015 that the Joint Science and Technology Office and PAIO, respectively, initiated studies to address the 2012 *CBDP Business Plan* proposal and 2008 recommendation to identify its required infrastructure capabilities. Figure 3 depicts the CBDP Enterprise's limited progress, as shown by the gap from 2008 to 2014, to complete its goal to identify its required infrastructure capabilities.

Figure 3: Timeline of the Chemical Biological Defense Program (CBDP) Enterprise's Limited Progress in Identifying Required Infrastructure Capabilities

Source: GAO analysis of Department of Defense (DOD) information. | GAO-15-257

[20]This proposed assessment in the 2012 *CBDP Business Plan* is a CBDP Enterprise goal; however, the *CBDP Business Plan* does not establish a timeline and milestones to achieve this goal, as discussed later in the report.

[21]In 2012, the committee published a report identifying core chemical and biological defense science and technology capabilities and whether these capabilities should be maintained within DOD's laboratory infrastructure, among other things. The report did not identify necessary infrastructure capabilities.

In December 2014, the Joint Science and Technology Office initiated a study of the CBDP Enterprise's existing intellectual infrastructure to (1) determine the knowledge and skill capabilities of its personnel and (2) identify the required capabilities of its personnel to implement its mission. According to Joint Science and Technology Office officials, they are using the 18 warfighter core capabilities—the framework for meeting the program's mission—to assist in identifying the CBDP Enterprise's required knowledge and skill capabilities for personnel.[22] (See app. IV for additional information about the 18 core capabilities.) These officials told us that they are working with CBDP's Senior Scientist Board and the leadership of the three primary CBDP research and development facilities to identify the required knowledge and skill capabilities for the CBDP Enterprise's personnel.[23] According to the official overseeing this study, the proposed methodology will help them identify expertise and leadership that currently exists within the primary research and development facilities. The methodology also will help them identify the required knowledge and skill capabilities of its personnel to (1) ensure that research and development products are making progress towards project goals and (2) address the 18 warfighter core capabilities. In addition, Joint Science and Technology Office officials stated that their study to identify required knowledge and skill capabilities of the CBDP Enterprise's personnel will also help them determine any existing capabilities gaps. As of January 2015, the Joint Science and Technology Office's infrastructure study produced a presentation on definitions for infrastructure-related issues and a proposed methodology to determine

[22]These capabilities—the framework for meeting the program's mission—were defined through a process led by the Joint Requirements Office with CBDP Enterprise organizations and are used to address chemical and biological threats. According to Joint Requirements Office officials, the core capabilities are a succinct, high-level description of desired chemical, biological, radiological, nuclear, and high-yield explosives (CBRNE) capabilities for the military forces. The 18 core capabilities include chemical detection; biological detection; radiological detection; expeditionary analytics; medical diagnostics; chemical, biological, radiological, and nuclear warning and reporting; decision analysis and management; respiratory and ocular protection; percutaneous protection; chemical prophylaxis; biological prophylaxis; radiological prophylaxis; expeditionary collective protection; personnel contamination mitigation; materiel contamination mitigation; chemical therapeutics; biological therapeutics; and radiological therapeutics.

[23]The Senior Scientist Board is a forum of CBDP senior scientists from across the CBDP Enterprise and DOD laboratories and test and evaluation organizations engaged in chemical and biological defense to (1) advance scientific capabilities, stature, and proficiencies; (2) encourage meaningful technical exchanges; and (3) promote open and transparent communication.

how required knowledge and skill capabilities of the CBDP Enterprise's personnel will be maintained. However, the office does not have an end date for this study or a timeline and milestones to assess its progress.

In addition, PAIO developed a physical infrastructure implementation plan in July 2014 to study the CBDP Enterprise's existing physical infrastructure capabilities. The study includes a timeline and milestones for various actions, including that, from July 2015 through February 2016, PAIO establish an inventory of all the physical infrastructure capabilities within the CBDP Enterprise and conduct an analysis of these capabilities to determine their specific functions and the CBDP Enterprise's level of reliance on these capabilities. According to PAIO officials, this analysis will help the CBDP Enterprise achieve its goal by determining its required physical infrastructure.

ODASD (CBD) officials acknowledged the need to identify required knowledge and skills capabilities of the CBDP Enterprise's personnel and physical infrastructure capabilities to ensure alignment of the Army-owned infrastructure to address current and emerging chemical and biological threats. PAIO officials stated that the information gained from their study and from the Joint Science and Technology Office study will need to be combined to gain a comprehensive understanding of the status of CBDP's infrastructure. Specifically, they stated that the studies will provide additional information to CBDP Enterprise leadership on the existing infrastructure capabilities to help determine required infrastructure and identify any potential gaps to address threats.

The CBDP Enterprise Does Not Have an Entity to Achieve Infrastructure Transformation and Has Not Established Timelines and Milestones to Identify Required Infrastructure Capabilities

The limited progress in fully achieving the CBDP Enterprise goal to identify required infrastructure capabilities, and transform the way infrastructure is managed, is because OASD (NCB) has not identified and designated an entity that has the responsibility and authority needed to lead the effort to ensure the achievement of this and other CBDP Enterprise goals (e.g., the other three 2008 PAIO recommendations, as identified in the Background section of this report, and the goal established in the 2012 *CBDP Business Plan*—an assessment of the CBDP Enterprise's required infrastructure capabilities), and no timelines or milestones have been established for their completion.[24] Key practices

[24]ODASD (CBD) is responsible for overseeing the CBDP Enterprise. However, the Army is responsible for the management and development of the infrastructure associated with the CBDP Enterprise.

for federal agencies to address challenges in achieving successful transformation of their organizations, particularly in the implementation phase, call for (1) establishing a dedicated authority responsible for the transformation's day-to-day management to ensure it receives the full-time attention needed to be sustained and successful and (2) establishing timelines and milestones for achieving goals.[25] The CBDP Enterprise does not have a dedicated entity with the responsibility and authority needed to lead the effort to ensure the achievement of its infrastructure goals.

OASD (NCB) officials previously identified the need for a CBDP Enterprise Infrastructure Manager. While the CBDP Enterprise has initiated separate efforts to identify required infrastructure capabilities, no entity is charged with the overall responsibility and authority to lead the effort to ensure CBDP Enterprise-wide infrastructure goals are achieved. In recent years, according to CBDP Enterprise officials, the CBDP Enterprise struggled to identify an Infrastructure Manager to ensure that CBDP Enterprise-wide goals were achieved. The 2010 *Plan for Implementing Oversight and Management Procedures for Non-Medical Physical Infrastructure Investments Supporting the Chemical and Biological Defense Program* stated that the CBDP Enterprise should establish mechanisms to ensure that infrastructure goals are met. Specifically, the plan called for oversight and management processes, including responsibilities that are performed by an assigned entity for infrastructure management. According to the plan, this role should include maintaining visibility and day-to-day management and providing oversight of the CBDP Enterprise's infrastructure. Additionally, CBDP's Strategic Portfolio Review,[26] in the March 2014 *Chemical and Biological Defense Annual Report to Congress*,[27] recommended that the CBDP Enterprise's Infrastructure Manager conduct a CBDP Enterprise-wide infrastructure assessment to integrate, align, and focus the CBDP Enterprise infrastructure initiatives, among other things.

[25]See GAO-03-669.

[26]The Strategic Portfolio Review assesses, among other things, how efficiently the CBDP Enterprise is maintaining its infrastructure.

[27]Department of Defense, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, *2014 DOD Chemical and Biological Defense Annual Report to Congress* (March 2014).

ODASD (CBD) officials confirmed that, initially, the Army's PAIO was designated as the Infrastructure Manager for the CBDP Enterprise. However, according to PAIO and ODASD (CBD) officials, PAIO does not have the authority to manage the CBDP Enterprise's infrastructure. A decision subsequently was made by ODASD (CBD) that PAIO would no longer serve in this capacity, but would continue in its role to provide infrastructure analysis and integration for the CBDP Enterprise.[28] In July 2014, ODASD (CBD) officials told us the U.S. Army and individual installation leadership were designated as Infrastructure Managers over intellectual and physical infrastructure capabilities for the CBDP's Enterprise's primary research and development and test and evaluation facilities under their purview. However, individual installation leadership does not have the responsibility and authority to maintain CBDP Enterprise-wide visibility and oversight to ensure that CBDP Enterprise-wide infrastructure goals are achieved. A dedicated authority, such as an entity responsible for the day-to-day management of the transformation, could lead the effort to help ensure the CBDP Enterprise receives the full-time attention needed to achieve and sustain its goals to help ensure progress is made as intended. By identifying and designating an entity with the responsibility and authority to lead the effort to set priorities, make timely decisions, and move quickly to implement leadership decisions for ensuring the timely achievement of the CBDP Enterprise's goals, such as identifying required infrastructure capabilities, the CBDP Enterprise would be better positioned to support resource decisions regarding the infrastructure capabilities needed to address threats.

Additionally, no timelines and milestones were established to complete the recommendations identified in the 2008 PAIO study or the goals established in the 2012 *CBDP Business Plan* or the 2014 Joint Science and Technology Office study to identify required knowledge and skill capabilities in its personnel because no entity has responsibility and authority needed to lead the effort to implement this and other CBDP Enterprise goals. Moreover, CBDP Enterprise officials told us that they were focused on higher priorities during this time, such as funding for medical countermeasures capabilities. As a result, the recommendation

[28]In this role, PAIO is responsible for integrating research and development and test and evaluation infrastructure plans, programs, and resources; monitoring the execution of infrastructure funds; and assessing alignment across the research and development and test and evaluation infrastructure investments to sustain core competencies and gain efficiencies.

made nearly 7 years ago and subsequent goals to address the recommendation have not been implemented and there is no timeline for their completion. According to key practices for transforming organizations, it is essential to set and track timelines to build momentum and to demonstrate progress from the beginning.[29] Establishing timelines and milestones for achieving these goals (e.g., the 2008 PAIO recommendations and the goal established in the 2012 *CBDP Business Plan*), would better position the CBDP Enterprise to track its progress towards meeting its infrastructure goals, pinpoint performance shortfalls and gaps, and suggest midcourse corrections to ensure progress is being made to address current and emerging threats and meet its mission. Further, identifying and designating an entity and establishing timelines and milestones would better position the CBDP Enterprise to address any existing challenges in transforming the way the CBDP Enterprise manages its infrastructure and completing its goal to identify the infrastructure capabilities needed to meet its mission.

The CBDP Enterprise Plans to Identify Potential Duplication in Its Chemical and Biological Defense Infrastructure but Does Not Plan to Consider Information from Existing Studies from Other Federal Agencies

The CBDP Enterprise has taken some actions to identify, address, and manage potential fragmentation, overlap, and duplication. Further, during the course of our review, in January 2015, PAIO began a study of CBDP Enterprise infrastructure to identify potential duplication. However, PAIO does not plan to identify, request, or consider information from existing infrastructure studies from other federal agencies. By identifying, requesting, and considering information from existing infrastructure studies from other federal agencies working in this area, PAIO will be better positioned to meet DOD's goal to avoid duplication by having more information about existing infrastructure across the federal government for use by the CBDP Enterprise to support its work.

[29]See GAO-03-669.

CBDP Enterprise Has Taken Some Actions to Identify, Address, and Manage Potential Infrastructure Fragmentation, Overlap, and Duplication

Based on our analysis of information from each of the four primary research and development and test and evaluation facilities and ODASD (CBD) on infrastructure capabilities, the CBDP Enterprise's primary research and development and test and evaluation facilities have taken some actions to identify, address, and manage fragmentation, overlap, and duplication. For example, the CBDP Enterprise has a research and development project-selection process in place, managed by the Joint Science and Technology Office, to help reduce the potential for fragmentation and overlap of CBDP Enterprise infrastructure and duplication of efforts within the research and development component. The Joint Science and Technology Office reviews and selects the projects that support the CBDP Enterprise mission at the CBDP Enterprise's primary research and development facilities. By having one entity (the Joint Science and Technology Office) make decisions regarding the selection of research and development projects to meet its mission, the CBDP Enterprise is able to help reduce the potential for fragmentation and overlap of its infrastructure and duplication of efforts within the research and development component of the CBDP Enterprise.

In addition, the U.S. Army Medical Research and Materiel Command is piloting a Competency Management Initiative, among other things, to identify any potential duplication and gaps across the knowledge and skills of command personnel. The initiative, which includes the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), examines intellectual capabilities and competencies needed to meet the mission based on chemical and biological threats. U.S. Army Medical Research and Materiel Command officials expect results from this initiative in 2015.

Furthermore, the potential for duplication is reduced because the missions of the CBDP Enterprise's four primary research and development and test and evaluation facilities are different. For example, USAMRICD focuses on medical chemical defense, USAMRIID focuses on medical biological defense, Edgewood focuses on nonmedical materiel solutions to chemical and biological threats, and West Desert conducts developmental and operational testing and evaluation. The difference in missions reduces the potential for fragmentation, overlap, and duplication within the CBDP Enterprise. In addition, in responding to our questionnaire, officials at CBDP's four primary facilities told us they consider potential infrastructure fragmentation, overlap, and duplication when determining whether additional infrastructure capabilities are needed to support their work. For example, officials found the potential for

duplication during the planning phase for a new facility, which would house animals for future research for USAMRIID on the National Interagency Biodefense Campus at Fort Detrick, Maryland. A set of studies on medical countermeasure test and evaluation facility requirements, conducted for the U.S. Army Assistant Chief of Staff for Facilities, Planning and Programming Division, determined, among other things, that there was sufficient capacity for holding animals in existing facilities that conduct research with animals. The study resulted in the cancellation of USAMRIID's plans to construct a new medical countermeasure test and evaluation facility, including a holding facility for animals (vivarium), with an overall estimated cost savings of about $600 million, according to USAMRIID officials.

PAIO Began a Study of CBDP Enterprise Infrastructure to Identify Potential Duplication and Unnecessary Redundancy

During the course of our review, PAIO began a study in January 2015 of the CBDP Enterprise's infrastructure, among other things, to inventory CBDP Enterprise infrastructure to support identification of (1) required infrastructure capabilities and (2) any potential duplication and unnecessary redundancy across the CBDP Enterprise's primary research and development and test and evaluation facilities' physical infrastructure. This study by PAIO will be the first CBDP Enterprise-wide review of infrastructure since its 2008 review of nonmedical physical infrastructure investments.

PAIO developed an infrastructure implementation plan in July 2014 to guide its study, among other things, to determine whether there are any potentially duplicative or unnecessary redundant infrastructure capabilities. PAIO plans to inventory CBDP Enterprise infrastructure from July 2015 to October 2015. In addition, PAIO plans to analyze the infrastructure information for potential duplication from October 2015 to February 2016. Its infrastructure implementation plan states that there can be value in some redundancy of infrastructure across the facilities and that the definition of duplication and unnecessary redundancy, which will be established during the study, will take this into account. For example, West Desert at Dugway Proving Ground and Aberdeen Test Center each has aircraft decontamination pads to support their testing and evaluation mission. However, if an aircraft became contaminated with a chemical or biological agent, the facilities have the infrastructure capability to decontaminate a civilian or military aircraft during a contingency or national emergency. According to West Desert officials, having the infrastructure at both facilities allows aircraft coming from the Pacific or Europe to be handled and decontaminated without the additional risk of continental travel and refueling.

However, during the course of our review, we found potential duplication or redundant swatch testing infrastructure capabilities that may not add value to CBDP's test and evaluation infrastructure capabilities. Specifically, West Desert and Edgewood both have the infrastructure to conduct testing of swatch material for chemical agents. In addition, the Quality Evaluation Facility at Pine Bluff Arsenal, Arkansas, a non-CBDP Enterprise DOD facility, also has swatch testing infrastructure capabilities. For example, officials from the Joint Program Executive Office for Chemical and Biological Defense, one of the swatch testing customers for all three facilities, told us that its current workload would not completely fill the capacity of either of the CBDP facilities, which could indicate potential duplication if other DOD or private sector customers did not require services to ensure each facility is at full capacity. According to Edgewood and West Desert officials, having swatch testing infrastructure capabilities in both locations enables efficient transition of technology and continuity of data from early research and development at Edgewood to advanced development and operational testing by West Desert. Officials from PAIO stated that their study will review similar infrastructure examples, but within the CBDP Enterprise only, to determine what infrastructure, if any, is duplicative or redundant and what infrastructure, if any, is necessary redundancy.

As part of the study methodology, PAIO plans to obtain input from the Joint Science and Technology Office, the Joint Program Executive Office for Chemical and Biological Defense, and the Deputy Under Secretary of the Army for Test and Evaluation and provide the results of its infrastructure inventory and any potential duplication found to the primary research and development and test and evaluation facilities. Once the results are known later in 2015, facility leadership is then expected to provide a rationale for sustaining any potentially duplicative or redundant infrastructure capabilities. Finally, in October 2015, the study's methodology provides that PAIO will analyze any additional information from facility leadership to determine which infrastructure capabilities are potentially duplicative or redundant. According to PAIO and ODASD (CBD) officials, the study will provide information to CBDP Enterprise leadership—the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs and the

Executive Agent—to support their decisions on any potential infrastructure efficiencies and to support oversight of investment.[30]

PAIO Does Not Plan to Identify, Request, or Consider Information from Existing Infrastructure Studies from Other Federal Agencies as Part of Its Duplication Study

PAIO plans to identify potential duplication within the CBDP Enterprise; however, PAIO does not plan to identify, request, or consider information from existing studies about infrastructure capabilities of other federal agencies with research and development or test and evaluation infrastructure to study chemical and biological threats. Additional information about other federal agencies' infrastructure capabilities may enhance PAIO's review of CBDP Enterprise infrastructure and potential duplication by providing more information on what infrastructure other federal agencies in this field have to support their work. For example, the Department of Health and Human Services' Centers for Disease Control and Prevention, the National Institutes of Health's National Institute of Allergy and Infectious Diseases, Integrated Research Facility; and the Department of Homeland Security's National Biodefense Analysis and Countermeasures Center have infrastructure and study chemical or biological threats. Information about existing infrastructure inventory, such as their capability to conduct specialized research of biological agents with a known potential for aerosol transmission or that may cause serious and potentially lethal infections, and whether that infrastructure is available for use to help avoid duplication within the CBDP Enterprise, would help bolster PAIO's study.

In addition, examples of our prior work on fragmentation, overlap, and duplication found that multiple agencies were involved in federal efforts to combat chemical or biological threats. We also found that it may be appropriate for multiple agencies or programs to be involved in the same area of work due to the nature or magnitude of the federal effort; however, multiple programs and capabilities may also create inefficiencies, such as the examples found in our prior reports.[31] For example, in 1999, prior to the anthrax attacks in the United States, we found ineffective coordination among DOD and other federal agencies

[30]Section 1522(c) (1) of Title 50 of the United States Code designates the Army as the Executive Agent for DOD to coordinate and integrate research, development, test and evaluation, and acquisition requirements of the military departments for DOD's chemical and biological warfare defense programs.

[31]See Section I: Areas in Which GAO Has Identified Fragmentation, Overlap, or Duplication in GAO-14-343SP.

with chemical and biological programs that could result in potential gaps or overlap in research and development programs.[32] Further, we found in September 2009 that there was no federal entity responsible for oversight of the expansion of high-containment laboratories—those designed for handling dangerous pathogens and emerging infectious diseases—across the federal government.[33] We also found in June 2010 that the mission responsibilities and resources needed to develop a biosurveillance capability—the ability to provide early detection and situational awareness of potentially catastrophic biological events—were dispersed across a number of federal agencies, creating potential inefficiencies and overlap and duplication of effort.[34] Finally, in May 2014, we found that the Department of Health and Human Services coordinates and leads federal efforts to determine CBRN medical countermeasure priorities and the development and acquisition of CBRN medical countermeasures for the civilian sector, primarily through the Public Health Emergency Medical Countermeasures Enterprise—an interagency body that includes other federal agencies with related responsibilities.[35] We made a number of recommendations to address these issues and, as of January 2015, about one-third have been partially or fully implemented. (See app. V for additional information about the findings, recommendations, and agency actions taken and see the Related GAO Products section at the end of this report for other reports on high-containment laboratories and biodefense.)

PAIO officials told us that they identified and requested some information from other federal agencies to support the development of PAIO's infrastructure implementation plan. However, according to PAIO and ODASD (CBD) officials, PAIO does not have the authority and resources to require other federal agencies to provide information about their

[32]See GAO, *Coordination of Non-medical Chemical and Biological R&D Programs*, GAO/NSIAD-99-160 (Washington, D.C.: Aug. 16, 1999).

[33]See GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574 (Washington, D.C.: Sept. 21, 2009).

[34]See GAO, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and Designated Leader*, GAO-10-645 (Washington, D.C.: June 30, 2010).

[35]See GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization*, GAO-14-442 (Washington, D.C.: May 15, 2014).

infrastructure capabilities. DOD Directives 5134.08 and 3200.11 outline policy goals, among other things, for avoiding duplication, such as using existing DOD and other federal agency facilities and conducting certain oversight activities aimed at avoiding unnecessary duplication within the CBDP Enterprise.[36] According to CBDP Enterprise officials, these types of deliberate data sharing arrangements can be enhanced by interagency agreements that are directed and supported at more senior levels within each department. Identifying, requesting, and considering information from existing infrastructure studies from other federal agencies about their chemical and biological infrastructure capabilities would not necessarily require new authority. PAIO would be better positioned to support the CBDP Enterprise's effort to meet DOD's goal to avoid duplication by determining what infrastructure is used by other federal agencies and whether that infrastructure could be available for use by the CBDP Enterprise to support its work in this area. Until PAIO determines what infrastructure capabilities exist outside of the CBDP Enterprise, there is potential for unnecessary duplication and inefficient and ineffective use of its government resources.

The CBDP Enterprise Used Threat Data and Plans to Use Data on Threats and Results of Risk Assessments to Support Future Research and Development Planning but Has Not Updated Its Guidance and Planning Process

The CBDP Enterprise used data on chemical and biological threats from the intelligence community and plans to use threat data and the results from risk assessments first conducted in 2014 by the Joint Requirements Office and ODASD (CBD) to support planning for its future portfolio planning process for research and development. However, the CBDP Enterprise has not updated its guidance and planning process to include specific responsibilities and timeframes for risk assessments.

[36]DODD 5134.08 (Feb. 14, 2013) and DODD 3200.11 (Dec. 27, 2007).

The Joint Requirements Office and ODASD (CBD) Piloted Risk Assessments in 2014 to Support the CBDP Enterprise's Future Portfolio Planning Process

ODASD (CBD) tasked the Joint Requirements Office to conduct an operational risk assessment of warfighter chemical and biological defense requirements to support the CBDP Enterprise's future years' portfolio planning process, according to ODASD (CBD) officials.[37] The assessment was based on threat information from the Defense Intelligence Agency's *Chemical, Biological, Radiological, and Nuclear Warfare Capstone Threat Assessment*,[38] a survey, and DOD guidance to determine the level of risk DOD is willing to accept in protecting its forces against chemical and biological threats under various operational conditions. CBDP Enterprise officials stated that they plan to use results from the piloted risk assessment during Phase I of their annual portfolio planning cycle, as stated in the 2012 *CBDP Business Plan*. Phase I includes a review of threats[39] and risk analyses to support the development of strategic investment guidance and focus areas by the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs. For example, the guidance may include specific chemical or biological threats or defense capabilities that the program leadership wants the CBDP Enterprise to address, which then guides the types of scientific and technology proposals the research and development facilities will submit to support CBDP Enterprise goals. This investment program guidance is then to be used by the CBDP Enterprise organizations to focus the development of capabilities to counter threats.[40]

When they conducted the pilot risk assessments, the Joint Requirements Office and ODASD (CBD) used a modified version of DOD's 2001 *Quadrennial Defense Review Report* risk framework—force management, future challenges, operational risk, and institutional risks—and guidance

[37]We did not assess the methodology of risk assessments conducted by the Joint Requirements Office or ODASD (CBD).

[38]The Defense Intelligence Agency's *Chemical, Biological, Radiological, and Nuclear Warfare Capstone Threat Assessment* is a report on chemical and biological programs of countries and technology that could be used by adversaries in a threat environment.

[39]In May 2014, we found that DOD had not updated its list of biological threat priorities annually. Therefore, we recommended that DOD develop and implement a process to update and validate its list of biological threats to ensure investments are made to address the most serious and likely biological threats. See GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization*, GAO-14-442 (Washington, D.C.: May 15, 2014).

[40]The Program Objective Memorandum displays the resource allocation decisions of the military departments in accordance with strategic guidance.

from the 2012 *CBDP Strategic Plan*.[41] For its assessment of current and future operational risk, the Joint Requirements Office defined operational risk as the ability of the current force to execute strategy successfully within acceptable human, materiel, financial, and strategic costs. To conduct the operational risk assessment, the Joint Requirements Office developed an operationally driven methodology that consisted of six interrelated elements.

The Joint Requirements Office used information from five of the elements—a joint assessment, survey, analysis, intelligence, and subject-matter expertise—to identify the topics of the tabletop exercise. Information from the sixth element—other exercises and operational evaluations, specific threats, potential gaps, potential risks, or the construct of potential threats on the battlefield—was used to develop scenarios for the tabletop exercise. According to Joint Requirements Office officials, the purpose of the tabletop exercise was to gain an understanding of the chemical and biological operational defense capabilities against the most demanding and dangerous threats.

The tabletop exercise was conducted through a series of action-reaction-counteraction sequences for each scenario. Officials facilitated discussions on military defense and key observations on defensive capabilities among CBDP Enterprise members, operational planners, and other subject-matter experts during the tabletop exercise using the framework of the CBDP Enterprise's 18 warfighter core capabilities categorized into four areas—Sense, Shape, Shield, and Sustain. (See app. IV for additional information about the core capabilities.) The Joint Requirements Office provided ODASD (CBD) with information about lessons learned from the tabletop exercise and other analyses, and identified other operational scenarios to support future operational risk assessments. According to ODASD (CBD) officials, the operational risk assessment provided recommendations and new information on the use of defense capabilities in an operational setting to CBDP Enterprise leadership to support future planning about the strategic direction of the CBDP Enterprise in addressing chemical and biological threats.

[41]See Department of Defense, *Quadrennial Defense Review Report*, for a discussion of DOD's risk assessment model.

Also, in 2014, ODASD (CBD) conducted its own assessment of force management and institutional risk to the CBDP Enterprise. A separate risk assessment of future challenges—the fourth risk area in the 2001*Quadrennial Defense Review Report*'s framework—was not conducted. According to ODASD (CBD) officials, future challenges were incorporated into the operational and institutional risk assessments by including planned future capabilities against future threats as well as the development of those future capabilities, respectively. To assess force management risk, the office assessed "equipping the force." Specifically, officials assessed 23 systems used by the military forces that were employed in the Joint Requirements Office's operational risk assessment. The focus of the force management risk assessment was to identify current or planned capabilities that did not meet the force planning construct levels.[42] According to the results of the assessment, there were no unacceptably high risks identified in equipping the force that needed to be address in fiscal year 2016–2020 program guidance. The assessment indicated the programs associated with the 23 systems appear to not pose an unacceptable risk. To assess the second area of risk—institutional risk—officials collected data on the CBDP Enterprise's infrastructure and processes.

The intent of the pilot infrastructure risk assessment was to identify unacceptably high-risk areas or concerns that would need additional guidance and be addressed during the fiscal year 2016–2020 planning cycle. ODASD (CBD) officials did not find any critical shortfalls in research and development or test and evaluation infrastructure or identify unacceptable risk. However, the assessment found some challenges in the process of moving capabilities from development to production. In addition, the results confirmed the difficulty of identifying shortfall risks in the CBDP Enterprise infrastructure because the primary research and development facilities are funded by proposal rather than by facility, thus requiring future risk assessments to look beyond the infrastructure that exists to determine whether unacceptable risk exists.[43] ODASD (CBD)

[42]The force planning construct, as described in the *Quadrennial Defense Review 2014*, is the ability to be capable of simultaneously defending the homeland; conducting sustained distributed counterterrorist operations; and, in multiple regions, deter aggression and assure allies through forward presence and engagement.

[43]According to officials from the primary research and development facilities, they generally do not submit proposals for research and development activities without already having the infrastructure in place to support the proposal.

officials stated that they expect the results of the risk assessments to support the CBDP Enterprise's future investment for research and development of chemical and biological defense capabilities.

The CBDP Enterprise Has Not Updated Its Guidance and Planning Process to Include Specific Responsiblities and Timeframes for Risk Assessments

The CBDP Enterprise's guidance and planning process does not include who will conduct and participate in risk assessments and when those assessments will be conducted. Federal standards for internal control state that, over time, management should continually assess and evaluate its internal control to assure activities being used are effective and updated when necessary. In addition, decision makers should identify risks associated with achieving program objectives, analyze them to determine their potential effect, and decide how to manage the risk and identify what actions should be taken.[44] The standards also call for written procedures, to better ensure leadership directives are implemented. However, which organizations within the CBDP Enterprise are responsible for conducting and participating in risk assessments and when the assessments will be conducted to support the portfolio planning process for research and development investment is not outlined in the CBDP Enterprise's guidance on roles and responsibilities or included in its planning process. Specifically, according to DOD Directive 5160.05E, the Joint Requirements Office is "responsible for collaborating with appropriate Joint Staff elements" on, among other things, chemical and biological risk assessment.[45] However, the guidance does not explicitly identify which organizations within the CBDP Enterprise are responsible for conducting and participating in risk assessments. The 2012 *CBDP Business Plan* identifies the Joint Requirements Office as the primary organization responsible for planning chemical and biological risk assessments for the CBDP Enterprise. Further, the plan includes steps in its planning process to review threats and risk analyses, but does not specify when risk assessments will be conducted. Without written procedures on who will conduct or participate in risk assessments and the use of DOD's risk framework, there is no guarantee that risk assessments will be conducted or when they will be conducted.

ODASD (CBD) and Joint Requirements Office officials stated that they plan to conduct additional risk assessments in the future, as reported to Congress, because of the increasing chemical and biological threats and

[44]GAO/AIMD-00-21.3.1.

[45]DODD 5160.05E (Oct. 9, 2008).

the challenges of the austere fiscal environment.[46] However, the use of risk assessments by the CBDP Enterprise has not been fully institutionalized because the CBDP Enterprise has not updated its guidance on roles and responsibilities and its planning process because this is the first year that risk assessments were conducted. According to ODASD (CBD) officials, updating the roles and responsibilities guidance and related planning process would be beneficial, but they have not done so because the CBDP Enterprise is evaluating the results and lessons learned from the pilot. As of March 2015, ODASD (CBD) and Joint Requirements Office officials had not formally committed to updating such guidance or established a time frame for doing so to fully institutionalize the use of risk assessments. Without updated guidance, the CBDP Enterprise will continue to rely on the Deputy Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs to request risk assessments, rather than having the assessments occur at established times during the investment planning process. Written guidance, as called for by federal standards for internal control, would better ensure that leadership directives are implemented as intended.[47] Written guidance that identifies which CBDP Enterprise entities are responsible for conducting and participating in risk assessments and when such assessments are to be conducted would help ensure that risk assessments are conducted as intended. In this way, new information from the results of the tabletop exercise from the risk assessment about how defense capabilities, such as 1 of the 18 warfighter core capabilities, are used in an operational setting would better position the CBDP Enterprise to prioritize future research and development investments. Going forward, addressing internal control standards by updating its guidance and the planning process to fully institutionalize the use of risk assessments would support planning, help ensure that the CBDP Enterprise leadership directives are implemented, and end dependence upon any particular agency official to request risk assessments to support future investment planning.

Conclusions

The CBDP Enterprise has taken a number of actions in recent years to address chemical and biological defense research and development and test and evaluation infrastructure, but initially did not develop a plan to

[46]Department of Defense, Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, *2014 DOD Chemical and Biological Defense Annual Report to Congress* (March 2014).

[47]GAO/AIMD-00-21.3.1.

address the 2008 PAIO recommendation or make infrastructure a priority. While the CBDP Enterprise should continue to address its priorities, it remains important that it also ensures that its infrastructure is aligned to meet its mission given ever-changing threats. Additional actions would help the CBDP Enterprise to more effectively and efficiently identify, align, and manage DOD's chemical and biological defense infrastructure. By identifying and designating an entity with the responsibility and authority to lead the effort for ensuring the timely achievement of the CBDP Enterprise's infrastructure goals to identify required infrastructure capabilities and by establishing timelines and milestones to implement the 2008 PAIO recommendations and the goal established in the 2012 *CBDP Business Plan*, the CBDP Enterprise would be better positioned to align its infrastructure to meet its mission to address threats. Thus, the CBDP Enterprise would be able to determine whether its infrastructure is properly aligned to meet its mission to address current and emerging chemical and biological threats. Implementing the 2008 PAIO recommendation that the CBDP Enterprise identify its required infrastructure capabilities is an important first step in identifying potential infrastructure duplication that may exist across the CBDP Enterprise. By identifying, requesting, and considering information from existing infrastructure studies of other federal agencies about their chemical and biological infrastructure capabilities, PAIO may be better positioned to enhance its study by providing additional information, for example, about infrastructure capability and the availability of facilities, to help the CBDP Enterprise avoid potential infrastructure duplication and gain potential efficiencies by using those agencies' existing infrastructure. Finally, the CBDP Enterprise can capitalize on its progress made in 2014, when the Joint Requirements Office and ODASD (CBD) conducted risk assessments, by updating the roles and responsibilities guidance in DOD Directive 5160.05E and the CBDP Enterprise's planning process to identify which organizations are responsible for conducting and participating in risk assessments and when they would occur. By updating guidance and the planning process, the CBDP Enterprise can fully institutionalize the use of risk assessments and not depend on an individual official to request risk assessments. Fully institutionalizing the use of risk assessments would support CBDP Enterprise planning and may provide new information about chemical and biological defense capabilities to further prioritize the CBDP Enterprise's future research and development investments.

Recommendations for Executive Action

We are making five recommendations to improve the identification, alignment, and management of DOD's chemical and biological defense infrastructure.

To help ensure that the CBDP Enterprise's infrastructure is properly aligned to address current and emerging chemical and biological threats, we recommend that the Secretary of Defense direct the appropriate DOD officials to take the following two actions:

- identify and designate an entity within the CBDP Enterprise with the responsibility and authority to lead the effort to ensure achievement of the infrastructure goals (e.g., the four 2008 PAIO recommendations, including the recommendation that the CBDP Enterprise identify its required infrastructure capabilities, and the goal established in the 2012 *CBDP Business Plan*), and

- establish timelines and milestones for achieving identified chemical and biological infrastructure goals, including implementation of the 2008 PAIO recommendation that the CBDP Enterprise identify its required infrastructure capabilities.

To enhance PAIO's ongoing analysis of potential infrastructure duplication in the CBDP Enterprise and gain potential efficiencies, we recommend that the Secretary of Defense direct the Under Secretary of Defense for Acquisition, Technology and Logistics to identify, request, and consider any information from existing infrastructure studies from other federal agencies with chemical and biological research and development and test and evaluation infrastructure.

To fully institutionalize the use of risk assessments to support future investment decisions, we recommend that the Secretary of Defense direct the Under Secretary of Defense for Acquisition, Technology and Logistics to take the following two actions:

- update the roles and responsibilities guidance in DOD Directive 5160.05E to identify which organizations are responsible for conducting and participating in CBDP Enterprise risk assessments, and

- update the CBDP Enterprise's portfolio planning process, to include when risk assessments will be conducted.

Agency Comments and Our Evaluation

In commenting on a draft of this report, DOD concurred with all five of our recommendations and discussed actions it is taking and plans to take to implement them. DOD concurred with our first recommendation to identify and designate an entity within the CBDP Enterprise with the responsibility and authority to lead the effort to ensure achievement of the infrastructure goals (e.g., the four 2008 PAIO recommendations, including the recommendation that the CBDP Enterprise identify its required infrastructure capabilities, and the goal established in the 2012 *CBDP Business Plan*). The department concurs that an entity needs to lead the effort to ensure achievement of the infrastructure goals. Further, OASD (NCB) officials believe that these responsibilities and authorities are currently in place under existing laws and regulations. The 2012 *Chemical and Biological Defense Program (CBDP) Strategic Plan* identified one of the four strategic goals of CBDP as "to maintain infrastructure to meet and adapt current and future needs for personnel, equipment, and facilities within funding constraints." To achieve this goal, OASD (NCB) and the U.S. Army, as the Executive Agent for Chemical and Biological Defense, share responsibility to ensure achievement of CBDP's strategic infrastructure goals in close collaboration and coordination with the infrastructure managers (i.e., the individual installation commanders and directors of the facilities). According to OASD (NCB) officials, the department is in the process of revising DOD Directive 5160.05E and will ensure that the directive appropriately captures the roles and responsibilities related to CBDP infrastructure capabilities. We believe these actions, if fully implemented, would address our recommendation.

DOD also concurred with our second recommendation to establish timelines and milestones for achieving identified chemical and biological infrastructure goals, including implementation of the 2008 PAIO recommendation that the CBDP Enterprise identify its required infrastructure capabilities. DOD officials agree that the most effective means of ensuring CBDP infrastructure goals are achieved is to set realistic timelines and milestones. According to OASD (NCB) officials, the CBDP Enterprise is undertaking a thoughtful effort to identify the infrastructure capabilities necessary to successfully complete its mission. The CBDP Enterprise solicited support from the National Research Council of the National Academies of Science to identify what science and technology core capabilities need to be in place within DOD laboratories to support CBRN research, development, test, and evaluation. The CBDP Enterprise also is in the midst of internal reviews of both current infrastructure capabilities and those that are needed to fulfill mission requirements. The combined results of these studies will enable

the CBDP Enterprise to align its core capabilities with the necessary supporting infrastructure, and to develop implementation and sustainment plans with timelines and milestones for required CBDP infrastructure capabilities and the studies will consider GAO's recommendation on this issue. We believe that if these studies are completed and implementation and sustainment plans are developed with established timelines and milestones, then these actions would address our recommendation.

DOD concurred with our third recommendation to identify, request, and consider any information from existing infrastructure studies from other federal agencies with chemical and biological research and development and test and evaluation infrastructure. OASD (NCB) officials said the department agrees that information from existing federal chemical and biological infrastructure studies should be considered as inputs to the CBDP Enterprise infrastructure analysis efforts. They added that DOD maintains strong partnerships with the Departments of Homeland Security and Health and Human Services, which will facilitate DOD's accomplishment of this recommendation. We agree.

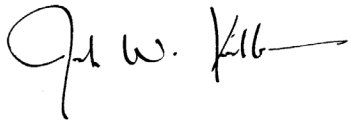
DOD concurred with our fourth recommendation to update the roles and responsibilities guidance in DOD Directive 5160.05E to identify which organizations are responsible for conducting and participating in CBDP Enterprise risk assessments. According to the OASD (NCB) officials, the department is in the process of revising DOD Directive 5160.05E, and will include the risk assessment process in the roles and responsibilities section. If fully implemented, this action would address our recommendation.

Finally, DOD concurred with our fifth recommendation to update the CBDP Enterprise's portfolio planning process, to include when risk assessments will be conducted. OASD (NCB) officials noted that the risk assessment process was initially piloted in 2014 to determine its utility for informing CBDP Enterprise portfolio planning and guidance. They said that, moving forward, the CBDP Enterprise plans to conduct risk assessments annually to support portfolio planning and guidance. We believe this action, if fully implemented, would address our recommendation.

The full text of DOD's comments is reprinted in appendix VI. DOD also provided us with technical comments, which we incorporated, as appropriate.

We are sending copies of this report to appropriate congressional committees; the Secretary of Defense; the Under Secretary of Defense for Acquisition, Technology and Logistics; the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs; the Deputy Assistant Secretary of Defense for Chemical and Biological Defense; the Chairman of the Joint Chiefs of Staff; the Secretary of the Army; and the Director, Office of Management and Budget. In addition, the report is available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions concerning this report, please contact me at (202) 512-9971 or KirschbaumJ@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VII.



Joseph W. Kirschbaum
Director
Defense Capabilities and Management

Appendix I: Chemical and Biological Defense Program Enterprise Organizations

The Chemical and Biological Defense Program (CBDP) Enterprise comprises 26 organizations from across the Department of Defense (DOD) that determine warfighter requirements, provide science and technology expertise, conduct research and development and test and evaluation on capabilities needed to protect the warfighter, conduct program integration, and provide oversight. These key organizations include the following:

- Secretary of the Army
  - Deputy Under Secretary of the Army
    - Assistant Secretary of the Army for Acquisition, Logistics and Technology
      - Joint Program Executive Office for Chemical and Biological Defense
  - Deputy Under Secretary of the Army for Test and Evaluation
  - U.S. Army Chief of Staff
    - Vice Chief of Staff of the Army
      - U.S. Army Test and Evaluation Command
        - West Desert Test Center
    - Office of the U.S. Army Deputy Chief of Staff, G-8
  - Program Analysis and Integration Office
  - U.S. Army Materiel Command
    - U.S. Army Research, Development, and Engineering Command
      - Edgewood Chemical Biological Center
  - U.S. Army Medical Command
    - U.S. Army Medical Research and Materiel Command
      - U.S. Army Medical Research Institute of Chemical Defense
      - U.S. Army Medical Research Institute of Infectious Diseases
- Chairman, Joint Chiefs of Staff
  - Director, Force Structure, Resources, and Assessment Directorate (J-8)
    - Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense
- Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
  - Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
    - Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense
    - Defense Threat and Reduction Agency
      - Joint Science and Technology Office for Chemical and Biological Defense

In addition, according to officials from the Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense, the Department of the Navy, the Department of the Air Force, the National Guard Bureau, and combatant commands also have key roles in the Chemical and Biological Defense Program.

Appendix II: Scope and Methodology

To determine the extent to which the Chemical and Biological Defense Program (CBDP) Enterprise has achieved its goal to identify required infrastructure capabilities to address current and emerging chemical and biological threats, we reviewed the Program Analysis and Integration Office's (PAIO) 2008 study, *Chemical and Biological Defense Program's Non-Medical Physical Infrastructure Capabilities Assessment*, which assessed the physical infrastructure capabilities of the CBDP Enterprise to support the CBDP mission. The study was requested by the Special Assistant, Chemical and Biological Defense and Chemical Demilitarization Programs, and it resulted in four recommendations that the CBDP Enterprise take to address its infrastructure. Specifically, we analyzed PAIO's 2008 recommendation that the CBDP Enterprise identify its required infrastructure capabilities, part of its core capabilities, and compared them to the actions taken by the CBDP Enterprise since then through January 2015.[1] We reviewed the recommendations with officials from the Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (ODASD [CBD]) and determined that the office recognized the 2008 recommendations to be valid and confirmed that the CBDP Enterprise recognizes the importance and necessity of addressing them. The CBDP Enterprise is using the recommendations as criteria in its efforts to address its research and development and test and evaluation intellectual and physical infrastructure.

We conducted site visits to the CBDP Enterprise's four primary research and development and test and evaluation facilities: Edgewood Chemical Biological Center (Edgewood) at Aberdeen Proving Ground, Maryland; U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) at Aberdeen Proving Ground; U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) on the National Interagency Biodefense Campus at Fort Detrick, Maryland; and West Desert Test Center (West Desert) at Dugway Proving Ground, Utah. We included the four primary facilities in our review because they conduct the majority of the research

[1]The Program Analysis and Integration Office (PAIO) recommendation states that the Chemical and Biological Defense Program (CBDP) Enterprise should define its "core physical infrastructure capabilities." According to the Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (ODASD [CBD]) officials, core infrastructure capabilities refer to the "required infrastructure capabilities" needed by the CBDP Enterprise to address its mission. Also, while the PAIO study makes recommendations about the physical aspect of infrastructure capabilities, the 2008 and 2012 *CBDP Strategic Plans* consider infrastructure to be defined by both the physical and intellectual capabilities required to meet its mission.

and development and test and evaluation activities for the program. By including all of the primary facilities, we are gaining information across the CBDP Enterprise. However, this information is not generalizable to all facilities that may be used by the program to implement its mission. We developed and administered a questionnaire to these facilities, based on the 2012 *Chemical and Biological Defense Program* (*CBDP*) *Strategic Plan* and our objectives, to collect information about the knowledge and skill capabilities of its personnel and physical infrastructure capabilities of each of the facilities, including any changes and challenges to the CBDP Enterprise's infrastructure, and any actions they have taken to identify required infrastructure capabilities (See app. III for additional information on these facilities.)

We pretested our questionnaire with officials from ODASD (CBD) and the following CBDP Enterprise organizations: Edgewood, PAIO, Joint Science and Technology Office, and the Office of the Deputy Under Secretary of the Army for Test and Evaluation. The pretest was intended to solicit feedback on whether our questionnaire (1) would provide answers to the engagement's objectives, (2) was written in a way that would be familiar to leadership officials of the primary research and development and test and evaluation facilities receiving them, and (3) should include additional questions to gain information about the CBDP Enterprise's infrastructure. We incorporated the feedback, as appropriate, into our final questionnaire sent to the primary research and development and test and evaluation facilities. We interviewed leadership officials of these facilities about their written responses to our questionnaire. During our site visits to the four primary research and development and test and evaluation facilities, we toured the facilities and new buildings under construction to gain an understanding of how the infrastructure supports their missions.

We also obtained information from officials from other CBDP Enterprise organizations that have responsibilities to the program, such as ODASD (CBD), the Joint Science and Technology Office, and PAIO, on their actions to identify required infrastructure capabilities and the CBDP Enterprise's progress. We reviewed their plans and presentation to identify required infrastructure capabilities and interviewed them to discuss the plans. Finally, we compared key practices on the implementation of organizational transformation, such as the importance of establishing a dedicated authority responsible for day-to-day management for an organization's change initiatives with the necessary authority and resources to set priorities, make timely decisions, and move quickly to implement top leadership's decisions regarding organizational

transformation, and a timeline and milestones to successfully implement organizational change,[2] with actions the CBDP Enterprise has taken to implement its goal to identify required infrastructure capabilities needed to address current and emerging chemical and biological threats.[3] We used these criteria from our work to analyze whether the CBDP Enterprise followed key implementation steps to successfully transform the way the CBDP Enterprise addresses its infrastructure goals.[4]

To determine the extent to which the Department of Defense's (DOD) CBDP Enterprise has identified, addressed, and managed potential fragmentation, overlap, and duplication in its chemical and biological defense infrastructure, we reviewed CBDP guidance and policies on the program and related testing facility guidance; a study in 2011 on infrastructure needs to support medical countermeasures; and a 2014 PAIO infrastructure implementation plan to support the CBDP Enterprise's efforts to avoid duplication. We reviewed the information to determine how the CBDP Enterprise identifies, addresses, and manages potential fragmentation, overlap, and duplication. We reviewed DOD Directive 5134.08 on the responsibilities of the Assistant Secretary of

[2]See GAO, *Results-Oriented Cultures: Implementation Steps to Assist Mergers and Organizational Transformations*, GAO-03-669 (Washington, D.C.: July 2, 2003). To identify the key practices and implementation steps for mergers and organizational transformation, the Comptroller General convened a forum in September 2002 of leaders who have had experience managing large-scale organizational mergers, acquisitions, and transformations, as well as academics and others who have studied these efforts to discuss and identify key practices and implementation steps for mergers and organizational transformation. We also interviewed selected forum participants and other experts about their experiences implementing mergers, acquisitions, and transformations.

[3]We have used these key practices on organizational transformation to examine federal agency management efficiencies. See GAO, *Streamlining Government: Key Practices from Select Efficiency Initiatives Should Be Shared Governmentwide*, GAO-11-908 (Washington, D.C.: Sept. 30, 2011) and *Streamlining Government: Questions to Consider When Evaluating Proposals to Consolidate Physical Infrastructure and Management Functions*, GAO-12-542 (Washington, D.C.: May 23, 2012).

[4]We used these criteria because a new focus on infrastructure by the CBDP Enterprise in recent years, such as developing a new goal to identify required infrastructure and identifying the need for an authority to oversee infrastructure changes, demonstrates a paradigm shift in the way the CBDP Enterprise is ensuring that its infrastructure is aligned with its mission. Therefore, we determined that implementation of organizational transformation criteria was relevant because the elements of the criteria are applicable to the CBDP Enterprise's focus on infrastructure management. ODASD (CBD) officials agreed that these criteria were appropriate to use for our review of the CBDP Enterprise's actions to address its infrastructure goals.

Defense for Nuclear, Chemical, and Biological Defense Programs and DOD Directive 3200.11 on the responsibilities of the Major Range and Test Facility Bases.[5] The directives outline policy goals, such as using existing DOD and other federal agencies' facilities and certain oversight activities aimed at avoiding unnecessary duplication. We did not conduct an independent assessment of potential fragmentation, overlap, and duplication within the CBDP Enterprise.

We developed and administered a questionnaire to CBDP's four primary research and development and test and evaluation facilities discussed above—Edgewood, USAMRICD, USAMRIID, and West Desert—based on our annual report to Congress on fragmentation, overlap, and duplication to identify any additional policies on duplication and understand their processes or actions to identify, address, and manage fragmentation, overlap, and duplication.[6] Using DOD's guidance[7] and responses to the questionnaire, we compared their processes and actions to DOD guidance to determine the extent to which the CBDP Enterprise reported that it avoided duplication and identified, addressed, and managed potential infrastructure duplication. In addition, we analyzed information about the facilities' missions and infrastructure. We interviewed research and development facility officials about their infrastructure studies and the steps that they had taken to identify, address, or manage fragmentation, overlap, and duplication. We analyzed the studies, conducted for the U.S. Army Assistant Chief of Staff for Facilities, Planning and Programming Division, that identified potential infrastructure duplication and that were used to make infrastructure decisions about USAMRIID's new facility. In addition, we reviewed the Competency Management Initiative program developed by the U.S. Army Medical Research and Materiel Command to identify knowledge and skill capabilities and potential duplication, among other factors, within the command, to include USAMRIID and USAMRICD.

[5]Department of Defense Directive 5134.08, *Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD (NCB))* (Feb. 14, 2013) (Hereinafter cited as DODD 5134.08 (Feb. 14, 2013)) and Department of Defense Directive 3200.11, *Major Range and Test Facility Base* (*MRTFB*) (Dec. 27, 2007) (Hereinafter cited as DODD 3200.11 (Dec. 27, 2007)).

[6]See GAO, *2014 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-14-343SP (Washington, D.C.: Apr. 8, 2014).

[7]DODD 5134.08 (Feb. 14, 2013) and DODD 3200.11 (Dec. 27, 2007).

We reviewed the plan and studies of the Joint Science and Technology Office and the Army's PAIO to identify required knowledge and skill capabilities and physical infrastructure capabilities, to include identifying potential duplication. We analyzed information about the missions and infrastructure of each CBDP primary research and development and test and evaluation facility to understand their role within the CBDP Enterprise. Based on the information from our questionnaire, we collected information from West Desert and Edgewood on their swatch testing infrastructure capabilities, infrastructure utilization, competitors, and customers. In addition, we interviewed research and development facility officials about the steps they have taken to identify, address, or manage fragmentation, overlap, and duplication. We did not collect information about the research and development and test and evaluation projects conducted at the facilities; therefore, we were unable to determine whether similar infrastructure capabilities at the facilities were overlapping or duplicative or used for different purposes.

To determine the extent to which the CBDP Enterprise has used threat data and plans to use threat data and the results of risk assessments to support future investment planning in research and development for chemical and biological threats, we received a threat briefing from the Defense Intelligence Agency and the U.S. Army's National Ground Intelligence Center, similar to the annual threat data received by the CBDP Enterprise, to understand the type of threat data on chemical and biological threats. We analyzed DOD Directive 5160.5E8 to determine which offices are responsible for conducting and participating in the CBDP Enterprise's risk assessments.[8] We reviewed the standards for internal control in the federal government for use of risk assessment and written procedures and compared them to any actions taken by the Joint Requirements Office and ODASD (CBD) to ensure the guidance and process are being followed.[9] We interviewed officials from the Joint Requirements Office and ODASD (CBD) about who is responsible for conducting risk assessments and about how they used the risk assessment framework, which was introduced in the 2001 *Quadrennial*

[8]*See* Department of Defense Directive 5160.05E, *Roles and Responsibilities Associated with the Chemical and Biological Defense (CBD) Program (CBDP)* (Oct. 9, 2008).

[9]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

Defense Review Report, to conduct their risk assessment.[10] We analyzed the program's annual portfolio planning process described in its 2012 *CBDP Business Plan* to understand the role of risk assessment in the CBDP Enterprise's planning process. We compared internal control standards on written procedures to those used by the CBDP Enterprise to conduct its risk assessments. We obtained information on the operational, force management, and institutional risk assessments conducted by the Joint Requirements Office and ODASD (CBD) to understand the process used to conduct the CBDP Enterprise's risk assessments. We interviewed officials from ODASD (CBD), which develops CBDP Enterprise-wide guidance to ensure strategic goals are achieved, to determine how threat data and the results of risk assessments are used—or will be used in the future—to support investment planning in research and development.

We obtained relevant documentation and interviewed officials from the following organizations:

Department of Defense

- Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
  - Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (ODASD [CBD])
- Office of the Assistant Secretary of Defense for Health Affairs
- Joint Chiefs of Staff
  - Force Structure, Resources, and Assessment Directorate (J-8)
    - Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense
- Defense Threat Reduction Agency
  - Joint Science and Technology Office for Chemical and Biological Defense
- Defense Intelligence Agency
- U.S. Army
  - Office of the Assistant Secretary of the Army for Acquisition, Logistics, and Technology
    - Joint Program Executive Office for Chemical and Biological Defense
- Office of the U.S. Army Deputy Chief of Staff, G-8
- Program Analysis and Integration Office (PAIO)

[10]See Department of Defense, *Quadrennial Defense Review Report* (Sept. 30, 2001).

- Office of the Deputy Under Secretary of the Army for Test and Evaluation
- U.S. Army Medical Research and Materiel Command
  - U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), National Interagency Biodefense Campus, Fort Detrick, Maryland
  - U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, Maryland
- U.S. Army Materiel Command
  - U.S. Army Research, Development and Engineering Command
  - Edgewood Chemical Biological Center (Edgewood), Aberdeen Proving Ground, Maryland
- U.S. Army Test and Evaluation Command
  - West Desert Test Center (West Desert), Dugway Proving Ground, Utah
- U.S. Army Intelligence and Security Command
  - National Ground Intelligence Center

Other

- National Interagency Confederation for Biological Research, National Interagency Biodefense Campus, Fort Detrick, Maryland

We conducted this performance audit from January 2014 to June 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix III: DOD's Chemical and Biological Defense Primary Research and Development and Test and Evaluation Facilities

The Chemical and Biological Defense Program (CBDP) Enterprise's research and development and test and evaluation infrastructure is a key component in defending the nation against chemical and biological threats. For example, prior to deploying the MV *Cape Ray* to the Mediterranean Sea to demilitarize chemical weapons from Syria, the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD) provided training to its medical staff, inspected the ship, and evaluated the medical preparedness of the mission. In July 2014, the United States began using equipment and personnel expertise from the U.S. Army's Edgewood Chemical Biological Center (Edgewood), according to Edgewood officials, to neutralize chemical weapons materials from Syria as shown in this video. In another example, according to a U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) official, USAMRIID is supporting the development of multiple products against Ebola, including the experimental therapeutic drug ZMapp, which was provided to the American health care workers infected with the Ebola virus during the outbreak in West Africa in 2014.

The CBDP Enterprise's primary research and development and test and evaluation facilities have different missions, but serve the same military population and engage in similar activities to protect the warfighter from chemical and biological threats. While these facilities support the CBDP Enterprise in carrying out its mission, they are owned and operated by the U.S. Army.

Edgewood Chemical Biological Center

Edgewood's mission is to be the nation's provider of innovative solutions to countering weapons of mass destruction. Edgewood is located on Aberdeen Proving Ground, Maryland. Edgewood aligns with the CBDP Enterprise by "enabling the warfighter to deter, prevent, protect against, mitigate, respond to, and recover from chemical, biological, radiological, and nuclear threats and effects as part of a layered, integrated defense." To do this, Edgewood's core areas of work include chemistry and biological sciences; science and technology for emerging threats; chemical, biological, radiological, nuclear, and high-yield explosives analysis and testing; chemical and biological agent handling and surety; and chemical and biological munitions and field operations. Edgewood also conducts training of civilians and military personnel to respond to chemical and biological threats, cosponsoring some training with USAMRICD. In fiscal year 2013, 40.8 percent of Edgewood's funding came from the CBDP Enterprise, and the remainder came from the Army (15.5 percent), non-CBDP Department of Defense (DOD) organizations (35.7 percent), federal agencies (4.1 percent), and nonfederal agencies

(3.9 percent). As of October 2014, Edgewood had a staff of 1,421 whose work is focused on nonmedical materiel solutions to chemical and biological threats.

Since 2008, Edgewood has completed projects intended to more safely perform the research and development required to address current and emerging chemical and biological threats. Changes at the facility's Advanced Chemical Laboratory include the addition of 10,000 square feet of state-of-the-art laboratories for safely handing emerging agents, including materials with no known medical countermeasures. According to Edgewood officials, planned changes at its Advanced Threat Defense Facility are expected to facilitate expansion of emerging threat bench-scale experiments to large-scale evaluations to enable enhanced research capabilities and to include unique infrastructure capabilities to address the challenges of emerging chemical threats from vapors, solids, liquids, and aerosols.

According to Edgewood officials, the biggest challenge for the future is sustaining core intellectual and physical infrastructure in a time of budget austerity. Second, these officials stated that a lack of a funding mechanism for sustainment of the facility is a challenge. The Program Analysis and Integration Office (PAIO) determined that the cost of sustainment is about $26.4 million for fiscal year 2015. There is a plan to fund sustainment of the chemical and biological infrastructure to support the CBDP mission in the *Fiscal Year 2015–2019 Program Objective Memorandum*;[1] however, as of January 2015, there was no agreement within the CBDP Enterprise to support the primary research and development facilities in this way. Third, officials told us that Edgewood is maintaining 28 abandoned buildings on its campus. Figure 4 shows an example of an abandoned facility at Edgewood. Building 3222, now over 70 years old, was a medical research laboratory with about 33,000 square feet and was built in 1944.

[1]See Department of Defense, Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, *Chemical and Biological Defense Program Infrastructure Guidance* (Dec. 11, 2013).

Figure 4: Example of an Abandoned Edgewood Chemical Biological Center Facility (Building 3222 Medical Research Laboratory)

Source: U.S. Army Edgewood Chemical Biological Center. | GAO-15-257

Figure 5 shows another example of an abandoned facility at Edgewood. Building 3300 was a chemistry laboratory used to develop and evaluate decontamination technology to mitigate chemical and biological threats. This facility has about 44,350 square feet and was built in 1966.

Figure 5: Example of an Abandoned Edgewood Chemical Biological Center Facility (Building 3300 Chemistry Laboratory)

Source: U.S. Army Edgewood Chemical Biological Center. | GAO-15-257

According to Edgewood officials, it will cost over $74 million to demolish all 28 buildings, which is equivalent to about 1 year's facilities sustainment and support costs for the CBDP Enterprise's three primary research and development facilities put together. In addition, according to Edgewood officials, to maintain one of its most expensive buildings until it is demolished is estimated to cost about $600,000 a year. Officials said that the ability to maintain and expand their intellectual infrastructure also is strained in the current fiscal environment. Currently, Edgewood plans to maintain these facilities until funding becomes available to demolish the buildings.

United States Army Medical Research Institute of Chemical Defense

USAMRICD's mission is to discover and develop medical products and knowledge solutions against chemical and biochemical threats by means of research, education and training, and consultation. USAMRICD is located on Aberdeen Proving Ground, Maryland. Its core areas of work include analytics, which includes diagnostics, forensics, and the Absorption, Distribution, Metabolism, Excretion, Toxicology Center of Excellence to support drug development; agent mitigation, which includes personnel decontamination and bioscavenger enzymes to neutralize chemical warfare agents; toxicant countermeasures, which includes countermeasures against vesicants,[2] metabolic poisons, and pulmonary toxicants; nerve agent countermeasures, and toxin countermeasures. USAMRICD develops educational tools and conducts training courses for military and civilian personnel, with emphasis on medical care of chemical causalities. USAMRICD's campus consists of 15 buildings and about 173,000 square feet of laboratories and support areas. In fiscal year 2013, about 61 percent of USAMRICD's funding came from the CBDP Enterprise, with about 15 percent coming from non-CBDP DOD organizations, and about 24 percent coming from non-DOD federal organizations. As of July 2014, USAMRICD had a staff of 362 personnel supporting its work to develop medical chemical defenses for the warfighter.

According to USAMRICD officials, there have been no major upgrades or additions to the current infrastructure since 2008 due to the construction of a new building. USAMRICD officials said they expect to begin moving into the facility in 2015. According to USAMRICD officials, the laboratory and research support areas of the facility will consist of about 250,000 square feet across four buildings when the new facility is complete. The entire new facility is about 526,000 square feet and is on track to be designated a Leadership in Energy and Environmental Design facility.[3] Figure 6 shows USAMRICD's new headquarters and laboratory facility.

[2]Vesicants, such as sulfur mustard agent, are a class of chemical warfare agent named for their ability to form vesicles, or blisters, on exposed skin.

[3]A Leadership in Energy and Environmental Design program promotes "green" building design, green construction practices, and evaluation of the whole building's lifetime environmental performance.

Figure 6: United States Army Medical Research Institute of Chemical Defense's New Headquarters and Laboratory Facility

Source: U.S. Army Medical Research Institute of Chemical Defense. | GAO-15-257

The facility will house laboratories to handle diluted and non-diluted chemical agents. In addition, USAMRICD officials stated that the new building will provide more capacity to perform work activities—including a larger animal holding facility (vivarium), larger training space, greater nuclear magnetic resonance capabilities, and flexible and modular equipment that will adapt to future technology and requirements. According to USAMRICD officials, the facility will have improved safety, security, and chemical surety processes. As a result of emerging chemical threats, such as nontraditional (chemical) agents, a sensitive compartmented information facility room and multiple secure workspaces

were added to the design of the new facility to maintain and work with classified information.

As a result of the building construction, officials stated that, as of July 2015, there will be no major physical infrastructure gaps or challenges.[4] However, officials identified gaps in intellectual infrastructure, that is, subject-matter expertise. Some of the identified gaps include subject-matter expertise in bioengineering, systems biology, microbiology, and molecular modeling.[5] According to USAMRICD officials, these gaps currently exist because of the limitation on hiring due to the Department of the Army civilian personnel caps. Facility officials stated that competencies that are not readily available from in-house civilian personnel are supplemented by a contingent of contract and military workforce.

United States Army Medical Research Institute of Infectious Diseases

USAMRIID's mission is to provide leading-edge medical capabilities to deter and defend against current and emerging biological threats. USAMRIID is located on the National Interagency Biodefense Campus at Fort Detrick, Maryland. After the terrorist attacks of September 11, 2001, additional funding allowed USAMRIID to increase its workforce to enhance its existing mission to address biological threats, to include biological threat characterization, enhanced studies of disease, and the development of medical countermeasures. Its core areas of work include preparing for uncertainty; research, development, test, and evaluation of medical countermeasures; rapidly identifying biological agents; training and educating the force; and providing expertise in medical biological defense. For example, USAMRIID also conducts field training for operational forces in areas such as threat identification and diagnostic methods. Figure 7 shows an example of a USAMRIID field training exercise.

[4]USMRICD officials did not identify sustainment costs as a challenge as did officials from the other primary research and development facilities. The Program Analysis and Integration Office (PAIO) estimated the cost of sustainment and other support activities for USAMRICD is about $15.3 million for fiscal year 2015.

[5]The complete list of identified gaps in subject-matter expertise from USAMRICD includes computational biology/bioinformatics, bioengineering, systems biology, mechanistic neurobiology, material science for drug delivery systems, inorganic chemistry, gene expression/splicing, biostatistics (experimental design), molecular modeling, organic/synthetic chemistry, structural biology, and microbiology.

Figure 7: United States Army Medical Research Institute of Infectious Diseases (USAMRIID) Field Training Exercise

Source: United States Army Medical Research Institute of Infectious Diseases. | GAO-15-257

USAMRIID's campus consists of 20 buildings and 582,369 square feet of laboratory and support space, with 134,469 square feet of Biosafety Level-2 (BSL-2), BSL-3, and BSL-4 laboratory space.[6] According to USAMRIID officials, USAMRIID is the only DOD facility with BSL-4 containment laboratories. In addition, USAMRIID officials stated that about 80 percent of USAMRIID's work is medical countermeasures research and development. Figure 8 shows USAMRIID staff in a BSL-4 containment laboratory.

[6]According to the U.S. Department of Health and Human Services, Biosafety Level 1 (BSL-1) is the basic level of protection in the laboratory and is appropriate for agents that are not known to cause disease in normal, healthy humans. Biosafety Level 2 (BSL-2) designation is appropriate for handling moderate-risk agents that cause human disease of varying severity by ingestion or through percutaneous or mucous membrane exposure. Biosafety Level 3 (BSL-3) designation is appropriate for agents with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections and that are indigenous or exotic in origin. Biosafety Level 4 (BSL-4) designation is for high-containment laboratories that handle exotic agents that pose a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available.

Figure 8: United States Army Medical Research Institute of Infectious Diseases (USAMRIID) Personnel Conducting Research in a Biosafety Level-4 (BSL-4) Laboratory

Source: United States Army Medical Research Institute of Infectious Diseases. | GAO-15-257

In 2012, the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (OASD [NCB]) assigned USAMRIID the responsibility of performing BSL-3 and BSL-4 developmental testing and evaluation of medical countermeasures. As a result, USAMRIID made adjustments to the facility's laboratory infrastructure and retained key subject-matter experts required to perform

studies under the Good Laboratory Practices system promulgated by the Food and Drug Administration.[7] In fiscal year 2013, about 50 percent of USAMRIID's funding came from the CBDP Enterprise, with about 38 percent coming from non-CBDP DOD organizations, and the remaining 12 percent from non-DOD federal agencies and non-federal agencies. As of July 2014, USAMRIID maintained a staff of 841 personnel to support its work in biological defense research.

USAMRIID is constructing a new headquarters and laboratory building, and officials said they expect to begin moving into the building in 2017. According to USAMRIID officials, the new facility will provide additional laboratory space and a new laboratory design to improve workflow and productivity, particularly when performing animal studies. The new facility will include several new capabilities, which may enhance understanding of the pathophysiology of animals and the effectiveness of medical countermeasures to address biological threats.

In response to our questionnaire, USAMRIID officials told us that they are concerned about a potential intellectual infrastructure gap in supporting medical countermeasures test and evaluation, a new responsibility as of 2013. The new mission will require USAMRIID personnel to meet additional standards for conducting research and testing. In addition, USAMRIID officials stated that it will be a challenge in sustaining their new facility. USAMRIID officials said that it would be helpful if the CBDP Enterprise provided stable, sustainment funding in a way similar to the funding received for the test and evaluation facilities. PAIO estimated that the cost of sustainment and other support activities at USAMRIID is about $32.7 million in fiscal year 2015. Currently, the research and development facilities receive funds to sustain the facilities through individual research and development projects awarded by ODASD (CBD) through the Joint Science and Technology Office.

West Desert Test Center

West Desert Test Center (West Desert) at Dugway Proving Ground, Utah, has a mission to safely test warfighters' equipment to high standards within cost and schedule. West Desert enables the delivery of reliable defense products to the warfighter through rigorous developmental and

[7]Good Laboratory Practices are intended to ensure the quality and integrity of data. The Good Laboratory Practices regulations were developed and promulgated in the United States during the late 1970s and 1980s in response to fraudulent laboratory activities and poor laboratory practices that occurred during that time.

operational testing from the test tube to the battlefield. Its core areas of work include chemical and biological laboratory, chamber, and field testing; dissemination and explosives; dispersion modeling; meteorology; data science; and test engineering and integration. Dugway Proving Ground is one of DOD's major range and test facility bases. In fiscal year 2013, about 77 percent of West Desert's work was conducted for the CBDP Enterprise, with the rest from other DOD organizations (15 percent), non-DOD federal government agencies (2 percent), and industry, academia, and international organizations (6 percent). In response to section 232 of the Bob Stump National Defense Authorization Act for Fiscal Year 2003,[8] West Desert charges DOD customers for the costs that are directly related to testing. Therefore, West Desert receives annual funding through the Army and OASD (NCB) for facility sustainment. As of July 2015, West Desert had a staff of 518 personnel on a facility of about 1,252 square miles, including mountain terrain, mixed desert terrain, and salt flats.

According to West Desert officials, some of the infrastructure capabilities added since 2008 include upgrades and improvements to their test grid and dynamic test chamber. Additionally, West Desert has two major ongoing efforts to align infrastructure with emerging chemical and biological threats. The Whole System Live Agent Testing Chamber allows full-system testing of biological detection equipment in a BSL-3 environment with controlled humidity and wind speed—a capability that does not exist elsewhere. The second capability, the Modular Chemical Chamber Test Capabilities, tests warfighter capabilities against emerging chemical threats. This testing capability will include the installation of Secondary Containment Modules to roll into and out of a large multipurpose chemical-warfare-agent-testing chamber in the West Desert's Bushnell Materiel Testing Facility. The use of modular chambers allows for reconfiguration of the facility for upcoming tests while other testing is being conducted within the Bushnell Materiel Testing Facility. According to West Desert officials, this modular concept is expected to reduce test costs and timelines, while increasing test throughput and adding flexibility in meeting customer test requirements.

As part of its future plans to ensure its infrastructure is aligned to address emerging threats, West Desert officials stated that upcoming test

[8]*See* Pub. L. No. 107-314, § 232(a) (2002).

requirements for conventional agents are in place and that priorities for future capabilities will focus on the ability to rigorously test military systems against threats from nontraditional chemical agents and toxic industrial chemicals and materials. In addition, West Desert is constructing an addition to its Life Sciences Test Facility. This annex, to support testing of field and chamber samples and analysis of test data, among other uses, will include about 41,200 square feet, with about 16,200 square feet of BSL-2 and BSL-3 laboratories, including an aerosol chamber. According to West Desert officials, this facility will address a current shortfall in BSL-3 laboratory and chamber testing capacity. Figure 9 shows West Desert's new Life Sciences Test Facility annex.

Figure 9: West Desert Test Center's Life Sciences Test Facility Annex

Source: West Desert Test Center. | GAO-15-257

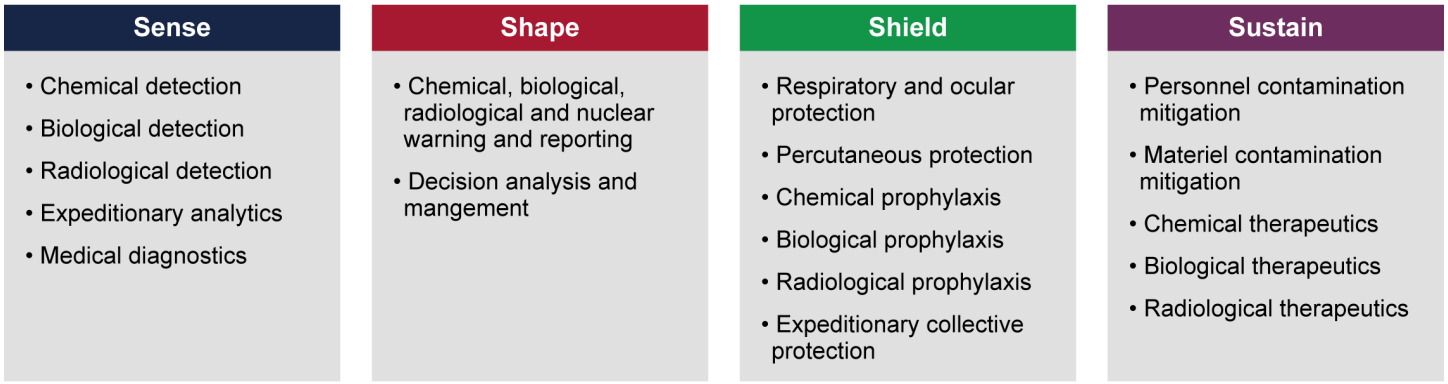
West Desert officials identified potential gaps in West Desert's physical infrastructure and knowledge and skill capabilities. West Desert plans to establish a nontraditional (chemical) agent staging facility to support the modular test chambers being installed in the Bushnell Material Testing Facility. According to West Desert officials, as of January 2015, the project had not been approved for funding through the Military Construction–Defense budget account. In addition, officials have identified gaps in subject-matter expertise in molecular biology, virology, chemical engineering, analytical chemistry, aerosol-dissemination technology, information technology, catalysis,[9] and automation technology. According to West Desert officials, government compensation restrictions will likely preclude the hiring of full-time personnel in the areas of information technology and chemical engineering.

[9]According to West Desert officials, catalysis involves self-decontaminating materials, which may include catalyzed reactions.

Appendix IV: Chemical and Biological Defense Program's 18 Core Capabilities

The Joint Requirements Office developed a list of capabilities needed by military forces to defend against chemical and biological threats in an operational environment. As shown in figure 10, the 18 core capabilities are categorized into four areas: Sense, Shape, Shield, and Sustain.

Figure 10: Core Capabilities Needed to Defend against Chemical and Biological Threats



Source: Joint Requirements Office. | GAO-15-257

These four areas are described as follows:

- The "Sense" area is the capability to continually provide information about the chemical, biological, radiological, and nuclear (CBRN) situation at a time and place by detecting, identifying, and quantifying CBRN hazards in air or water, and on land, personnel, equipment, or facilities. This capability includes detecting, identifying, and quantifying those CBRN hazards in all physical states (solid, liquid, and gas).

- The "Shape" area provides the ability to characterize the CBRN hazard to the force commander and to develop a clear understanding of the current and predicted CBRN situation; to collect, query, and assimilate information from sensors, intelligence, and medical personnel in near-real time to inform personnel, among other actions and responsibilities.

- The "Shield" area capabilities provide protection to the force from chemical and biological threats by preventing or reducing individual and collective exposures, applying prophylaxis to prevent or mitigate negative physiological effects, and protecting critical equipment.

- The "Sustain" area capabilities allow forces to conduct decontamination and medical actions that enable the quick restoration of combat power, maintain or recover essential functions that are free from the effects of CBRN hazards, and facilitate the return to preincident operational capability as soon as possible.

Appendix V: Our Work on Potential Fragmentation, Overlap, and Duplication of the Federal Government's Chemical and Biological Research and Development Laboratory Facilities

Since 1999, we have found potential fragmentation, overlap, and duplication of the federal government's chemical and biological research and development laboratory facilities, but also we have found improved coordination among federal agencies developing biological countermeasures.[1]

Lack of Coordination among Federal Chemical and Biological Programs

In 1999 and 2000, prior to the anthrax attacks in the United States, we found ineffective coordination among the Department of Defense (DOD) and other federal agencies with chemical and biological programs that could result in potential gaps or overlap in research and development programs.[2] In August 1999, we found that the formal and informal program coordination mechanisms that existed between four military and civilian nonmedical chemical and biological programs may not ensure that potential overlap, gaps, and opportunities for collaboration would be addressed. Specifically, we found that coordinating mechanisms between DOD's Chemical and Biological Defense Program (CBDP), DOD's Defense Advanced Research Projects Agency's Biological Warfare Program, the Department of Energy's Chemical and Biological Nonproliferation Program, and the Counterterror Technical Support Program lacked information on prioritized user needs, lacked validated chemical and biological defense equipment requirements, and lacked information on how these programs relate their research and development projects to needs. We concluded that information on user needs and defined requirements may allow coordination mechanisms to compare the specific goals and objectives of research and development

[1]GAO defines "duplication" as two or more agencies or programs engaged in the same activities or providing the same services to the same beneficiaries; "overlap" occurs when multiple agencies or programs have similar goals, engage in similar activities or strategies to achieve them, or target similar beneficiaries; and "fragmentation" refers to those circumstances in which more than one federal agency (or more than one organization within that agency) is involved in the same broad area of national need, and opportunities exist to improve service delivery. See *2014 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-14-343SP (Washington, D.C.: Apr. 8, 2014).

[2]See GAO, *Chemical and Biological Defense: Coordination of Nonmedical Chemical and Biological R&D Programs*, GAO/NSIAD-99-160 (Washington, D.C.: Aug. 16, 1999) and *Chemical and Biological Defense: Observations on Nonmedical Chemical and Biological R&D Programs*, GAO/T-NSIAD-00-130 (Washington, D.C.: Mar. 22, 2000).

projects to better assess whether overlaps, gaps, and opportunities for collaboration exist. We did not make recommendations in this report.

In July 2014, we testified before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations on recent incidents at government high-containment laboratories and the need for strategic planning and oversight of high-containment laboratories.[3] In September 2009, we found that there was no federal entity responsible for strategic planning and oversight of high-containment laboratories—those designed for handling dangerous pathogens and emerging infectious diseases—across the federal government.[4] We concluded in September 2009 that without an entity responsible for oversight and visibility across the high-containment laboratories and a strategy for requirements for the laboratories, there was little assurance of having facilities with the right capacity to meet the nation's needs. We made several recommendations to address these issues, including identifying a single entity charged with periodic government-wide strategic evaluation of high-containment laboratories, developing a mechanism for sharing lessons learned from reported laboratory accidents, and implementing a personnel reliability program for high-containment laboratories, among other recommendations. In our February 2013 report on high-containment laboratories, we made two recommendations—first, that periodic assessment of national biodefense research and development needs be conducted and, second, that the Executive Office of the President, Office of Science and Technology Policy, examine the need to establish national standards for high-containment laboratories.[5] The Executive Office of the President, Office of Science and Technology Policy, concurred with our two recommendations.

[3]See GAO, *High-Containment Laboratories: Recent Incidents of Biosafety Lapses*, GAO-14-785T (Washington, D.C.: July 16, 2014).

[4]See GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-1045T (Washington, D.C.: Sept. 22, 2009); *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-1036T (Washington, D.C.: Sept. 22, 2009); and *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574 (Washington, D.C.: Sept. 21, 2009).

[5]See GAO, *High-Containment Laboratories: Assessment of the Nation's Need Is Missing*, GAO-13-466R (Washington, D.C.: Feb. 25, 2013).

Lack of Biosurveillance Focal Point

Regarding biosurveillance, in June 2010, we found that the federal government could benefit from a focal point that provides leadership to the interagency community developing this capability.[6] Biosurveillance is the ability to provide early detection and situational awareness of potentially catastrophic biological events. Specifically, we found that the mission responsibilities and resources needed to develop a biosurveillance capability were dispersed across a number of federal agencies, creating the potential for overlap and duplication of effort. In addition, we found that there was no broad, integrated national strategy that encompassed all stakeholders with biodefense responsibilities to guide the prioritization and allocation of investment across the entire biodefense enterprise, among other responsibilities. We made two recommendations to the Homeland Security Council within the Executive Office of the President to (1) identify a focal point, which was implemented when an Interagency Policy Group was convened to complete a National Biosurveillance Strategy in 2012 and (2) develop a national biosurveillance strategy, which remains open until a mechanism to identify resource and investment needs, including investment priorities, is included in an implementation plan.[7]

Coordination on Biological Countermeasures

In April 2011 and May 2014, respectively, we found that DOD and other federal agencies were coordinating their efforts to research and develop biological countermeasures, which may reduce fragmentation, overlap, and duplication. We testified in April 2011 on the efforts of the Department of Health and Human Services' chemical, biological, radiological, and nuclear (CBRN) medical countermeasures development and acquisition.[8] Specifically, we testified that the Department of Health and Human Services coordinates and leads federal efforts to determine priorities to develop and to acquire CBRN medical countermeasures, primarily through the Public Health Emergency Medical Countermeasure Enterprise—an interagency body that includes other federal agencies with related responsibilities, such as DOD and the Department of Homeland

[6]See GAO, *Biosurveillance: Efforts to Develop a National Biosurveillance Capability Need a National Strategy and Designated Leader*, GAO-10-645 (Washington, D.C.: June 30, 2010).

[7]The White House, *National Strategy for Biosurveillance* (July 31, 2012).

[8]See GAO, *Public Health Preparedness: Developing and Acquiring Medical Countermeasures Against Chemical, Biological, Radiological, and Nuclear Agents*, GAO-11-567T (Washington, D.C.: Apr. 13, 2011).

Security. This organization is a decision-making body responsible for providing recommendations to the Secretary of Health and Human Services on coordination of medical countermeasures development against chemical and biological threats, among other responsibilities. Similarly, in May 2014, we found coordination of effort among federal agencies located on the National Interagency Biodefense Campus.[9]

The following textbox provides our observations on the program's efforts at the National Interagency Biodefense Campus to collaborate with other federal agencies to reduce potential infrastructure fragmentation, overlap, and duplication.

[9]See GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization*, GAO-14-442 (Washington, D.C.: May 15, 2014). We found that DOD's efforts to coordinate with the Departments of Health and Human Services and Homeland Security align with best practices for collaborating across agency boundaries—specifically, to leverage available resources; establish mutually reinforcing joint strategies; and develop compatible policies, procedures, and other tools to operate across agency boundaries. We recommended that DOD develop and implement a process to update and validate DOD's list of biological threats or implement a process that aligns with the department's current policies, practices, and priorities. DOD concurred with our recommendation.

GAO Observations on the National Interagency Biodefense Campus

The National Interagency Biodefense Campus at Fort Detrick, Maryland, was established in 2004. An official with the U.S. Army Medical Research and Materiel Command testified before the House Select Committee on Homeland Security in 2004 that the campus would share common infrastructure and supporting requirements, such as roadways, libraries, and regulatory and quality assurance responsibility. In addition, the official stated that the campus would minimize duplication of effort, technology, and infrastructure.
During the course of our review, we found some examples of actions taken by the CBDP Enterprise's primary research and development facility at the National Interagency Biodefense Campus to reduce the potential for duplication of physical and intellectual infrastructure.

- A set of studies on medical countermeasure test and evaluation facility requirements, conducted for the U.S. Army Assistant Chief of Staff for Facilities, Planning and Programming Division, determined, among other things, that there was sufficient capacity for holding animals in existing facilities that conduct research with animals. During planning for a new medical countermeasure test and evaluation facility, a decision was made that the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) on the National Interagency Biodefense Campus would cancel its own plans to construct this building, including an animal holding facility (vivarium). According to USAMRIID officials, the cancellation had an overall estimated cost savings of about $600 million.

- USAMRIID and the National Institute of Allergy and Infectious Diseases Integrated Research Facility plan to share Biosafety Level-3 (BSL-3) and BSL-4 imaging laboratories capabilities. USAMRIID officials said that this reduces the need for each facility to have a BSL-3 and BSL-4 imaging laboratory.

- The National Interagency Confederation for Biological Research, a governance structure for the National Interagency Biodefense Campus, encourages intellectual collaboration in efforts related to research of biological pathogens across agency boundaries, such as collaborative award programs and annual scientific forums.

Source: US Army Medical Research Institute of Infectious Disease.

We conducted a number of reviews since 1999 on the efforts of federal agencies to reduce potential fragmentation, overlap, and duplication through coordination of their efforts to manage chemical and biological programs.[10] We found improved coordination that may reduce potential fragmentation, overlap, and duplication of research and development of medical countermeasures.

[10]In addition, outside of the chemical and biological research and development area, we found that the Environmental Protection Agency needs to revise its overall approach to managing its laboratories to address potential overlap and fragmentation, including alternative approaches to organizing workforce and infrastructure and managing individual laboratory facilities as part of an interrelated portfolio to improve efficiency and identify opportunities to reduce costs. We made seven recommendations to reduce the potential for overlapping laboratory activities, including establishing an entity with the authority and responsibility to coordinate and oversee laboratories, and reduce cost associated with maintaining laboratories. The agency generally agreed with the recommendations and has taken some steps to address all of the recommendations. *See* GAO, *2012 Annual Report: Opportunities to Reduce Duplication, Overlap, and Fragmentation, Achieve Savings, and Enhance Revenue*, GAO-12-342SP (Washington, D.C.: Feb. 28, 2012) and *Environmental Protection Agency: To Better Fulfill Its Mission, EPA Needs a More Coordinated Approach to Managing Its Laboratories*, GAO-11-347 (Washington, D.C.: July 25, 2011).

Appendix VI: Comments from the Department of Defense

In addition to providing agency comments, DOD conducted a security review of a draft of this report under report number GAO-15-257SU. DOD determined that the draft report is unclassified, does not contain any sensitive information, and the final report is cleared for open publication. We subsequently changed the report number to GAO-15-257 to reflect this status.

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

NUCLEAR, CHEMICAL, AND
BIOLOGICAL DEFENSE PROGRAMS

JUN - 1 2015

Mr. Joseph Kirschbaum
Director, Defense Capabilities and Management
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Kirschbaum:

This is the Department of Defense (DoD) response to the Government Accountability Office (GAO) Draft Report, GAO-15-257SU, "CHEMICAL AND BIOLOGICAL DEFENSE: Designated Entity Needed to Identify, Align, and Manage DOD's Infrastructure" dated April 28, 2015 (GAO Code 351885).

The Department appreciates the opportunity to review the draft report and concurs with the recommendations of the GAO. The Department is actively reviewing and assessing the core capabilities and infrastructure that are critical in supporting the research, development, testing, and evaluation of effective countermeasures against chemical and biological threats. As we look to revise the DoD Directive on Roles and Responsibilities Associated with the Chemical and Biological Defense (CBD) Program (CBDP) (DoDD 5160.05E), we will ensure that the roles and responsibilities are updated to appropriately capture the focus on infrastructure capabilities and risk assessments.

If you need additional information, please do not hesitate to call me at 703-697-1771. My point of contact for this effort is Ms. Karan Williams, Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense, 703-695-5486, karan.y.williams.civ@mail.mil.

Sincerely,

Arthur T. Hopkins

Enclosure:
As stated

GAO DRAFT REPORT DATED APRIL 28, 2015
GAO-15-257SU (GAO CODE 351885)

"CHEMICAL AND BIOLOGICAL DEFENSE: DESIGNATED ENTITY NEEDED TO IDENTIFY, ALIGN, AND MANAGE DOD'S INFRASTRUCTURE"

DEPARTMENT OF DEFENSE COMMENTS TO THE GAO RECOMMENDATIONS

RECOMMENDATION 1: To help ensure that the CBDP Enterprise's infrastructure is properly aligned to address current and emerging chemical and biological threats, the GAO recommends that the Secretary of Defense direct the appropriate DoD officials to identify and designate an entity within the CBDP Enterprise with the responsibility and authority to lead the effort to ensure achievement of the infrastructure goals (e.g. the four 2008 PAIO recommendations, including the recommendation that the CBDP Enterprise identify its required infrastructure capabilities, and the goal established in the 2012 *CBDP Business Plan*).

DoD RESPONSE:

Concur. *The Department concurs that an entity needs to lead the effort to ensure achievement of the infrastructure goals; further, we believe that these responsibilities and authorities are currently in place under existing laws and regulations. The 2012 Chemical and Biological Defense Program (CBDP) Strategic Plan identified one of the four strategic goals of the CBDP to "maintain infrastructure to meet and adapt current and future needs for personnel, equipment, and facilities within funding constraints." To achieve this goal, the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs and the US Army, as the executive agent for Chemical and Biological Defense, share responsibility to ensure achievement of CBDP's strategic infrastructure goals in close collaboration and coordination with the infrastructure managers (the individual installation commanders and directors of the facilities). The Department is in the process of revising DoDD 5160.05E and will ensure that the directive appropriately captures the roles and responsibilities related to CBDP infrastructure capabilities.*

RECOMMENDATION 2: To help ensure that the CBDP Enterprise's infrastructure is properly aligned to address current and emerging chemical and biological threats, the GAO recommends that the Secretary of Defense direct the appropriate DoD officials to establish timelines and milestones for achieving identified chemical and biological infrastructure goals, including implementation of the 2008 PAIO recommendation that the CDBP Enterprise identify its required infrastructure capabilities.

DoD RESPONSE:

Concur. *The Department agrees that the most effective means of ensuring CBDP infrastructure goals are achieved is to set realistic timelines and milestones. The CBDP Enterprise is in the midst of a thoughtful effort to identify the infrastructure capabilities and capacities necessary to*

successfully complete its mission. CBDP first solicited support from the National Research Council of the National Academies of Science to identify what science and technology core capabilities need to be in place within DoD laboratories to support CBRN Research, Development, Test, and Evaluation. The Enterprise is also in the midst of internal reviews of both our current infrastructure capabilities and those that are needed to fulfill mission requirements. The combined results of these studies will enable the CBDP Enterprise to align our core capabilities with the necessary supporting infrastructure, and to develop implementation and sustainment plans with timelines and milestones for required CBDP infrastructure capabilities and will consider GAO's recommendation on this issue.

RECOMMENDATION 3: To enhance PAIO's ongoing analysis of potential infrastructure duplication in the CBDP Enterprise and gain potential efficiencies, the GAO recommends that the Secretary of Defense direct the Under Secretary of Defense for Acquisition, Technology and Logistics to identify, request, and consider any information from existing infrastructure studies from other federal agencies with chemical and biological research and development and test and evaluation infrastructure.

DoD RESPONSE:

Concur. *The Department agrees that information from existing and ongoing Federal chemical and biological infrastructure studies should be considered as inputs to the CBDP Enterprise infrastructure analysis efforts. We maintain strong partnerships with the Department of Homeland Security and the Department of Health and Human Services, which will facilitate our accomplishment of this recommendation.*

RECOMMENDATION 4: To fully institutionalize the use of risk assessments to support future investment decisions, the GAO recommends that the Secretary of Defense direct the Under Secretary of Defense for Acquisition, Technology and Logistics to update the roles and responsibilities guidance in DoD Directive 5160.05E to identify which organizations are responsible for conducting and participating in CBDP Enterprise risk assessments.

DoD RESPONSE:

Concur. *The Department is in the process of revising DoDD 5160.05E and will include the risk assessment process in the roles and responsibilities section.*

RECOMMENDATION 5: To fully institutionalize the use of risk assessments to support future investment decisions, the GAO recommends that the Secretary of Defense direct the Under Secretary of Defense for Acquisition, Technology and Logistics to update the CBDP Enterprise's portfolio planning process, to include when risk assessments will be conducted.

DoD RESPONSE:

Concur. *The risk assessment process was initially piloted in 2014, to determine its utility for informing CBDP Enterprise portfolio planning and guidance. Moving forward, the CBDP Enterprise plans to conduct risk assessments annually to support portfolio planning and guidance.*

Appendix VII: GAO Contact and Staff Acknowledgments

GAO Contact

Joseph W. Kirschbaum, (202) 512-9971 or KirschbaumJ@gao.gov

Staff Acknowledgments

In addition to the contact named above, GAO staff who made significant contributions to this report include Mark A. Pross, Assistant Director; Richard Burkard; Russ Burnett; Jennifer Cheung; Rajiv D'Cruz; Karen Doran; Edward George; Mary Catherine Hult; Mae Jones; Amie Lesser; Elizabeth Morris; Steven Putansu; Sushil Sharma; Sarah Veale; and Michael Willems.

Related GAO Products

High-Containment Laboratories: Recent Incidents of Biosafety Lapses. GAO-14-785T. Washington, D.C.: July 16, 2014.

Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization. GAO-14-442. Washington, D.C.: May 15, 2014.

High-Containment Laboratories: Assessment of the Nation's Need Is Missing. GAO-13-466R. Washington, D.C.: February 25, 2013.

Public Health Preparedness: Developing and Acquiring Medical Countermeasures Against Chemical, Biological, Radiological, and Nuclear Agents. GAO-11-567T. Washington, D.C.: April 13, 2011.

Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue. GAO-11-318SP. Washington, D.C.: March 1, 2011.

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