



The Department of Defense
Chemical and Biological Defense Program

2015 Annual Report to Congress



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Summary

The Department continues to protect our forces deployed around the world against weaponized agents, diseases, and emerging threats using a layered defense and risk-informed approach. Our programs provide effective and affordable countering weapons of mass destruction (WMD) capabilities for the United States (U.S.) and our international partners and allies. Highlighted in this report are some of the many accomplishments of the Department in fiscal year (FY) 2014. Most notably the Department:

- **Developed the Field Deployable Hydrolysis System used to destroy the Schedule 1 components of the declared Syrian chemical stockpile.**

The Cooperative Threat Reduction Program outfitted the Motor Vessel (M/V) Cape Ray, a U.S. National Defense Reserve Fleet Vessel, with two specially-designed neutralization systems operated by Department of Defense (DoD) personnel to neutralize the most dangerous of the declared Syrian chemical weapons in a safe and environmentally sound manner. This operation was the first ever chemical weapons destruction operation aboard a sea-based vessel.

- **Improved national capabilities to respond to emergencies and to address threats to DoD personnel and U.S. citizens across the globe.**

The Department augmented the detection and diagnostic capabilities of the international response to the West Africa Ebola outbreak of 2014 by prepositioning diagnostic assays used in areas with high potential for an outbreak, which was unprecedented within the DoD. Meanwhile, we rapidly pursued an Emergency Use Authorization on the BioThreat Ebola assay on our Next Generation Diagnostics System Increment 1, which will result in an improved analytical system to detect and identify the presence of several biological agents.

- **Advanced medical countermeasure (MCM) candidates to mitigate biological threats.**

While there are no U.S. Food and Drug Administration (FDA)-approved MCMs available to address the current Ebola virus outbreak, the Department expedited development of a promising therapeutic candidate which was used to treat several Ebola patients. Also, the Department accelerated multiple potential Ebola vaccine candidates and specific product development tools to support Ebola Vaccine clinical trials. Meanwhile, the Department continued developing potential vaccines to protect against plague, botulinum toxin, filoviruses (Sudan and Marburg), and equine encephalitis viruses and equine encephalitis viruses.

- **Strengthened integrated chemical and biological (CB) preparedness and response capabilities through collaboration with key partners and allies.**

The Department partnered with more than a dozen allied countries to exchange innovative CB defense solutions, to improve interoperability, and to develop new CB defense technologies. The annual Able Response exercise between the U.S. and the Republic of Korea enhanced our ability to prepare for and respond to an intentional biological incident by employing a "whole-of-government" approach.

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Introduction

The Department of Defense (DoD) Chemical and Biological Defense Program (CBDP)¹ develops capabilities to enable the Joint Force to deter, prevent, protect from, mitigate, respond to, and recover from chemical, biological, radiological, and nuclear (CBRN) threats and effects as part of a layered, integrated defense. Rapid advancements in technology are making it easier for an adversary, whether state or non-state, to develop chemical and biological (CB) weapons. The DoD faces CB threats that are complex, diverse, and pose enduring risks to our Joint Force and the Homeland. The CBDP Enterprise is an integral contributor to a global systems approach to countering weapons of mass destruction (CWMD), global health security, and other pertinent mission areas.

The 2015 DoD CBDP Annual Report to Congress, per title 50 United States (U.S.) Code Section 1523, highlights CBDP fiscal year (FY) 2014 accomplishments in the focus areas of Equip the Force, Prevent Surprise, Maintain Infrastructure, and Lead the Enterprise based on the format of the CBDP Strategic Plan.² This report also aligns with other key strategies such as the 2014 DoD Strategy for Countering Weapons of Mass Destruction, the 2014 Quadrennial Defense Review, the National Strategy for Biosurveillance, and the Strategy for Homeland Defense and Defense Support of Civilian Authorities.

A. U.S. Support to the Ebola Epidemic Response

The CBDP has played a critical role in the U.S. Government's response to the Ebola epidemic in West Africa. Prepositioned assays from the CBDP's Critical Reagent Program were used to confirm the first diagnosis of Ebola virus in Sierra Leone in real-time. These assays received an Emergency Use Authorization from the U.S. Food and Drug Administration (FDA), allowing them to be ready for use, both abroad and domestically. Overall, the CBDP significantly augmented the detection and diagnostic capabilities of the international response to the West Africa outbreak of 2014. While there are no FDA-approved medical countermeasures (MCM) available to address the current Ebola virus outbreak, the CBDP is developing and tracking several candidate prophylaxis and therapeutic products (e.g., VSVdeltaG, ZMapp) which may ultimately prove safe and effective against Ebola virus. The CBDP expedited development of a promising therapeutic candidate which was used to treat several Ebola patients. This product is the lead DoD Ebola virus therapeutic candidate, has achieved investigational new drug status, and is currently in clinical trials through FDA-approved protocols. The CBDP also accelerated development activities for two additional Ebola virus vaccine candidates. To enable tracking of the epidemic and sharing of information, the Ebola Portal website was created to provide resources and capabilities for DoD personnel responding to the outbreak. At the request of U.S. Transportation Command, the CBDP also initiated development of a transport isolation system to enable safe transport of Ebola patients on U.S. military lift aircraft.

B. M/V Cape Ray and the Syrian Chemical Warfare Agent (CWA) Destruction Mission

To support international efforts to safely eliminate the Syrian CWA stockpile, the Department developed the Field Deployable Hydrolysis System (FDHS), and modified the system for shipboard use. The FDHS is a transportable, high throughput neutralization system that converts chemical agents into compounds not usable as weapons. The FDHS was installed onto the M/V Cape Ray, which was outfitted by the U.S.

¹ For a list of CBDP Enterprise Stakeholders, please see Enclosure A.

² Title 50 U.S. Code Section 1523, (a) 1: The overall readiness of the Joint Force to fight in a chemical-biological warfare environment and shall describe steps taken and planned to be taken to improve such readiness.

Navy with collective protection systems to ensure the readiness and safety of the crew and passengers. In FY14, the M/V Cape Ray sailed to international waters where operators completed the full destruction of Schedule 1 components of the declared Syrian chemical weapons (CW) stockpile. This mission was widely recognized as a success.

Equip the Force

The CBDP is equipping the force to successfully conduct military operations to prevent, protect, and respond to CBRN threats and effects. This section details CBDP Enterprise accomplishments in diagnostics, MCMs, non-traditional agents (NTA), fielding capabilities, non-materiel solutions, and support to the U.S. Special Operations Command (USSOCOM).

A. Advances in Diagnostics

In FY14, the CBDP Enterprise invested in a number of efforts to enhance diagnostic capabilities against CB threats. The CBDP continued to advance its Next Generation Diagnostics System (NGDS) Increment 1 program which will result in an improved analytical system capable of detecting and identifying the presence of biological warfare agents and infectious disease pathogens. The CBDP has down-selected to a single vendor who will provide FDA-cleared medical diagnostic devices and develop in vitro diagnostic assays. NGDS Increment 1 will provide enhanced diagnostic and environmental analytical capabilities over the existing Joint Biological Agent Identification and Diagnostic System (JBAIDS) with reduced cost and manpower burden to the Joint Force. The NGDS Increment 1 is estimated to begin replacing the JBAIDS in 2017.

Additionally, the CBDP continued its 24-Month Challenge project to develop point-of-care diagnostics for mobile and clinic-based applications. This effort has initiated an evaluation process for new multiplexed assays for the detection of *Yersinia pestis* and *Burkholderia pseudomallei* species (the causative agents of plague and melioidosis, respectively), dengue viruses, and protozoa of the *Plasmodium falciparum* (the causative agents of malaria) to enable a prototype demonstration in the field with endemic diseases. A demonstration of these capabilities will occur in South America, Southeast Asia, and, Sierra Leone, and the data will be incorporated into the Biosurveillance (BSV) Ecosystem, a global information system designed to accelerate disease detection, identification, and response capabilities.

B. Advances in Medical Countermeasures

In FY14, the CBDP continued development of numerous MCMs, including therapeutics and vaccines against chemical and biological threats. The CBDP internally transitioned scopolamine, an FDA-approved drug for the treatment of motion sickness that also improves survival against several nerve agents, from S&T to advanced development activities in support of the Improved Nerve Agent Treatment System. In addition to the work on Ebola countermeasures mentioned previously, research into MCMs against agents with the likelihood of high impact to the force, such as plague, botulism toxin, and NTAs continued. CBDP's recombinant plague vaccine received acceptance from the FDA for the methods developed to determine nonclinical efficacy and cross-species comparison—critical items required for FDA licensure under the FDA's Animal Rule. Meanwhile, CBDP's recombinant botulinum vaccine completed pivotal nonclinical efficacy testing and demonstrated the vaccine was efficacious – also required for FDA licensure under the Animal Rule. Finally, CBDP's program to develop countermeasures

for multi-drug resistant bacteria continued to work on requirements and technology assessments toward a future request for proposals, the formal solicitation to submit offers to the Government.

CBDP established the Absorption-Distribution-Metabolism-Excretion Center to institute industry best practices. The Center is working to enhance the design and facilitate the development of new MCMs prior to animal testing in order to reduce costs, timelines, and MCM attrition.

FY14 saw the development of data resources in the CBDP, including a microbial threat information center data resource to streamline assay development and enhance the support of the Critical Reagents Program. Another developed resource was the online database that allows scientists to study the secretion systems of *Burkholderia mallei*, and the host pathways this bacterial species targets.

In FY14, the CBDP coordinated with Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) partners to conduct government-wide reviews of the botulism and smallpox MCM portfolios, as well as Radiological/Nuclear MCM program efforts.³ A significant accomplishment this year through the PHEMCE was a review and prioritization of vaccines and therapeutics for Ebola virus, leading to the selection of two vaccines (one NIH and one DoD) and one therapeutic (DoD) for development.

C. Advances in Non-Traditional Agent Defense

Research is critical for developing NTA defense capabilities, and in FY14, the CBDP conducted numerous studies and experiments towards this goal. The Operational Interim Standards Working Group, which includes subject matter experts representing Defense Threat Reduction Agency (DTRA), Edgewood Chemical Biological Center (ECBC), U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), and the U.S. Army Public Health Command among others, provided human toxicity estimates based on non-human animal challenges via multiple routes of exposure for high priority NTAs. These estimates provide the basis for health-based criteria concerning these agents. The CBDP delivered critical physiological and chemical properties for prioritized NTAs to develop physical countermeasures and MCMs. These properties contribute to developing NTA threshold values for security policies, setting detector levels, developing and evaluating protective equipment, and informing decision support tools and concepts of operations. Additionally, the community continued advanced development of MCMs against some NTAs.

The CBDP internally transitioned two NTA decontamination data packages from science and technology (S&T) activities to the acquisition community in support of the Decontamination Family of Systems acquisition program. These packages will allow the Joint Force to understand the uses and limitations of the current inventory of decontaminants for NTAs, as well as establishing a roadmap for improved decontamination systems development.

CBDP completed fabrication and installation of the Non-Traditional Agent Defense Test System (NTADTS) at ECBC. The NTADTS consists of three agent test chambers for the purpose of testing CBDP equipment against emerging threats under real world environmental conditions and a revised

³ PHEMCE coordinates Federal efforts to enhance CBRN and emerging infectious disease preparedness from a MCM perspective. PHEMCE is led by the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response, and comprises the CDC, FDA, National Institutes of Health, DoD, U.S. Department of Veterans Affairs, DHS, and U.S. Department of Agriculture.

laboratory outfitted with advanced analytical equipment. The intent of NTADTS is to support S&T activities and the acquisition lifecycle to potentially include developmental testing for programs with NTA requirements.

CBDP sponsored and published results of testing involving fielded government-off-the-shelf and commercial-off-the-shelf detection and individual protection products against select NTAs. The data informed analysis of existing capabilities to assess operational gaps and risks and may be used to inform supplemental tactics, techniques, and procedures (TTP) for chemical defense.

The CBDP test and evaluation (T&E) community developed the roadmap for NTA developmental and developmental/operational testing. Plans for the completion and validation of NTA test capabilities at ECBC and West Desert Test Center (WDTC) were finalized to ensure acquisition program support starting in FY15.

D. Fielding of Prioritized Capabilities for the Joint Force^{4,5}

The CBDP fielded numerous CB defense capabilities to meet wartime and peacetime requirements for support to the Joint Force. The FY14 accomplishments and quantities of fielded capabilities are provided in Enclosure B, with several notable capabilities highlighted below.

Detection

CBDP completed fielding Domestic Response Capability (DRC) Kits to all 57 National Guard Bureau Weapons of Mass Destruction Civil Support Teams (WMD CST). The DRC Kit was developed by the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) in response to a 2011 Operational Need Statement requesting NTA detection, protection, and decontamination for the WMD CSTs. Fielding began in July 2012 and was completed in March 2014.

CBDP continued to field the Joint Chemical Agent Detector (JCAD) M4A1 to U.S. Army and National Guard Bureau units in FY14. The JCAD M4A1 and the JCAD M4 systems provide low-cost, portable CWA detection to individuals throughout the Joint Force.

CBDP completed production of the Joint Biological Point Detection System (JBPDS) in 2014. The JBPDs began Low-Rate Initial Production in 2001, and was initially fielded as a component of the Biological Integrated Detection System in 2003. A total of 990 JBPDs have been procured for use by the U.S. Army, U.S. Army Reserve, National Guard, and U.S. Navy. The program is on schedule to transition to sustainment in September 2015.

⁴ Title 50 U.S. Code 1523 (a) 2: Requirements for the chemical and biological warfare defense program, including requirements for training, detection, and protective equipment, for medical prophylaxis, and for treatment of casualties resulting from use of chemical or biological weapons.

⁵ Title 50 U.S. Code 1523 (b) 1: The quantities, characteristics, and capabilities of fielded chemical and biological defense equipment to meet wartime and peacetime requirements for support of the Joint Force, including individual protective items.

Protection

CBDP continued fielding its Joint Service General Purpose Mask, which provides improved face, eye, and respiratory protection against CB agents, to include toxins; radioactive particulates; and specific toxic industrial materials.

Information Systems

The CBDP Joint Warning and Reporting Network (JWARN) program completed post-Operational Test updates and was fielded to 29 Global Command and Control System – Joint sites worldwide. Additionally, software updates for the JWARN web application and the CBDP Joint Effects Model were provided to operational users for training purposes.

E. Non-materiel Solutions to Capability Gaps⁶

The CBDP also provided non-materiel solutions to ensure the integration of requirements for CB defense equipment and materiel among the Joint Force. The Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense (JRO-CBRND) established formal processes for coordinating threat intelligence support to operational risk analysis and capability requirements development. These efforts include the first formal Joint Threat Coordination Group to assign accurate risk evaluations to capability gaps and inform capability requirements documents. Additionally, extensive improvements were made to formalize the Priority Intelligence Requirements (PIR) process, align the process to the annual budget cycle, and streamline the annual CBRN Warfare Capstone Assessment. Furthermore, the threat assessment and PIR review will inform the CBDP as it develops future S&T activities.

The CBDP conducted the first comprehensive Operational Risk Assessment in support of the Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs/Chemical and Biological Defense (OASD(NCB/CB)) decisions and requirements. This effort used approved Defense Planning Scenarios to ascertain and quantify the impact of current and future adversary WMD capabilities on amphibious, land force, air, and littoral operations. It was conducted in close cooperation with the Military Services, Joint Staff Directorates, DTRA, and JPEO-CBD.

The CBDP provided input into more than 20 Joint Publications (JP) and supported revisions of JPs 3-26, *Counterterrorism*; 3-40, *Countering Weapons of Mass Destruction*; 3-41, *Chemical, Biological, Radiological, and Nuclear Consequence Management*; 4-02, *Health Service Support*; and 4-06, *Mortuary Affairs*.

Oversight was provided by JRO-CBRND in the revision of numerous Multi-Service Tactics, Techniques, and Procedures (MTTP) during FY14, including *MTTP for Treatment of Chemical Agent Casualties and Conventional Military Injuries*, *MTTP for Health Service Support*, and *MTTP for Potential Military Chemical/Biological Agents and Compounds (Retitled CBRN Threats and Hazards)*. The development for the *MTTP for CBRN Passive Defense* revises and combines the contents from three MTTPs: *MTTP for CBRN Contamination Avoidance*, *MTTP for NBC Protection*, and *MTTP for CBRN Decontamination*.

⁶ Title 50 U.S. Code 1523 (b) 3: Measures taken to ensure the integration of requirements for chemical and biological defense equipment and material among the Joint Force.

F. Support to U.S. Special Operations Command

In FY14, the CBDP continued to support USSOCOM by focusing on protective ensembles, detection and identification equipment, decontamination, and situational awareness tools. These activities included fielding and deployment of the Uniformed Integrated Protective Ensemble, Increment 1, which provides improved individual protective capabilities through reduced weight, bulk, and thermal burden; quality deficiency corrective action for the M53 field protective mask to improve reliability and maintainability; contracting action for the All Purpose-Personal Protective Ensemble suit enabling technology refresh, expansion, and replenishment for a critical Special Operations ensemble; and collaboration with USSOCOM to evaluate biological identification technologies that might serve as inserts into current or planned joint programs. These activities have enhanced those programs and the capabilities within the Joint Force. Finally, USSOCOM validated a Joint Requirement for the Global Biosurveillance Portal (G-BSP), which is intended to enhance situational awareness for all-hazard threats to human, plant, or animal health of impact to the force.

Prevent Surprise

The CBDP is preventing surprise by anticipating CBRN threats and developing new capabilities for the Joint Force to counter emerging threats. Highlights include DoD activities supporting implementation of the Chemical Weapons Convention (CWC), advances in biosurveillance, and other S&T research highlights.

A. Chemical Weapons Convention Implementation Activities^{7,8}

In addition to working with international partners and the Organisation for the Prohibition of Chemical Weapons (OPCW) United Nations Joint Mission to help destroy declared chemical agents and precursors in Syria, the DoD continues to provide support around the world to reduce CW threats in compliance with the CWC. The DoD hosted six OPCW inspections and visits to CW storage and destruction facilities to ensure no removal of CW took place and to familiarize the OPCW with the newly constructed destruction facilities in Pueblo, Colorado, and Blue Grass, Kentucky. ECBC's Forensic Analytical Center, one of only two OPCW-designated laboratories in the U.S., successfully passed its April 2014 OPCW Proficiency Test with their 20th "A" score.

The CBDP continued the Technical Equipment Inspection (TEI) Program, ensuring that OPCW equipment meets U.S. safety, environmental, and security requirements and verifying OPCW equipment entering and exiting the U.S. is in accordance with the U.S. Certification Report. The TEI Program also performs chemical agent monitoring of inbound inspection equipment at the point of entry to protect personnel from possible preexisting contaminants on the OPCW verification equipment.

⁷ Title 50 U.S. Code 1523 (b) 7: A description of the chemical warfare defense preparations that have been and are being undertaken by the Department of Defense to address needs which may arise under article X of the Chemical Weapons Convention.

⁸ Title 50 U.S. Code 1523 (b) 8: A summary of other preparations undertaken by the Department of Defense and the On-Site Inspection Agency to prepare for and to assist in the implementation of the convention, including activities such as training for inspectors, preparation of defense installations for inspections under the convention using the Defense Treaty Inspection Readiness Program, provision of chemical weapons detection equipment, and assistance in the safe transportation, storage, and destruction of chemical weapons in other signatory nations to the convention.

The DoD, Military Departments/Services, and Components all developed CWC implementation and compliance plans, and conducted exercises to ensure that all military elements are fully prepared for inspections under the CWC. The Services initiated efforts to ensure that, in the case of a challenge inspection, affected commands take timely and appropriate measures, based on lessons learned, to demonstrate compliance while protecting security concerns.

In accordance with a condition established in the U.S. Senate's Advice and Consent to the Ratification of the CWC, the U.S. will provide "no assistance...other than medical antidotes and treatment" to those countries deemed ineligible to receive full Article X assistance under the Foreign Assistance Act of 1961. Under the CWC, the DoD has provided neither CW detection equipment nor assistance in the transportation, storage, and destruction of CW to other State Parties, except that which has been provided to Russia, Albania, Libya, and Syria under the DoD's Cooperative Threat Reduction Program.

B. Advances in Biosurveillance

In FY14, the CBDP continued development of several efforts to foster collaboration among all aspects of the biosurveillance community. CBDP addressed U.S. Forces Korea and U.S. Pacific Command biosurveillance and biodefense requirements through the Joint United States Forces Korea (USFK) Portal and Integrated Threat Recognition (JUPITR) advanced technology demonstration (ATD). The objective of this ATD is to significantly increase defense capabilities to mitigate impending biological threats to U.S. Forces Korea and the Republic of Korea. JUPITR demonstrates an unclassified web-based portal capability that facilitates collaboration, cutting edge laboratory equipment to identify biological toxins and pathogens of concern, an assessment of environmental field sensors, and an integration of a suite of CB and non-CB force protection sensors to demonstrate an early warning capability. The web-based portal has been formalized to improve collaborative information sharing among interagency, academia, national laboratories, and DoD laboratories.

The CBDP has continued partnering with other nations to enable our biosurveillance capabilities. Working with Australia, Canada, and the United Kingdom, the CBDP provided overviews of biological detection efforts, including bioinformatics and next generation sequencing research, and discussed the draft program of work to further coordination. Additionally, the CBDP continues to work with the Republic of Korea to enable threat detection and characterization for early warning.

DoD and the Center for Disease Control and Prevention (CDC) signed a memorandum of understanding (MOU) to improve the coordination of their international engagement on global health security objectives related to biosurveillance information systems. Coordination of DoD and CDC efforts will help ensure that activities are appropriate, sustainable, and facilitate International Health Regulations compliance. Together, these activities will foster enduring health-security relationships between the U.S. Government and partner nations.

C. Advances in Science and Technology Research

Finally, CBDP has also made significant advancements in S&T research, particularly in developing new CBRN defense technologies, coordinating with Defense Advanced Research Projects Agency (DARPA), and developing CB threat studies and risk assessments.

1. New CBRN defense technologies

In FY14, the CBDP developed a host of new CBRN defense technologies. DTRA has developed a number of technologies for more accurate detection of CB threats. These technologies include those currently undergoing testing, such as the DNATrax bioaerosol simulant technology and a field-portable mass spectrometer. In FY14 DNATrax was tested at the Pentagon, and was briefed to the T&E Capabilities and Methodologies Integrated Process Team (TECMIPT), while the field-portable mass spectrometer has undergone testing as part of Next Generation Chemical Detector program. Additional work to develop prototypes of the Chemical Agent Raman Detector and the Single Particle, Infrared Elastic Scattering aerosol chemical detection technologies is also underway, with delivery of each prototype sensor system anticipated in FY15 for testing. The CBDP also developed a supplemental filter composite for use on the masks that protect users against additional toxic chemical threats.

The CBDP successfully transitioned the Threat Characterization Consortium sequencing data of Biosafety Level (BSL)-2 and BSL-3 bacteria to other government agencies including the FDA, CDC, and the Department of Homeland Security (DHS) in FY14. These transitions support development databases to rapidly detect and appropriately respond to biothreats and pathogens of national security concern.

Additionally, the CBDP has partnered with the Maryland Transit Administration (MTA) to evaluate a chemical detector system capable of detecting and identifying toxic industrial chemicals and CWA in the Baltimore, Maryland transit system. The MTA is planning to install the detector in the Baltimore transit system in late 2014 or early 2015.

2. DARPA Coordination⁹

The CBDP Enterprise collaborated with DARPA on innovative diagnostic sample collection, preservation, and analysis technologies to mature these technologies to address specific needs of the Joint Force for use in austere environments. DARPA provided programmatic updates, presentations, or technical expertise in the areas of threat reduction, biodefense, diagnostics, viral forecasting, biosurveillance, and regulatory reviews including the National Academy of Sciences Committee on the DoD's Programs to Counter Biological Threats and the 2014 JASON Study with HHS. JASON is an independent scientific advisory group that provides consulting services to the U.S. government on matters of defense science and technology.

3. CB threat studies and risk assessments

In FY14, CB threat studies and risk assessments were undertaken by the CBDP and interagency to inform CBDP activities and investments. A consolidated list of studies is included in Enclosure C.

⁹ Title 50 U.S. Code 1523 (b) 10: A description of the coordination and integration of the program of the Defense Advanced Research Projects Agency (DARPA) on basic and applied research and advanced technology development on chemical and biological warfare defense technologies and systems under section 1522(c)(2) of this title with the overall program of the Department of Defense on chemical and biological warfare defense, including—(A) an assessment of the degree to which the DARPA program is coordinated and integrated with, and supports the objectives and requirements of, the overall program of the Department of Defense; and (B) the means by which the Department determines the level of such coordination and support.

Maintain Infrastructure

The CBDP Enterprise maintains infrastructure to meet current and future needs for personnel, equipment, and facilities within funding constraints and to adapt to those needs as conditions change through policy, training and education activities, and maintenance of physical and intellectual infrastructure capabilities.

A. Policy, Training, and Education

The CBDP Enterprise continued to develop and integrate Joint CBRN defense capabilities in support of the national military strategies. Enclosure D details the readiness exercises, while Enclosure E details the courses and attendees for training activities given in FY14.

1. Policy

The CBDP implemented the U.S. Government Policy on Dual Use Research of Concern (DURC) for its funded research programs. DURC is life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety. Additionally, the CBDP re-wrote its CB agent security policies. Both policies emphasize security options based on site-specific assessments, and the biological security policy reflects Presidential Executive Order 13546 requirements¹⁰. The CB agent security policies assign responsibilities to DoD components and provide procedures for physical security, information security, and personnel reliability for handling Biological Select Agents and Toxins and chemical agents. With more than 150 working group members providing input, the CB agent security policies now capture consensus text and views of the working group in a manner that permits options based on site-specific assessments.

The CBDP has made tremendous progress as it coordinates Chemical, Biological, and Radiological (CBR) defense requirements and capability development with Australia, Canada, and the United Kingdom through the CBR MOU. The CBR MOU is the premiere multilateral mechanism for international engagement within the CBDP. The four member nations of the CBR MOU are collaborating across the spectrum of CB defense technology development and fielding of capabilities. The agreement provided the basis for participation in live agent outdoor field trials in the United Kingdom, where the U.S. was able to test equipment in realistic situations and gather important data to inform improvement and performance measures.

2. Support of the Force's CBRN defense capabilities through education, training, and exercises¹¹

U.S. Army

The Maneuver Support Center of Excellence (MSCoE), U.S. Army Chemical, Biological, Radiological, and Nuclear School (USACBRNS), and partner CBRN Service schools continue to provide superior joint Military Service-specific CBRN training and education at Fort Leonard Wood (FLW), Missouri. The

¹⁰ Executive Order 13546, Optimizing the Security of Biological Select Agents and Toxins in the United States, July 2, 2010.

¹¹ Title 50 U.S. Code 1523 (b) 4: The status of nuclear, biological, and chemical (NBC) warfare defense training and readiness among the Joint Force and measures being taken to include realistic nuclear, biological, and chemical warfare simulations in war games, battle simulations, and training exercises.

USACBRNS was recognized and accredited by the U.S. Army Training and Doctrine Command (TRADOC) as an Institution of Excellence, the highest level of accreditation offered by TRADOC. Additionally, during FY14, USACBRNS worked with expert professional organizations and various agencies to enhance its technical courses such as the Defense Support of Civil Authorities (DSCA) CBRN consequence management curricula. MSCoE and USACBRNS also initiated formal planning efforts to provide four of the Services with a modern CBRN defense facility at FLW that will enhance the quality and realism of CBRN defense training and education. USACBRNS partnered with ECBC and the Geisel School of Medicine, Dartmouth College to publish the *Guidelines for Mass Casualty Decontamination During a HAZMAT/Weapons of Mass Destruction Incident*, for use by emergency management personnel.

In 2014, the USACBRNS conducted more than 40 resident and non-resident CBRN courses, graduating more than 6400 students from all Services and more than a dozen countries (see Enclosure D, Fort Leonard Wood CBRN Courses).

U.S. Air Force

Over 106,000 Airmen completed the new CBRN Defense Awareness course, which takes 33% less time to complete than the course it replaced. The course incorporates technological and content innovations to improve comprehension and knowledge retention. The U.S. Air Force also developed a comprehensive and standardized emergency responder training and assessment guidance, known as the Response Training and Assessment Program (RTAP), to be rolled out in 2015. RTAP provides installations with a set of tools to optimize cross-functional first/emergency response planning, training, exercising, and assessing. Additionally, the U.S. Air Force is implementing Biological Detection Concept of Employment (BDCOE). BDCOE is a layered defense system designed to provide multiple opportunities and avenues for commanders to ensure affected locations are aware of specific biological weapons attacks in time to effectively implement the appropriate medical treatment measures.

U.S. Navy

U.S. Navy updated training systems plans, course curricula, and shipboard practices using the standards outlined by the current Naval Ships' Technical Manual Chapter 470 for Shipboard Biological Warfare/Chemical Warfare Defense and Countermeasures. These changes include an established shipboard decontamination station training unit at FLW and updated curricula for decontamination and collective protection system operations and maintenance courses. These changes were addressed during four decontamination drills and trained on 75 ships currently operating and maintaining CBR defense systems and equipment. Navy also completed a training exercise aboard the USS ESSEX for casualty decontamination procedures. Navy filmed the exercise to develop future training media. Navy has also developed a new instruction, COMNAVAIRPAC/COMNAVAIRLANT Instruction 3100.10A, CBR Defense Training and Readiness. This instruction establishes and implements CBR defense training and readiness programs and provides requirements and procedures that enable individuals, units, ships, and personnel to survive and operate in a CBR environment.

U.S. Marine Corps (USMC)

USMC incorporated CBRN awareness into training and readiness manuals at all levels of training. Marines were trained using the individual training standards outlined in the Marine Corps Common Skills manuals and Marine Corps Order 3400.3G, *CBRN Defense Training Requirements*. Due to an update in the Marine Corps CBRN Training and Readiness Manual, CBRN Specialists now receive increased training in hazardous material operations, resulting in an increased certification level. This training is being conducted in participation with the USACBRNS in FLW. In conjunction with CBRN training, all Marines completed an Individual Protective Equipment confidence exercise as well as collective CBRN

training during exercises and pre-deployment training. USMC conducted a CWMD Capabilities Based Assessment (CBA) and combined the results with their CWMD Operational Concept and Marine Air Ground Task Force (MAGTF) CBRN Operating Concept into the Marine Corps Warfighting Publication (MCWP) 3-37, *CBRN Support to CWMD Operations*. As a result of the CWMD Operational Concept and CWMD CBA, USMC updated the MCWP 3-37, *MAGTF CBRN Support for CWMD Objectives*, providing tactical-level solutions to strengthen its ability to conduct and support CWMD operations.

Office of the Assistant Secretary of Defense for Health Affairs (OASD)HA through the Defense Health Agency

CBRN defense training provided by the OASD(HA) or funded by the Defense Health Program for healthcare providers and planners occurs through the Armed Forces Radiobiology Research Institute (AFRRI); Defense Medical Readiness Training Institute (DMRTI); U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID); and USAMRICD. AFRRI provided numerous Medical Effects of Ionizing Radiation Courses in FY14. DMRTI provides basic Chemical, Biological, Radiological, Nuclear, and High-Yield Explosive (CBRNE) Training to the tri-service medical personnel corps. USAMRIID and USAMRICD provided in-residence courses in FY14, including the Field Management of Chemical and Biological Casualties Course, Medical Management of Chemical and Biological Casualties Course, and Hospital Management for CBRNE Incidents Course.

B. Maintenance of CBDP Physical and Intellectual Infrastructure Capabilities¹²

1. Industrial Base Update

The JPEO-CBD's Joint Logistics Advisory Council for Chemical and Biological Defense Industrial Base Working Group's (IBWG) core assessment areas included CBDP items, Organic Industrial Base (OIB), and Critical CBRN Manufacturers. The IBWG executed several key initiatives during FY14, to include:

- Supporting the Defense Production Act Title III Activated Carbon Manufacturing Base project with technical, business, and production information to ensure that DoD requirements are achieved.
- Surveying CBRN manufacturers in support of the Thirty Year Assessment project which will encompass products in all life-cycle phases with the end state objective of identifying technological, production, and transitional risks and issues.
- Assessing the OIB in support of the U.S. Army Materiel Command's OIB Workforce Fragility and Criticality (FaC), which incorporates OSD FaC assessment criteria to identify critical workforce skills and determine the fragility of the identified skills.
- Analyzing select CBRN manufacturers with the end state being to present greater CBRN sector trends, paying special attention to financial ratio standings, production capabilities, and emerging technologies.

Contributing factors that influence the domestic and global production base include availability of raw materials, research and development focus areas, and the increased life cycles of CBRN defense equipment. Currently, the major challenge facing the CBRN defense industrial base (IB) is the constrained investment level coupled with uncertain operational tempo created by regional and

¹² Title 50 U.S. Code 1523 (b) 2: The status of research and development programs, and acquisition programs, for required improvements in chemical and biological defense equipment and medical treatment, including an assessment of the ability of the Department of Defense and the industrial base to meet those requirements.

international CBRN-related incidents and associated requirements. Although the CBRN defense IB will continue to face these challenges, the IBWG mission is to develop and execute the processes to proactively identify and mitigate risks enabling the CBRN defense IB's ability to remain responsive in the support of readiness for the Joint Force.

2. State-of-the-Art Capabilities

Through its contract partners, the CBDP MCM Advanced Development and Manufacturing (ADM) capability Joint Product Support Office began construction of the ADM facility, placed procurement orders for major equipment items, and continued consultations with the FDA regarding facility design during FY14.

The CBDP's Advanced Chemistry Laboratory (ACL), a state-of-the-art facility designed for working with the most toxic agents known to man, was completed in summer 2014. The ACL also has the flexibility to address evolving chemical threats and assist leadership with their decision-making. This facility provides the CBDP the capability to conduct groundbreaking chemical research that benefits the nation's Joint Force.

3. Test and Evaluation

In FY14, the CBDP T&E community led the implementation of an improved Enterprise process to efficiently plan, develop, and sustain core T&E infrastructure. The *CBDP T&E Infrastructure Analysis and Decision Process* was published to define the process. In addition, the CBDP continued to lead the effort to establish whole-of-government CBRN T&E standards through the Joint Service, federal interagency TECMIPT. CBRN T&E standards inform T&E infrastructure planning and provide the highest quality data for analysis to inform decision makers while enabling test data sharing across the federal government. To date, this ongoing effort produced 43 T&E standards documents that cover T&E and test infrastructure, 13 of which are standard test methodologies that are published on the National Institute of Standards and Technology website. The T&E community published the *CBRN T&E Standards Establishment Process* and updated the version of the original 2010 TECMIPT guiding document, with full CBDP Enterprise concurrence.

Additionally, the CBDP expanded its international T&E collaboration by presenting the TECMIPT T&E standards establishment process at the European Defense Agency's (EDA) Biological Detection, Identification, and Monitoring workshop in Brussels, Belgium, the first time the U.S. participated in this forum. The presentation yielded multiple international collaborations to develop T&E standards with the EDA and its member countries.

OASD(NCB/CB) and the Deputy Under Secretary of the Army for Test and Evaluation Office (DUSA-TE) co-sponsored the Sophos/Kydoimos (S/K) Challenge in September 2014 at WDTA. The purpose of the S/K Challenge is to enable the chemical and biological defense community, both government and industry, to gain early insight of system capabilities in a real world threat scenario. Open to industry, government, and international CB defense communities, the S/K Challenge included participants from 17 companies, several DoD and Federal organizations, as well as Israel, Norway, Poland, the United Kingdom, Australia, and Canada. This event resulted in plans for T&E collaboration with each of these countries. The U.S. Army Test and Evaluation Command plans to make the S/K Challenge an annual event.

The T&E community continued to support the national biosurveillance strategy by leading an interagency collaboration to begin development of biological assay T&E standards. This effort is ongoing and will provide significant benefit for developing and evaluating biological assays for environmental detection equipment.

Lead the Enterprise

The CBDP is leading the Enterprise Components to integrate and align activities toward fulfillment of the CBDP mission through identifying issues and areas for improvement, as well as leading Enterprise-wide initiatives and collaborative efforts.

A. Issues Encountered or Areas for Improvement¹³

The CBDP is addressing quality concerns in the Advanced Anticonvulsant System and Convulsant Antidote for Nerve Agent, which potentially would result in a production shortage. The CBDP Enterprise Components have met continually to remain up-to-date on the issues and take action, such as the issuance of a Request for Information on current industry interest and capability to develop an autoinjector drug-delivery device.

The Government Accountability Office (GAO) completed two audits on the CBDP in 2014. In one, GAO found that the DoD has strengthened coordination on MCMs that respond to biological threat agents, but can still improve its process for threat prioritization. In response, the CBDP has modified existing reviews and discussions on threats to improve the process, ensuring current and future threats are being appropriately addressed. In the second, GAO recommended development of a DoD NTA Strategy and interim guidance on NTAs that can be widely distributed to CBRN and other military units. In response, the CBDP initiated development of the DoD NTA Strategic Guidance Fiscal Year 2015 to 2020, which will increase coordination and collaboration. A third GAO audit assessing the status of CBDP Infrastructure is ongoing. Facility site visits and field data collection have been completed, and the final report publication is anticipated in calendar year 2015.

B. Management Initiatives¹⁴

To better integrate, align, and focus Enterprise initiatives in the future, the CBDP began addressing recommendations from the FY13 Strategic Portfolio Review (SPR) in FY14. The FY13 SPR assessed how appropriately the CBDP's investments provide the Joint Force with needed capabilities and how efficiently the CBDP is managing its business processes and maintaining its critical infrastructure. The SPR panel noted several recommendations for areas in which improvements can be made to the CBDP, including development of an integrated strategy to enhance engagements with other communities/agencies through the Risk Assessment Working Integrated Product Team; conduct of a complete infrastructure assessment to determine which capabilities to keep and which to terminate; and assessment of the roles and responsibilities of the CBDP Component organizations to identify if realignments are appropriate.

¹³ Title 50 U.S. Code 1523 (b) 6: Problems encountered in the chemical and biological warfare defense program during the past year and recommended solutions to those problems for which additional resources or actions by the Congress are required.

¹⁴ Title 50 U.S. Code 1523 (b) 5: Measures taken to improve overall management and coordination of the chemical and biological defense program.

In FY14, the Enterprise also executed CBDP-wide collaborative management efforts, including the Senior Scientist Board (SSB). In FY14, the SSB convened several meetings, with the primary functions of 1) engaging the Military Services on their concepts of operation, capability needs, and gaps for input to the technology objective activities; and 2) discussing the core capability/competency input received from the CBDP Military Service Laboratories.

Path Forward

The Department's efforts to defend against CBRN threats will strengthen as the CBDP Enterprise continues to prioritize increasing requirements to counter WMD threats; address numerous national, Departmental, Service, and Combatant Command priorities; and allocate available resources to balance modernization goals and objectives. This prioritization will facilitate continued delivery of militarily significant, multi-purpose capabilities that will enable deterrence, prevention, protection, mitigation, response to, and recovery from CBRN attacks in defense of the Joint Force and the nation.

The CBDP Enterprise will continue to focus in the near term on the following activities:

- Updating doctrine and TTP to effectively address biological and NTA defense challenges, acknowledging any technology or utility gaps.
- Implementing additional Better Buying Power 3.0 and research and development best practice recommendations.
- Providing increasingly effective and efficient management and oversight structures and processes where appropriate.

The DoD will continue to invest in CBRN defense efforts to define and develop transformational capabilities, provide operational capabilities to the Joint Force, sustain the Force to operate jointly and effectively, and improve management practices to fulfill Enterprise strategic roles and missions. The DoD will utilize innovative program management techniques to develop and field CBRN defense equipment that meets the challenges associated with both individual service and joint threat profiles and operating environments. The CBDP's FY14 accomplishments have prepared the Joint Force and the nation to deter, prevent, protect against, mitigate, respond to, and recover from CBRN threats and effects as part of an end-to-end, layered, integrated defense.

Enclosure A: CBDP Enterprise Stakeholders

- Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD(NCB))
- Deputy Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs/Chemical and Biological Defense (DASD(CBD))
- Combatant Commands (CCMD)
- Defense Threat Reduction Agency (DTRA) Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD)
- Joint CBRN Defense Program Analysis and Integration Office (PAIO)
- Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD)
- Joint Requirements Office for Chemical and Biological Defense (JRO-CBRND)
- National Guard Bureau
- Office of the Army for Test and Evaluation (CBRN Defense Test and Evaluation (T&E)) Executive
- Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA))
- The Joint Staff
- U.S. Military Services
- Other DoD agencies

Enclosure B: FY14 CBDP Fielding Accomplishments and Quantities

The CBDP fielding accomplishments and quantities in FY14 are detailed below.

Description of Fielding Accomplishment
<p>Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) completed fielding of Domestic Response Capability (DRC) Kits to all 57 National Guard Bureau's Weapons of Mass Destruction Civil Support Teams (WMD CST). The DRC Kit was developed by JPEO-CBD in response to a 2011 Operational Need Statement requesting Non-Traditional Agent (NTA) detection, protection and decontamination for the WMD CSTs. Fielding began in July 2012 and was completed in March 2014.</p>
<p>JPEO-CBD sponsored and published results of testing involving fielded commercial-off-the-shelf (COTS) and government-off-the-shelf (GOTS) and detection and individual protection products against select NTA. The data informed analysis of existing capabilities to assess operational gaps and risks and may be used to inform supplemental tactics, techniques, and procedures for chemical defense.</p>
<p>JPEO-CBD continued to field the Joint Chemical Agent Detector (JCAD) M4A1 to U.S. Army and National Guard Bureau units in FY14. The JCAD M4A1 and the JCAD M4 systems provide low cost portable Chemical Warfare Agent detection to individuals throughout the Joint Services.</p>
<p>JPEO-CBD completed production of the Joint Biological Point Detection System (JBPDS) in 2014. The JBPDS began Low-Rate Initial Production in 2001, and was initially fielded as a component of the Biological Integrated Detection System in 2003. A total of 990 JBPDSs have been procured for use by the Army, Army Reserve, National Guard, and Navy. The program is on schedule to transition to sustainment in September 2015.</p>
<p>JPEO-CBD approved entry of the Chemical, Biological, Radiological, and Nuclear Dismounted Reconnaissance Sets, Kits, and Outfits (CBRN DR SKO) program into Full Rate Production following verification the Operational Effectiveness, Suitability, and Survivability of the CBRN DR SKO during a September 2013 Multi-Service Operational Test. The CBRN DR SKO consists of COTS and GOTS equipment to provide detection, presumptive identification, sample collection, marking, personnel protection, decontamination, and immediate reporting of standard nuclear, biological, and chemical (NBC) hazards, to include toxic industrial chemicals.</p>
<p>JPEO-CBD completed full rate production of sensor suites for the Stryker Nuclear, Biological, and Chemical Reconnaissance Vehicle. The sensor suite provides NBC Reconnaissance capabilities to Armor Brigade Combat Teams, Stryker Brigade Combat Teams, and Army Chemical Companies.</p>
<p>JPEO-CBD's Uniform Integrated Protection Equipment Increment 1, which provides improved individual protective capabilities through reduced weight, bulk, and thermal burden, received a Full Rate Production decision in March 2014 that allowed the initiation of fielding to the United States Special Operations Command.</p>
<p>JPEO-CBD continued fielding its Joint Service General Purpose Mask, which provides improved face, eye, and respiratory protection against CB agents, to include toxins; radioactive particulates; and toxic industrial materials.</p>
<p>JPEO-CBD's Joint Warning and Reporting Network (JWARN) web application successfully completed Full Operational Test at the Army's Network Integration Evaluation 14.1 and the follow on Army Interoperability Certification event, both on the Army's Common Operating Environment version 1. JWARN then underwent a successful Joint Operational Test by U.S. Forces in the Republic of Korea during the exercise Ulchi Freedom Guardian 2014.</p>
<p>JPEO-CBD's JWARN program completed post-Operational Test updates and fielded to 29 Global Command and Control System - Joint sites worldwide.</p>
<p>The Joint Project Manager for Protection outfitted the motor vessel (M/V) Cape Ray for the destruction of Syria's declared chemical weapons. Collective protection was added to the ship's house and temporary deck berthing space. The effort included design, procurement, fabrication, installation, testing, and training of the crew. The entire outfitting process was completed within seven weeks. Installation of collective protection on the M/V Cape Ray provided the ship's personnel with working locations safe from potential chemical incidents.</p>

Product/System	Total Fielded to the Warfighter in FY14 (Military Services and/or Combatant Commands)
Joint Project Manager (JPM) Nuclear, Biological, Chemical Contamination Avoidance	
CBRN DR SKO	11
DRC – Lite	15
IPDS-LR	28
M4A1 JCAD	3,765
M98 JBPDS	6
NBCRV VCT	10
AP4C	40
JPM Guardian	
Blauer XRT	1,125
BlauerMT 2012	5,225
Globe CBRN Boot	640
HazMatID360	57
HAZMAX Boot	6,200
IBAC	91
LionMT94FE	480
MultiRAE Pro	32
OneSuit Pro	268
RAID-M	119
JPM Protection	
JSGPM	117,005
UIPE Incr 1	7,634
JPM Medical Countermeasure Systems (MCS)	
JBAIDS Assay Kits	3,740
CANA	17,566
SNAPP	11,640
Total Products/Systems Fielded	175,697
Product	Total Fielded to the Warfighter (Military Services and/or Combatant Commands)
JPM MCS	
Anthrax Vaccine Adsorbed	523,130
Smallpox Vaccine	21,500
Total Medical Countermeasures Acquired from the Strategic National Stockpile (Doses)	544,630

Enclosure C: NCB Experiments and Studies

The CBDP executed or participated in numerous experiments and studies in FY14. These efforts are detailed below.

Description	Status
Joint Requirements Office for Chemical and Biological Defense (JRO-CBRND)	
A study was conducted and resulted in Joint Requirements Oversight Council approval for Outside of the Continental United States-use of the United States Marine Corps Chemical Biological Incident Response Force, placement of a key laboratory, and headquarters on a heightened state of deployment readiness, and inclusion of all chemical, biological, radiological, and nuclear defense units in the Global Force Management Implementation Guidance.	Complete
Two operational experiments were conducted to establish Elimination-related capability gaps and develop a formal Joint Concept to Prevent the Use and Transfer of Weapons of Mass Destruction. This concept is the first of two to replace the 2007 Joint Integrating Concept and draws significantly on U.S. Special Operations Command lessons learned over the past 12 years of counter terrorism operations.	Complete
A multi-year effort was completed on Response to Unforeseen Biological and Chemical Hazards. This study is forming the basis for new requirements and operational concepts that better position us for dealing with strategic technical surprise and “black swan” events.	Complete
An Integrated Risk Assessment was conducted to prepare U.S. Forces to prevail on a future battlefield. Informed by the Defense Intelligence Agency 2013 Chemical, Biological, Radiological, and Nuclear Warfare Capstone Threat Assessment, plausible operational futures over the near, mid, and long-term were identified. This analysis became the foundation for the scenario-based Operational Risk Assessment. The compiled results from the Risk Methodology guided the CBDP Enterprise in visualizing and forming a comprehensive risk assessment of the operational hazards, threats, and challenges that U.S. Forces may face.	Complete
The first comprehensive Operational Risk Assessment in support of OASD(NCB) Program decisions and requirements was conducted. This effort used approved Defense Planning Scenarios to ascertain and quantify the impact of current and future adversary weapons of mass destruction capabilities on amphibious, land force, air, and littoral operations. It was conducted in close cooperation with the Services, other Joint Staff Directorates, the Defense Threat Reduction Agency, and JPEO-CBD.	Complete
A formal process was established for coordinating threat support to operational analysis and requirements development. This includes: the first formal Joint Staff CBRND Priority Intelligence Requirements list process, relocations, and restructuring of the Joint Threat Support Branch resulting in cost savings and increased production, and formal analysis of the 2013 Chemical Biological, Radiological, and Nuclear Warfare Capstone Threat Assessment.	Complete
An Advanced Threat-to-Risk Study examining Advanced Toxins was published. This document was the first in a series of critical studies which will ensure that CBRND requirements take into account advancing technologies so as to avoid over- or under-reactions to emerging threats. Six additional studies (operational impacts of three novel types of NTAs, encapsulation, anti-material agents, and emerging infectious diseases) were also initiated.	Ongoing
Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD)	
Toxicological Studies	
Validated constant concentration toxicity data to predict effects for time-varying concentration conditions in a real-world hazard release. The results were published by Toxicological Sciences.	Complete
Completed studies of the toxicokinetics of NTAs to develop a physiologically-based pharmacokinetic model of how agents are distributed throughout the body after absorption.	Complete
Conducted studies into the contact hazard and bioavailability of priority NTAs. Findings contributed to interim toxicological estimates discussed in the NTA section of this report.	Ongoing

Initiated an effort to develop the first qualified animal model for inhalational <i>Burkholderia</i> .	Ongoing
Therapeutic-related Studies	
Submitted an NDA to the FDA for treatment of inhalational plague with moxifloxacin.	Complete
Demonstrated efficacy for ZMapp in non-human primates for treatment of Ebola virus infection when given as late as 5 days post-infection.	Complete
Continued activities to produce novel bioscavenger molecules with efficacy against nerve agents with increased drug safety and reduced costs.	Ongoing
Continued research on a medical countermeasure (MCM) with proven efficacy against <i>B. pseudomallei</i> and multi-drug resistant clinical pathogens.	Ongoing
Identified the first small-molecule therapeutic that protects nonhuman primates from Marburg virus as long as 48 hours post-infection.	Ongoing
Developed and advanced a monoclonal antibody cocktail therapy against alphaviruses including Venezuelan equine encephalitis virus (VEEV), Eastern equine encephalitis virus (EEEV), and Western equine encephalitis virus (WEEV).	Ongoing
Identified 27 FDA-approved drugs with activity against Middle East respiratory syndrome and severe acute respiratory syndrome viruses as potential MCMs.	Ongoing
Vaccine-related Studies	
Continued investigating the protective capacity of novel, broad spectrum, subunit vaccine formulations for development of a broad-spectrum multivalent <i>Burkholderia</i> vaccine candidate	Ongoing
Phase I clinical trial for the ricin vaccine (RVEc) identified an alternative mutant protein with satisfactory yield, stability, and in vitro potency.	Ongoing
Initiated a Phase I trial of deoxyribonucleic acid (DNA)-based vaccine against VEEV.	Ongoing
Developing a non-human primate model to evaluate vaccines for VEEV, EEEV, and WEEV.	Ongoing
Other	
Developed a library of eight strains of "barcoded" biological spores for use as agent simulants. The barcodes are small DNA tags that can be used to track the material in the environment.	Complete
Continued investigating immunological responses to <i>B. pseudomallei</i> .	Ongoing
Continued identifying small molecule inhibitors of filovirus.	Ongoing
Continued developing a novel ribosome inhibitor with a reduced rate of resistance development and enhanced potency against <i>Francisella tularensis</i> , <i>B. pseudomallei</i> , and <i>B. mallei</i> .	Ongoing
Began developing GSK'944 as a potential candidate technology as part of the Countermeasures for Multidrug-Resistant Bacteria Program.	Ongoing
Investigated resistant and potentially reactive coatings for aircraft while developing acceptance standards for chemical agent resistance for the Chemical Agent Resistant Coating MIL-DTL.	Ongoing
Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD)	
A series of NTA scoping tests were being conducted to investigate air shock pressure damage to containers. The data will be used to validate the Industrial Facilities and Industrial Transportation source term models currently in use in the Joint Effect Model (JEM) Science and Technology Prototype/Hazard Prediction and Assessment Capability and JEM.	Ongoing

Enclosure D: Exercises and Technology Demonstrations

The CBDP executed and participated in a number of exercises and technology demonstrations in FY14. These events are detailed below.

Date	Exercise/Demonstration Objectives
Objectives: Facilitate Collaboration and Information Sharing	
November 3, 2013	The annual North Atlantic Treaty Organization (NATO) "Steadfast Jazz" exercise addressed alliance chemical, biological, radiological, and nuclear (CBRN) response.
March 31 – April 4, 2014	Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) provided technical expertise to the military exercise Saber Guardian 14. Training objectives included international cooperation between military and civilian authorities in science, medicine, and disaster preparedness. The exercise was conducted in Bulgaria and included 13 additional partner nations.
April 1-4, 2014	JSTO-CBD, Armed Forces Health Surveillance Center, U.S. Northern Command, Department of State, U.S. Department of Health and Human Services (HHS)/Assistant Secretary for Preparedness and Response, HHS/Centers for Disease Control and Prevention, United States Department of Agriculture, and 11 Latin American nations participated in a biosurveillance (BSV) Workshop hosted by U.S. Southern Command in Miami, FL to improve national level coordination among different ministries and regional information sharing mechanisms to improve BSV systems.
June 2013 – February 2014	U.S. Strategic Command and U.S. Pacific Command co-led a BSV information tabletop exercise (TTX) to identify and document interaction among BSV stakeholders, resulting in the generation of a Baseline Operational Assessment report which will aid non-materiel recommendations from the BSV Joint Doctrine, Organization, Training, Materiel, Leadership, Personnel, Facilities, and Policy change Requirement.
August 11 – 14, 2014	Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) sponsored the Able Response 2014 exercise in South Korea, during which the United States Forces Korea (USFK) Biosurveillance Portal (BSP) facilitated unclassified collaboration and information sharing within and across more than 30 organizations from three countries to support the detection, management, and mitigation of man-made and naturally occurring biological events. Deputy Under Secretary of the Army for Test and Evaluation participated in the evaluation of the USFK BSP, a tool that can be used by the Republic of Korea/U.S. Forces to prepare for and respond to naturally occurring or intentional biological incidents.
Objectives: Technology Demonstrations	
Complete	The Hazard Mitigation, Materiel and Equipment Restoration (HaMMER) advanced technology demonstration (ATD) transitioned to the Joint Project Manager for Protection, providing state-of-the-art technology options for decontamination, strippable protective coatings, and agent disclosure/decontamination assurance. HaMMER products directly support JPEO's Contamination Indicator, Decontamination Assurance System, Joint Sensitive Equipment Wipe, and the Joint General Purpose Decontaminant for Hardened Military Equipment Programs of Record. The ATD's Capstone document, the Joint Military Utility Assessment, indicated that the hazard mitigation capabilities demonstrated through HaMMER had high utility in enhancing the decontamination mission.
Ongoing	JPEO-CBD addressed USFK and U.S. Pacific Command biosurveillance and biodefense requirements through the Joint USFK Portal and Integrated Threat Recognition ATD. Led by JPEO-CBD and supported by the U.S. Army Edgewood Chemical Biological Center, this ATD is providing specific detection and analysis resources to address the need for biosurveillance on the Korean Peninsula. The objective is to significantly increase defense capabilities to mitigate impending biological threats to USFK and the Republic of Korea.
Ongoing	The test program for the Integrated Protective Fabric System (IPFS) began in 2014. IPFS

Date	Exercise/Demonstration Objectives
	explores a range of ensemble configurations, material technologies, and concepts of use to support requirements development for CB protective uniforms. The project addresses protection against various threat levels and durations, effectiveness of the Joint Force, durability, thermal burden, and service-life. The system will transition to the Uniform Integrated Protective Ensemble Increment 2 Program of Record in 2015.
Ongoing	The Joint Biological Agent Decontamination System (JBADS) Joint Capabilities Technology Demonstration (JCTD) completed three Technical Demonstrations and initiated an Operational Utility Assessment (OUA) in 2014. The JBADS JCTD demonstrates the capability of using forced hot, humid air to decontaminate the interior and exterior of biologically contaminated aircraft. Technology and data from the JCTD will transition to the Joint Biological Aircraft Decontamination System program in 2015.
Ongoing	Six major Transatlantic Collaborative Biological Resiliency Demonstration (TaCBRD) ATD activities were conducted during 2014, including the Polish collaborative effort in the BIOSAFE Field Exercise. TaCBRD aims to develop and demonstrate the capability to counter a wide area biological incident that impacts U.S. or Partner Nation civilian personnel, military personnel, and key infrastructure. TaCBRD will provide a capability to prepare for, respond to, and recover from a biological attack.
Ongoing	JPEO-CBD presented the Installation as a System (IaaS) Concept and a Physical Security Integration Framework (PSIF) Demonstration to key stakeholders from the installation protection community, Northern Command, and National Guard Bureau. The IaaS concept provides a deliberate approach to the development of integrated and interoperable installation capabilities that can improve operational effectiveness and efficiency. The PSIF demonstration showed a potential solution utilizing a Government-off-the-shelf capability. Stakeholder consensus on the IaaS approach will enable the community to move forward in unified effort to improve installation capabilities.
February 3-7, 2014; April 10-11, 2014	The EDGE Bioinformatics Program, which provides Outside of the Continental United States laboratories with bioinformatic tools and reach-back capability, conducted two successful demonstrations running sequence data to generate results in hours versus days and weeks.
May 13, 2014	The United States Marine Corps used the Rapid Area Sensitive-site Reconnaissance as part of a training exercise simulating nerve agent contamination at Marine Corps Air Station Kaneohe Bay, Hawaii.
July 2014	Assessment of the Air Force (AF) biological detection concept of employment to enhance the AF biological detection capability, through a TTX in the National Capital Region and a field exercise at Osan Air Base Korea.
June 15-19 2014	The JPEO-CBD Joint Effects Model (JEM) engineering support staff provided onsite support for Canada during the NATO exercise Brave Bedouin in Denmark. JPEO-CBD and the Canadian Government participated in a multinational European exercise utilizing the JEM as their chemical, biological, radiological, nuclear, and explosive hazard prediction tool. The program delivered software to Canadian Defense Forces and provided training to operational users.

Enclosure E: FY14 CWMD and CBRN Responder Training and Education

Fort Leonard Wood CBRN Courses (all Services)	Attendees
CBRN Specialist Course	2,136
CBRN Basic Officer Leader-Branch Course	311
CBRN Captain's Career Course	127
CBRN Captain's Career Course RC Phase 2	55
CBRN Captain's Career Course RC Phase 4	55
CBRN Defense (USMC)	300
CBRN Basic Warrant Officer Course (USMC)	13
Operational Radiation Safety	96
Radiological Safety	68
CBRN Warrant Officer Basic Course (Army)	16
Joint Senior Leader Course	72
Installation Emergency Management Planning	32
CBRN Recon for Brigade Combat Teams	144
Civil Support Skills Course	220
CBRN Responders Course	472
CBRN Mass Casualty Decontamination Course	630
CBRN Dismounted Reconnaissance Course	184
Civil Support Team Pre-Command Course	40
CBRN Pre-Command Course	16
Decontamination Procedures (Non-U.S.)	225
Joint Biological Point Detection System Course	254
Technical Escort Course	336
M93 Series CBRN Recon System FOX Course	38
Analytical Laboratory System Operator Course	34
Unified Command Suite Operator Course	24
Civil Support Team Operations	23
Shipboard CBR Defense Operations and Training Specialist Course (U.S. Navy)	180
Emergency Management Craftsman Course (U.S. Air Force)	93
Emergency Management Apprentice Course (U.S. Air Force)	173
Readiness Flight Officer Course (U.S. Air Force)	76
Readiness Flight Officer Course (U.S. Air Force)	14
TOTAL	6,457

Defense Medical Readiness Training Institute Courses	Attendees
Clinicians Course (distance learning)	10,458
Operator/Responder Course (distance learning)	16,076
Basic Awareness Course (distance learning)	33,329
Executive/Commander's Course (distance learning)	900
Clinicians Course (on-site)	830
Basic Awareness Course (on-site)	250
TOTAL	61,843

Armed Forces Radiobiology Research Institute	Attendees
MEIR Course	1,200
Hospital Management of Chemical, Biological, Radiological, Nuclear and Explosive (HM-CBRNE) incidents course	101
TOTAL	1,301

U.S. Army Medical Department Center and School Courses	Attendees
JBAIDS Operator Training Course	41
Patient Decontamination Course	304
Bioenvironmental Readiness and Deployment Skills	60
Enhanced First Responder	366
First Receiver Awareness	13,762
First Receiver Awareness and Operations	590
TOTAL	15,123

Edgewood Chemical Biological Center Training Courses	Attendees
ECBC CBRN Course (WMD-CST)	528
CB-2 Course (22nd & 110th Chemical Battalion)	128
Captain's Course (CBRN School)	48
Sampling Course (CBRN School)	32
CB Course	48
TOTAL	784

U.S. Army Medical Research Institute of Chemical Defense Courses	Attendees
Field Management of Chemical and Biological Casualties (FCBC) course	365
Medical Management of Chemical and Biological Casualties (MCBC) course	312
HM-CBRNE incidents course	101
Distance Learning via Defense Connect Online - Webinars	482
Off-site (Korea)	200
Off-site (Fort Bragg, NC)	64
Classified	235
TOTAL	1,759

U.S. Army Medical Research Institute of Infectious Diseases Courses	Attendees
FCBC MCBC/HM-CBRNE	665
Offsite Course, 1 Week, MCBC (Korea)	200
Offsite Course, 2 days, MCBC (Ft Bragg)	60
TOTAL	925

Enclosure F: Acquisition Program Accomplishments

FY14 acquisition program accomplishments are described below.

Anti-viral therapeutics to address Ebola and Marburg viruses

JPEO-CBD continued to develop anti-viral therapeutics to address Ebola and Marburg viruses. The emergence in 2014 of the largest outbreak of Ebola viral disease in history spotlighted therapeutics funded by JPEO-CBD, specifically TKM-Ebola and Favipiravir. The FDA partially lifted its hold on TKM-Ebola Phase 1 clinical trials to determine safety in healthy adult volunteers to allow the potential use of the product during the 2014 Ebola outbreak. Meanwhile, initial proof-of-concept experiments on non-human primates were undertaken to determine the efficacy of Favipiravir against Ebola virus.

Botulinum Toxin Vaccine

In FY14, CBDP's recombinant botulinum vaccine completed pivotal nonclinical efficacy testing and demonstrated the vaccine was efficacious – this was also required for FDA licensure under the Animal Rule. The approval of the Joint Medical Biological Warfare (BW) Agent Prophylaxis: Botulinum Toxin Vaccine Increment Capability Production Document is pending revision of the Acquisition Program Baseline.

Common Analytical Laboratory System (CALS)

When fielded CALS will provide a field analytical capability to detect, analyze, and identify chemical, biological, radiological, nuclear, and (high-yield) explosive agents and threats through its integrated suite of equipment. Approval and validation of the CALS Capability Development Document (CDD) in March 2014 provided clarity and solidification of program parameters. This resulted in the successfully released request for proposal (RFP) leading to Milestone B and the Engineering & Manufacturing Development phase. Progress was further obtained with the completion of Tier II testing and the start of Tier III testing.

Global Biosurveillance Portal (G-BSP) Information Systems

U.S. Special Operations Command validated requirements for the G-BSP through an Information Systems CDD, which formally outlines an affordable increment of militarily useful, logistically supportable, and technically mature information systems capability. The G-BSP will leverage the web-based portal used for JUPITR to enhance collaboration, planning, and awareness for special operations forces across the globe.

Joint Biological Tactical Detection System (JBTDS)

The Joint Biological Tactical Detection System (JBTDS) program entered the Engineering and Manufacturing Development Phase, which will lead to development, integration, and operational testing of a tactical BWA detection, collection, identification, and networking capability for the Joint Forces. The JBTDS Increment I CDD was completed and a RFP was released to industry to solicit proposals in a full and open competition.

Joint Warning and Reporting Network (JWARN)

JWARN Increment 2 will interface directly with chemical, biological, and radiological sensors as they are fielded. The JWARN program completed the RFP and contract award for its Increment 2 capability.

Next Generation Chemical Detector

The CBDP conducted a successful Milestone A decision for the Next Generation Chemical Detector (NGCD) and allowed the NGCD program to proceed into the Technology Maturation Risk Reduction (TMRR) phase of the Defense Acquisition System. The NGCD team successfully awarded 10 Cost Plus Incentive Fee contracts to mature technologies consistent with NGCD program requirements. The CBDP completed four NGCD CDD drafts in support of Milestone A decision and TMRR acquisition phase. The four NGCD CDD drafts are for: Increment 1, Detector Alarm; Increment 2, Survey Detector; Increment 3, Chemical Analysis; and Increment 4, Wearable Detector.

Next Generation Diagnostic System (NGDS) Increment 1

The CBDP continued to advance its NGDS Increment 1 program which will result in an improved analytical system capable of detecting and identifying the presence of BW agents and infectious diseases over the existing JBAIDS with reduced cost and manpower burden. NGDS Increment 1 will begin replacing the JBAIDS in 2017. Three vendors were down-selected to a single vendor who will provide FDA cleared medical diagnostic devices and develop in vitro diagnostic assays. In FY14, the NGDS Increment 1 CDD was completed. This CDD addresses a requirement for an analytical system capable of detecting and identifying the presence of BW agents and infectious diseases using commercial-off-the-shelf (COTS) platforms instead of DoD-specific platforms.

NGDS Increment 2

NGDS Increment 2 is intended to provide expanded diagnostics for biological pathogens and toxins, and diagnostics for chemical and radiological exposures. NGDS Increment 2 is comprised of a set of materiel solutions that provide or improve medical capabilities to diagnose exposure to BW agents for which there are no current diagnostic tests. Staged development of toxin, chemical, and radiological diagnostic capabilities are planned and will be driven by biomarker maturity. An Analysis of Alternatives was conducted for NGDS Increment 2 in FY14.

Plague Vaccine

In FY14, the CBDP's recombinant plague vaccine received acceptance from the FDA for the methods developed to determine nonclinical efficacy and cross-species comparison—critical items required for FDA licensure under the FDA's Animal Rule.

Enclosure G: Description of Testing Involving Human Subjects¹⁵

No individuals have been used as subjects of any chemical and biological (CB) agent tests in the U.S. since 1975. Human biological agent testing ended on November 25, 1969, and human chemical agent testing ended on July 25, 1975. Department of Defense continues to work with the Department of Veterans Affairs to identify and locate previous human test subjects so they can receive appropriate attention. To provide the public with the information on human exposures related to historic CB testing, the Office of the Assistant Secretary of Defense for Health Affairs maintains CB exposure databases and updates the CB Warfare Exposures website:

http://mcm.fhpr.osd.mil/cb_exposures/cb_exposures_home.aspx).

¹⁵ Title 50 U.S. Code 1523 (b) 9: A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the Department of Defense during the period covered by the report.

Enclosure H: Acronyms

ACRONYM	TERM
ACL	Advanced Chemistry Laboratory
AFRRI	Armed Forces Radiobiology Research Institute
ADM	Advanced Development & Manufacturing
ASD(NCB)	Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs
ATD	Advanced Technology Demonstration
BDCOE	Biological Detection Concept of Employment
BSL	Biosafety Level
BSP	Biosurveillance Portal
BSV	Biosurveillance
BW	Biological Warfare
CALS	Common Analytical Laboratory System
CB	Chemical and Biological
CBA	Capabilities Based Assessment
CBDP	Chemical and Biological Defense Program
CBR	Chemical, Biological, and Radiological
CBRN	Chemical, Biological, Radiological, and Nuclear
CBRN DR SKO	Chemical, Biological, Radiological, and Nuclear Dismounted Reconnaissance Sets, Kits, and Outfits
CBRNE	Chemical, Biological, Radiological, Nuclear, and High-Yield Explosive
CCMD	Combatant Command
CDC	U.S. Centers for Disease Control and Prevention
CDD	Capability Development Document
COTS	Commercial-Off-the-Shelf
CW	Chemical Weapon
CWA	Chemical Warfare Agent
CWC	Chemical Weapons Convention
CWMD	Countering Weapons of Mass Destruction
DARPA	Defense Advanced Research Projects Agency
DSCA	Defense Support of Civil Authorities
DHS	U.S. Department of Homeland Security
DMRTI	Defense Medical Readiness Training Institute
DoD	U.S. Department of Defense
DRC	Domestic Response Capability
DTRA	Defense Threat Reduction Agency
DURC	U.S. Government Policy on Dual Use Research of Concern
DUSA-TE	Deputy Under Secretary of the Army for Test and Evaluation
ECBC	U.S. Army Edgewood Chemical Biological Center
EDA	European Defense Agency
EEEV	Eastern Equine Encephalitis Virus

FaC	Fragility and Criticality
FDA	U.S. Food and Drug Administration
FDHS	Field Deployable Hydrolysis System
FLW	Fort Leonard Wood
FY	Fiscal Year
G-BSP	Global Biosurveillance Portal
GAO	Government Accountability Office
GOTS	Government-Off-the-Shelf
HaMMER	Hazard Mitigation, Material and Equipment Restoration
HHS	U.S. Department of Health and Human Services
IaaS	Installation as a System
IB	Industrial Base
IBWG	Industrial Base Working Group
IPFS	Integrated Protective Fabric System
JBADS	Joint Biological Agent Decontamination System
JBAIDS	Joint Biological Agent Identification and Diagnostic System
JBPDS	Joint Biological Point Detection System
JBTDS	Joint Biological Tactical Detection System
JCAD	Joint Chemical Agent Detector
JEM	Joint Effects Model
JP	Joint Publication
JPEO-CBD	Joint Program Executive Office for Chemical and Biological Defense
JRO-CBRND	Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense
JSTO-CBD	Joint Science and Technology Office for Chemical and Biological Defense
JUPITR	Joint United States Forces Korea (USFK) Portal and Integrated Threat Recognition
JWARN	Joint Warning and Reporting Network
M/V	Motor Vessel
MAGTF	Marine Air Ground Task Force
MCM	Medical Countermeasures
MCWP	Marine Corps Warfighting Publication
MOU	Memorandum of Understanding
MSCoE	Maneuver Support Center of Excellence
MTA	Maryland Transit Administration
MTTP	Multi-Service Tactics, Techniques, and Procedures
NATO	North Atlantic Treaty Organization
NBC	Nuclear, Biological, and Chemical
NDU	National Defense University
NGCD	Next Generation Chemical Detector
NGDS	Next Generation Diagnostic System
NTA	Non-Traditional Agent
NTADTS	Non-Traditional Agent Defense Test System

OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OASD(NCB/CB)	Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs/Chemical and Biological Defense
OIB	Organic Industrial Base
OPCW	Organisation for the Prohibition of Chemical Weapons
OSD	Office of the Secretary of Defense
PAIO	Program Analysis and Integration Office
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PIR	Priority Intelligence Requirements
RFP	Request for Proposals
RTAP	Response Training and Assessment Program
S&T	Science and Technology
S/K	Sophos/Kydoimos
SSB	Senior Scientist Board
SPR	Strategic Portfolio Review
T&E	Test and Evaluation
TaCBRD	Transatlantic Collaborative Biological Resiliency Demonstration
TECMIPT	T&E Capabilities and Methodologies Integrated Process Team
TEI	Technical Equipment Inspection
TIC	Toxic Industrial Chemical
TMRR	Technology Maturation Risk Reduction
TRADOC	U.S. Army Training and Doctrine Command
TTP	Tactics, Techniques, and Procedures
TTX	Tabletop Exercise
U.S.	United States
USACBRNS	U.S. Army Chemical, Biological, Radiological, and Nuclear School
USAMRICD	U.S. Army Medical Research Institute of Chemical Defense
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
USFK	U.S. Forces Korea
USMC	U.S. Marine Corps
USSOCOM	U.S. Special Operations Command
VEEV	Venezuelan Equine Encephalitis Virus
WEEV	Western Equine Encephalitis Virus
WDTC	West Desert Test Center
WMD	Weapons of Mass Destruction
WMD CST	Weapons of Mass Destruction Civil Support Teams