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Annual Report to Congress

May 2008

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May 2008

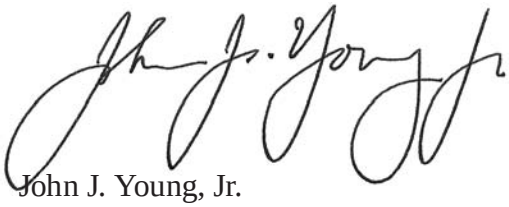
I am proud to submit the Department of Defense (DoD) Joint Chemical and Biological Defense Program (CBDP) 2008 Annual Report to Congress (ARC). This report details progress made by the Department to protect our nation and allies from current and emerging threats posed by weapons of mass destruction (WMD). It also reviews current programs which provide Soldiers, Sailors, Airmen, and Marines with the best possible chemical and biological (CB) defense training, equipment, and planning to ultimately achieve our CBDP vision of military operations wholly unconstrained by WMD effects.

The mission of DoD's Joint CBDP is to provide CB defense capabilities in support of our national military strategies. We undertake this mission in partnership with Congress, other federal agencies, academia, international partners, and the private sector. We structure this mission to be forward thinking, responsive to warfighter and national security needs, and streamlined with authority and accountability vested in specific executives. Our immediate goal is to develop, deliver, and support systems that provide strategic resilience—systems flexible enough to detect, protect, and remediate attacks by terrorists or hostile forces using a variety of WMD devices.

CBDP accomplishments include significant advances in research supporting key mission areas such as: the Transformational Medical Technologies Initiative (TMTI); strengthening chemical, biological, radiological, and nuclear (CBRN) homeland defense initiatives; maintaining a strong industrial base; improving Joint education, training, and doctrine; supporting cross-agency coordination; and establishing new international CBRN cooperative research and development agreements. To continue progress and reduce strategic risk, the CBDP must increase capacity to maintain Joint Force readiness and sustain our nation's competitive advantage. We depend on continued Congressional support in three priority areas:

1. TMTI research
2. Adequate long term investments in our laboratory and test infrastructure to ensure safe, secure, and productive operations
3. Stable resources overall to ensure that, year after year, initiatives to field improved defensive capabilities may move forward without unintended costs associated with restructuring contracts, interrupting research and development, test and evaluation (T&E) activities, and maintaining stable production lines.

With support of the President, the Secretary of Defense, and Congress, DoD will continue to develop and resource an integrated CBDP to best serve the nation, to build readiness for current and future challenges, and to sustain our Armed Forces in time of war.



John J. Young, Jr.
Under Secretary of Defense for Acquisition, Technology and Logistics

This report was coordinated and prepared by the office of the Under Secretary of Defense for Acquisition, Technology and Logistics and the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs in accordance with Title 50 U.S.C. 1523 and related requirements.

Copies of this report may be downloaded from the World Wide Web through the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs Website at http://www.acq.osd.mil/cp under the reports section as an Adobe Acrobat (.pdf) file.

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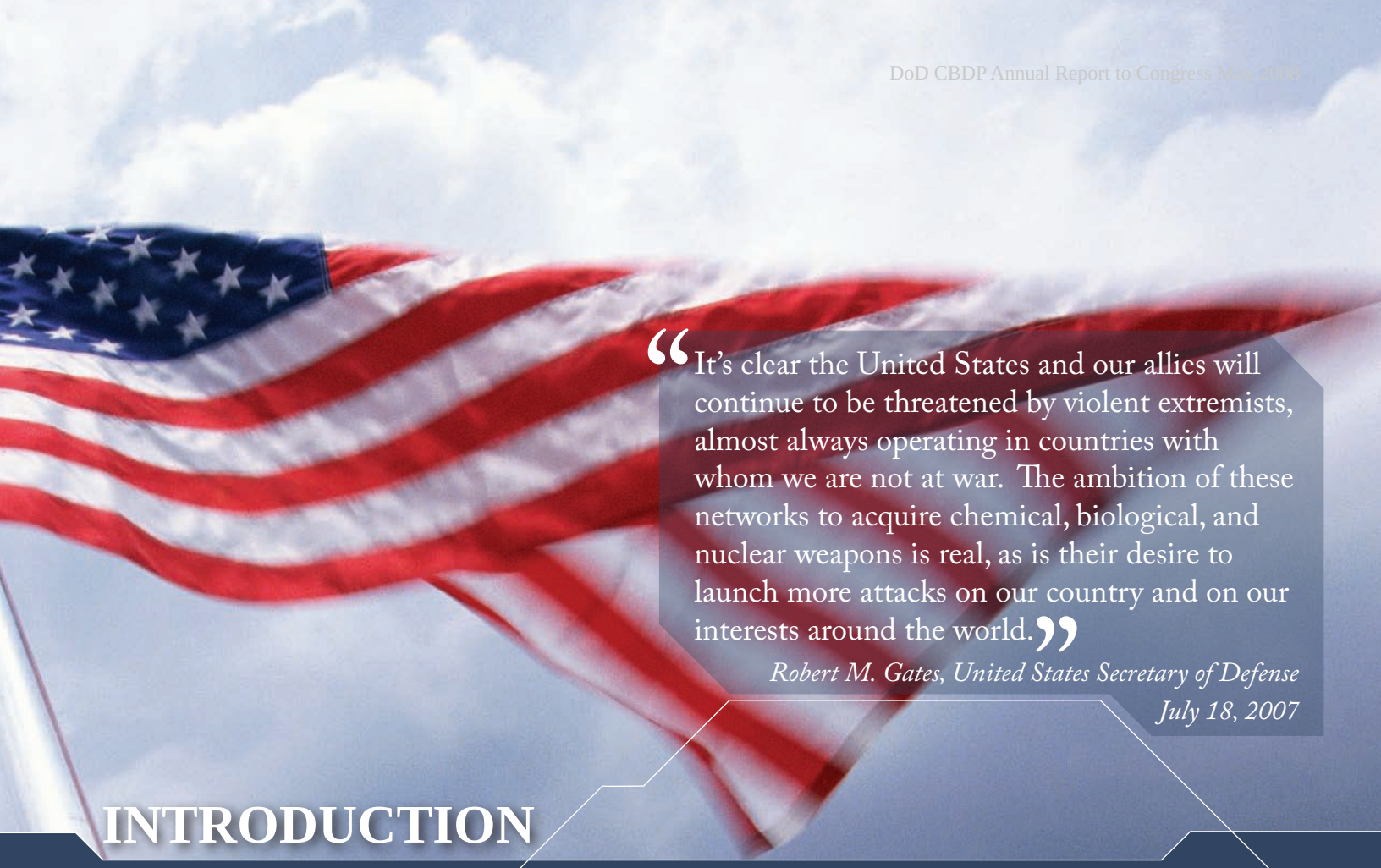


> "It's clear the United States and our allies will continue to be threatened by violent extremists, almost always operating in countries with whom we are not at war. The ambition of these networks to acquire chemical, biological, and nuclear weapons is real, as is their desire to launch more attacks on our country and on our interests around the world."
>
> *Robert M. Gates, United States Secretary of Defense*
> *July 18, 2007*

INTRODUCTION

Today, the United States Armed Forces are engaged in global operations while simultaneously protecting the homeland. Our Service members face many challenges, but the threat posed by weapons of mass destruction (WMD) is among the greatest. The Chemical and Biological Defense Program (CBDP) provides support and world class capabilities, which enable them to survive and operate successfully in chemical, biological, radiological, and nuclear (CBRN) environments.

The CBDP is an essential component of Department of Defense (DoD) efforts supporting national and military strategies to combat WMD. The CBDP supports a comprehensive strategic framework to improve CBRN defense preparedness and readiness, reduce risk to the warfighter, and field the appropriate mix of capabilities for sustained military operations with minimum degradation of combat effectiveness attributed to CBRN hazards.

In accordance with the *2006 National Military Strategy to Combat Weapons of Mass Destruction*, the DoD seeks to "dissuade, deter and defeat those who seek to harm the United States, its allies, and partners through WMD use or threat of use and, if attacked, to mitigate the effects and restore deterrence."

Research, development, and acquisition (RDA) of chemical and biological (CB) defense equipment and capabilities is executed by DoD as a Joint Service program in accordance with Title 50 United States Code (U.S.C.) 1522 (Public Law 103-160). The CBDP also addresses radiological and nuclear defense requirements; however, these activities are limited by U.S.C. 1522 to specific types of radiation detection equipment, modeling and simulation (M&S) capabilities, and medical countermeasures to treat the physiological effects of radiological and nuclear source material exposure.

This May 2008 CBDP Annual Report to Congress (ARC) is provided in accordance with Title 50 U.S.C. 1523. It describes progress made by DoD to protect our nation and our allies from the threat or actual use of WMD, and outlines management initiatives undertaken to identify and balance investment priorities against risks over time. In addition, the report:

- Outlines CBDP organizational structure, roles and responsibilities, oversight procedures, and program plans
- Describes and assesses CBDP research, development, test, and evaluation (RDT&E) programs and infrastructure, and summarizes accomplishments
- Reports CBDP equipment logistics postures
- Presents an overview of CBRN defense, doctrine, training, exercises, leadership, and education.

Chemical and Biological Defense Program Vision and Mission

U.S. Armed Forces execute a wide range of missions from traditional combat to homeland defense, civil support, installation protection, and consequence management to special operations, counterterrorism, and security. The *2006 Quadrennial Defense Review (QDR)* outlines DoD's Force Planning Construct supporting each of these mission areas. It reflects the potential for overlapping missions and tasks, operations in and from forward areas, and maintenance of capabilities and forces to wage multiple campaigns in a given timeframe. It also considers that operations may be conducted continuously (steady state) or periodically (surge). The CBDP utilizes DoD's Force Planning Construct as the foundation for identification and analysis of required capabilities to ensure that operations are unconstrained by CBRN effects. This vision brings together doctrine, organization, training, materiel, leadership and education, personnel, and facilities (DOTMLPF) and technology toward improved CB defense capabilities for our warfighters and national defense.

Of all the forms of WMD, CB weapons are among the cheapest, easiest, and quickest to produce and to deploy with the likelihood for catastrophic effect.

In turn, the CBDP's mission is to provide the best CB defense capabilities in support of the national military strategies. The following strategic goals are key to achieving success:

- **Goal 1:** Provide operational capabilities to the Joint Force to ensure they are prepared to operate successfully within all Combatant Commanders' (COCOM) area of responsibility in current CBRN threat environments to include support to civil authorities within the Homeland Defense Mission.
- **Goal 2:** Define and develop transformational capabilities to increase significantly our ability to dissuade, deter, defend, and defeat any future adversary in any CBRN threat environment.
- **Goal 3:** Sustain the capability of the Joint Force to operate jointly and provide an effective response in any CBRN crisis.
- **Goal 4:** Improve management practices to fulfill enterprise strategic roles and missions, meet the letter and intent of Title 50 U.S.C. 1522/23, and ensure effective and efficient use of Department resources in accordance with the priorities established in our national military strategies.

Impact of the Global Security Environment

Conflict is not unique to today's global environment. What has changed dramatically is the expanding roster of terrorists and antagonist nations possessing or seeking weapons with the capacity to inflict catastrophic damage on our nation. This increasingly dangerous strategic context gives urgency to countering the proliferation of WMD. CB weapons are among the cheapest, easiest, and quickest to produce and deploy. The challenge of combating WMD is compounded by the ease with which knowledge related to WMD development could be disseminated, the increasingly dual-use nature of technologies, the rapid technological advancements that continue to lower the threshold for acquiring WMD, and the development of novel threats through various techniques, including genetic engineering. Implications for the CBDP include the following:

- Our nation will continue to be engaged in a struggle of evolving conflict against adversaries employing irregular, disruptive, and potentially catastrophic strategies—including the use of terror, asymmetric attacks, and WMD to challenge, marginalize, erode, and paralyze U.S. power
- Military forces must be prepared to deal with a full spectrum of threats and must be able to operate in all WMD environments, unconstrained by CBRN effects

- CBDP must provide improved defensive equipment capabilities, trained personnel, and doctrine and logistical CBRN sustainment capabilities to prepare military units for immediate deployment from our power projection infrastructure.

Failure to address these challenges by not investing in CBDP capabilities (e.g., DOTMLPF) will increase risk to national security. Sustaining and further improving DoD's CBDP is a strategic imperative in today's global security environment.

Shaping the Chemical and Biological Defense Program

The DoD is simultaneously transforming and recapitalizing U.S. Armed Forces while prosecuting conventional operations in Iraq and Afghanistan and unconventional warfare against global terrorism. The CBDP is shaped by these events, as it must satisfy geographic combatant commander, Joint Forces Command (JFCOM), Service, and warfighter requirements; however, adequate funding and resources must be provided to address operational capability gaps and achieve modernization objectives. Failure to maintain a robust CBRN defense capability may result in unnecessary risk to our total force of Active, Guard, and Reserve Forces at home and abroad. To accomplish its strategic goals for CB defense, the CBDP continuously looks to improve its management practices and actively coordinates with other government agencies to ensure programs are coordinated and integrated, to leverage resources, and to eliminate duplication.

The CBDP also requires support from Congress in three areas which will ensure continued progress in developing and fielding capabilities to protect U.S. Forces against existing and future CBRN threats and meet critical ongoing operational needs to fill current-, near-, and far-term capability gaps in the CBDP:

1. Stable funding for the Transformational Medical Technologies Initiative (TMTI) to fully exploit advanced science and technology (S&T) innovation necessary to successfully counter future genetically engineered biological weapons
2. Adequate long-term investment in infrastructure to enhance RDT&E capabilities, including modernization and construction of laboratories and test facilities to ensure development of advanced countermeasures against current and emerging CBRN threats
3. Adequate resources to ensure procurement and fielding of improved defensive capabilities essential to the Armed Forces' ability to operate in any environment, unconstrained by CB weapons.

The CBDP is further shaped by three rapidly changing factors influenced by socioeconomic, political, and environmental impacts. These three factors are the threat, funding, and policy, as exemplified below:

- A growing strategic threat from state and non-state actors
- Identification of additional CBRN defense DOTMLPF requirements
- Planning for transition to a new force-sizing construct, and maintaining capabilities and forces to wage multiple campaigns in an overlapping timeframe
- An evolving geopolitical environment
- Continued WMD proliferation in spite of the Chemical Weapons Convention (CWC), Biological and Toxin Weapons Convention (BWC), and application of other non-military elements of national power
- The need for innovative, less costly technology approaches to support force modernization.

Threat

WMD related threats remain a primary driver for CBRN defense RDA. The potential for our adversaries to use these weapons in overseas combat operations requires continuous evolution in reconnaissance, detection, and protection equipment.

Simultaneously, a significant effort is under way to defend against asymmetric attacks by terrorists. The increased possibility of attacks on the battlefield and at home involving non-traditional agents (NTA), toxic industrial chemicals (TIC), toxic industrial materials (TIM), and genetically modified agents, underscores need for a broad-spectrum approach to passive CB defense research and development (R&D).

The potential for hostile release or dissemination of commercially available chemical materials continues to be a concern on and off the battlefield. TIC/TIMs are readily available, inexpensive, and can be easily concealed. Since many of the most frequently mentioned TIC/TIMs could be as toxic as traditional chemical warfare agents (CWA), a determined adversary could certainly use industrial poisons to cause injury and disrupt operations.

Today, and in the foreseeable future, the threat posed by the effective delivery of lethal CWAs remains one of the key concerns in the defense against catastrophic attacks. New agents are believed to be under investigation, and many traditional agents have a capacity to disrupt and degrade U.S. operations, especially if their use is unanticipated. Since 2001, the expectation has increased that smaller scale chemical warfare (CW) attacks by terrorist organizations will occur. Although the chemical threat from foreign military action remains the rationale for most chemical defense programs, increasing attention needs to be paid to the potential that lethal and effective attacks by al Qaeda, other terrorist organizations, or even independent "lone wolf" extremists may be much more likely than long-range artillery or missile attacks.

Biological warfare (BW), or bioterrorism, is expected to remain a significant threat to U.S. Armed Forces. Hostile state and non-state actors are aware of the potential catastrophic effects of a successful biological attack. U.S. intelligence agencies have documented the extent and capabilities of national- and terrorist-level adversaries. Numerous terrorist organizations have stated the goal to develop biological warfare capability and evidence gathered in Afghanistan and Iraq proves that goal. The al Qaeda organization is believed to be the primary threat in this regard.

Terrorists and various other non-state actors will present the most likely radiological threat to U.S. Armed Forces and their allies. Hostile efforts to acquire diverse radiological capabilities could lead to the development of radiological dispersion devices or "dirty bombs." The use of these weapons, in conjunction with more conventional explosives, complicates and delays investigative operations, causes widespread panic, and will most likely increase the overall psychological effectiveness of any attack.

The Director of National Intelligence recently singled out Iran and North Korea as the greatest threat to nuclear stability. These countries continue to challenge the nuclear compliance and safeguard agreements set forth by the International Atomic Energy Agency.

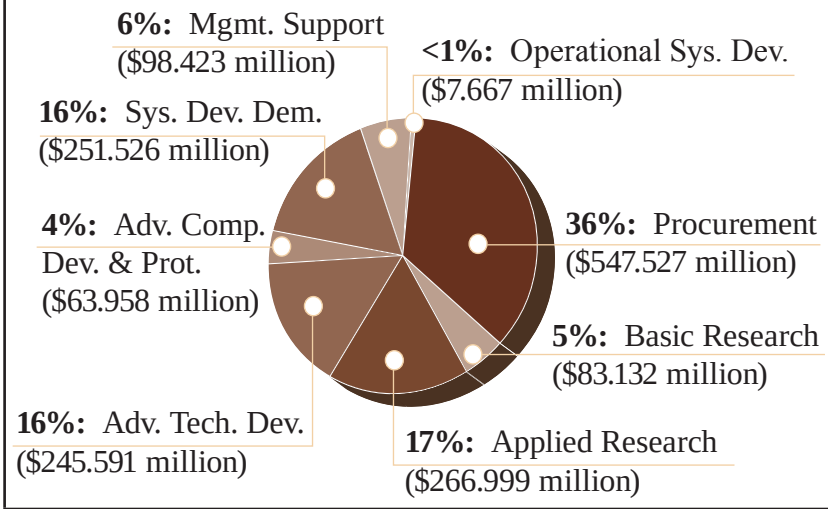
The proliferation of CBRN weapons and the potential for a WMD attack remain direct threats to U.S. interests worldwide. Treaties and international trade restrictions cannot be relied on to fully counter the ongoing proliferation of CBRN technologies, materials, and expertise. Because the United States possesses substantial military superiority, we must anticipate and prepare for selective asymmetric attacks with nontraditional tactics and means.

Funding

The CBDP budget is set forth as a separate DoD account, with a single program element for each category of RDT&E, acquisition, and military construction (MILCON). The DoD Appropriations Act for 2008 appropriated $1.565 billion to the CBDP in fiscal year (FY) 2008. Funding is apportioned between levels of research, development, and procurement to

Chemical and Biological Defense Program FY 2008 Resource Allocation

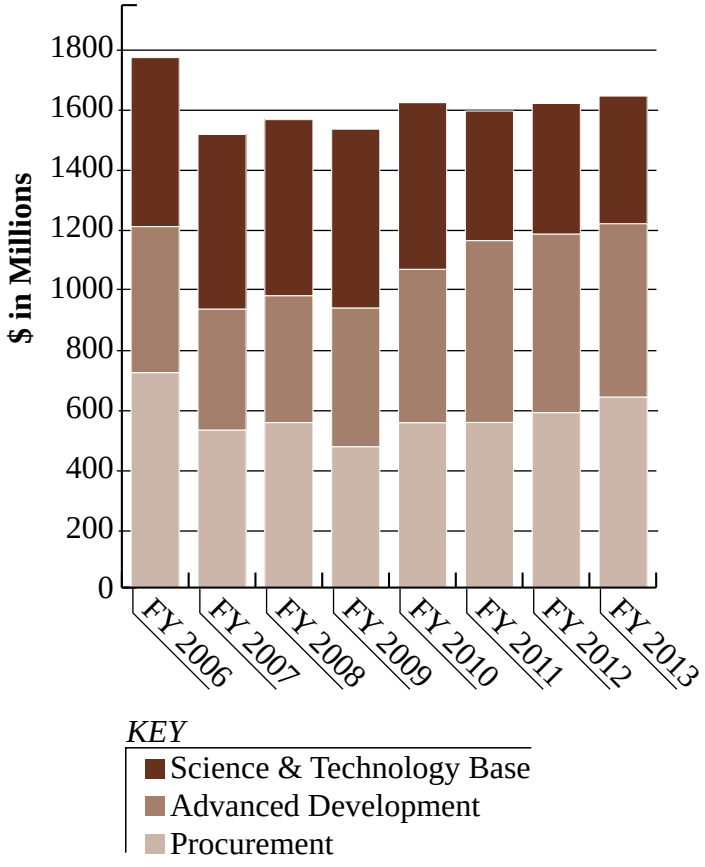
Total Funding FY 2008: $1.565 Billion



Based on 2008 Defense Appropriations Bill

Chemical and Biological Defense Program Appropriated Values FY 2006-2007

President's Budget Request FY 2008-2013



balance technology transitions, development and test schedules, production capabilities, and warfighter priorities.

To continue countering the existing and emerging CBRN threats and to gain a competitive advantage, congressional support for the CBDP's FY 2009 President's Budget Request is essential to sustain progress and to meet the critical operational needs of our warfighters and homeland defense requirements.

Operations and sustainment (O&S) funding for CBRN defense materiel is not consolidated at the DoD level. The Military Departments are responsible for separately funding replenishment and sustainment of CBRN defense secondary equipment items (e.g., consumables such as decontamination kits, detection kits, and filters). Depot maintenance and contractor logistics support for some low-density major items are also O&S-funded, and therefore not included in the Joint CBDP budget.

The figure on the previous page shows the CBDP appropriated values for FY 2006 through FY 2008 and the President's Budget Request for FY 2009 - 2014 broken out by procurement, advanced development, and S&T funds.

Our comprehensive strategy to combat WMD includes counterproliferation efforts that will be proactive, impede WMD proliferation with diplomacy and when necessary, interdict; and finally, to enhance consequence management to restore operations.

Policy and Guidance

The CBDP supports multiple national strategies and provides a strategic approach with an operative focus on deterring and preventing our enemies from threatening the United States and our allies with WMD. Specifically, the CBDP supports the President's National Strategy to Combat WMD, which acknowledges that the gravest danger for our nation lies at the crossroads of radicalism and technology. This requires cooperative initiatives with international, interagency, and industry partners to field key capabilities today, and technology thrusts that will ensure the men and women of the military always possess state-of-the-art capabilities.

Together the U.S. national and military strategies present a layered defense approach for non-proliferation, counterproliferation, and consequence management that has been codified into a DoD strategy to dissuade, deter, defend against, and defeat any potential adversary. The CBDP comprehensive strategy to combat WMD includes counterproliferation efforts that will be proactive, impede WMD proliferation with diplomacy–and when necessary interdict, and finally enhance consequence management to restore operations.

In support of these strategies, the CBDP will:

- Continue to research, develop, and acquire transformational capabilities that provide forces, key personnel, and other assets with reliable prediction, warning, and detection capabilities to characterize CBRN threats
- Provide a more effective set of protective measures to minimize the effects of chemical and biological warfare agents (CBWA) and exposure to radiological and nuclear sources
- Emphasize broad-spectrum therapeutics and diagnostics that protect against emerging threats.

DEPARTMENT OF DEFENSE CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM MANAGEMENT AND OVERSIGHT

In accordance with Title 50 U.S.C. 1522, oversight of the CBDP is assigned to a single office within the Office of the Secretary of Defense (OSD). The Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs (ATSD(NCB)) is responsible for RDA of CBRN defense materiel and for overall coordination and integration of CBRN defense programs within DoD and across the Department of Homeland Security (DHS), Department of Health and Human Services (DHHS), and other federal agencies. These responsibilities are executed in accordance with the Under Secretary of Defense's *Implementation Plan for Management of the CBDP*, April 22, 2003 to include the two subsequent revisions in 2006 and 2007. This plan further assigns other organizational roles and responsibilities, outlines processes and reporting requirements, and provides implementing instructions. The ATSD(NCB) reviews the plan annually to ensure continuous process improvement.

Management Initiatives for 2007

The *Implementation Plan for Management of the CBDP* was revised this year to require semi-annual review of the alignment among requirements, S&T, advanced development, test and evaluation (T&E), and procurement. This provides data for effectively evaluating program execution and facilitates necessary adjustments in the investment strategy. Results are reported through ATSD(NCB) to the Under Secretary of Defense for Acquisition, Technology and Logistics (USD(AT&L)).

In April 2007, DoD Directive (DoDD) 2060.02, *DoD Combating Weapons Mass Destruction Policy*, was approved to enhance coordination among DoD organizations tasked with various aspects of the combating WMD mission. This directive assigns clear lines of responsibility and formalizes relationships among DoD components.

Also in April 2007, ATSD(NCB) requested that DoDD 5160.05E, *Responsibilities for Research, Development, and Acquisition of Chemical Weapons and Chemical and Biological Defense*, be updated and reissued. Issued originally in 1976, then 1985, this directive assigns responsibilities specifically for RDA of CB defense materiel. Once approved, DoDD 5160.05E and its implementing instruction will replace the Implementation Plan as the CBDP's primary authorization.

In June 2007, the USD(AT&L) submitted draft DoD Instruction (DoDI) 3150.cc, *The CBRN Survivability Program* for review and comment. DoDI 3150.cc will implement processes and standards for improving survivability of mission critical systems operating in potentially contaminated CBRN environments. The ATSD(NCB) will chair a CBRN Survivability Oversight Group to ensure compliance.

Finally, during 2007 the CBDP began preparations for transitioning to a "Joint Capability Portfolio" management process. The *QDR* and the DoD strategic planning guidance emphasized the need to continue building on capability based planning and management efforts. Joint Capability Portfolio management provides an approach for managing groups of related capabilities across the enterprise to improve interoperability, minimize capability redundancies and gaps, and maximize capability effectiveness. Joint Capability Portfolios will allow the entire Department to shift to an output-focused model that enables progress to be measured from strategy to outcomes. The ultimate criterion for success in this effort is delivering needed capabilities to the joint warfighter more rapidly and efficiently.

Key Organizational Relationships, Roles, and Responsibilities

The CBDP oversight and management structure is organized to focus attention on policy and governance, planning and programming, military requirements and doctrine, S&T, advanced development and acquisition, T&E, and analysis. Organizational relationships are established to ensure single decision authorities, effective coordination, integration of program efforts, and appropriate checks and balances.

Under Secretary of Defense for Acquisition, Technology and Logistics

The USD(AT&L) serves as the Principal Staff Assistant and advisor to the Secretary of Defense for all RDA matters relating to CBRN defense. The USD(AT&L) exercises authority, direction, and control over the ATSD(NCB) and oversees DoD RDA programs to ensure they support combating WMD policy efforts.

Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs

The ATSD(NCB) coordinates and integrates the CBDP as a single responsible office within OSD and executes program oversight activities, related acquisition policy guidance, and interagency and international coordination. The ATSD(NCB) also provides oversight of funds allocation for CBDP defense-wide accounts.

Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense (JRO-CBRND)

The JRO-CBRND coordinates and integrates requirements and capability needs for all DoD CBRN defense programs, ensuring that Military Service and Combatant Command capability needs are developed and approved in a prompt and efficient manner. The JRO-CBRND also leads development

of the CBDP Program Objective Memorandum (POM) Strategy, and supports and facilitates the development of multi-Service and Joint CBRN defense doctrine, tactics, techniques, and procedures (TTP), and training.

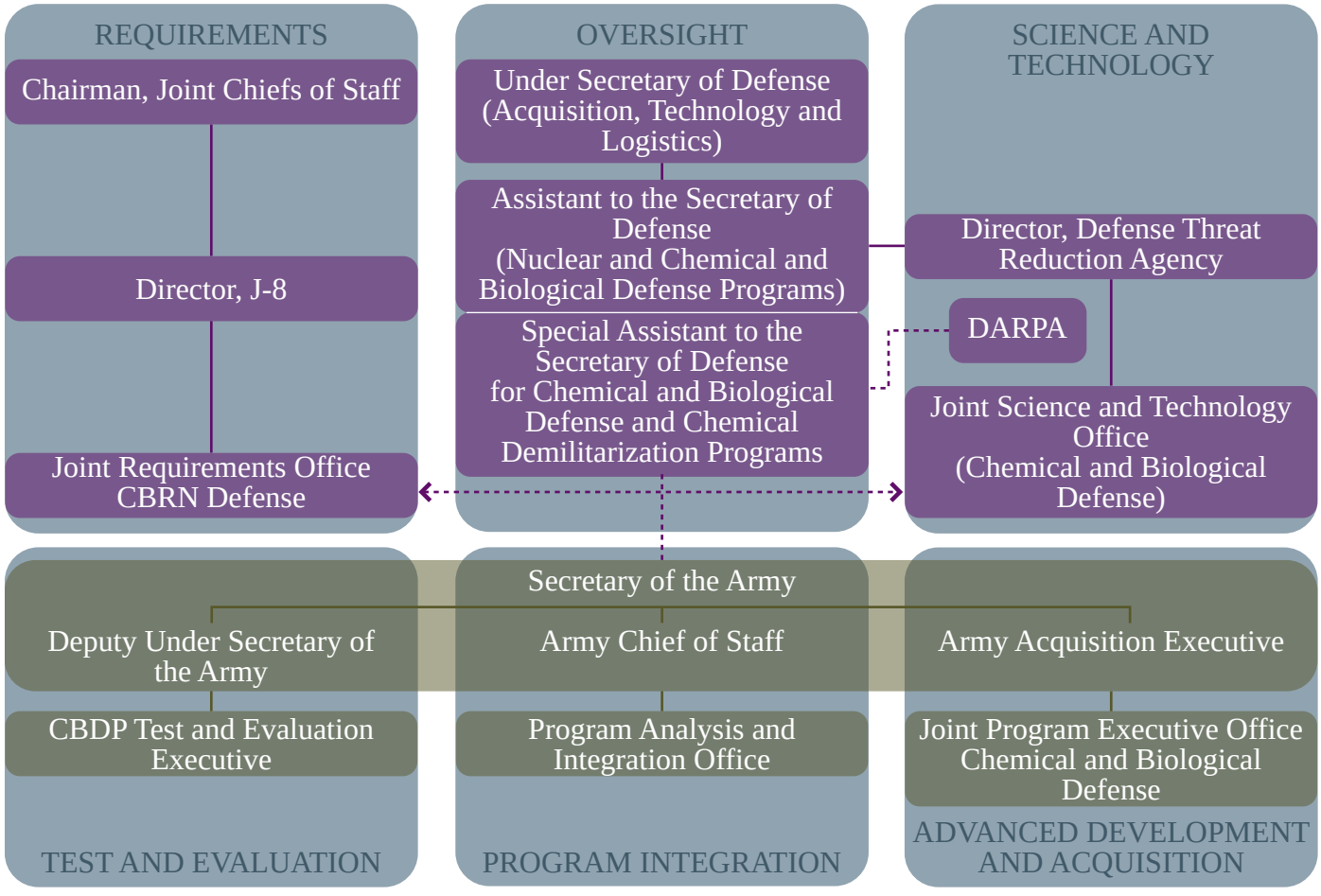
Army as the Executive Agent

The U.S. Army, as Executive Agent for the CBDP, serves as the Milestone Decision Authority (MDA) for delegated CB defense programs. The U.S. Army also coordinates and integrates RDT&E and acquisition requirements of the Military Departments for chemical and biological warfare (CBW) defense programs of the DoD and reviews all funding requirements for the CBDP.

Joint Program Executive Office–Chemical and Biological Defense (JPEO-CBD)

The JPEO-CBD is the Joint Service Materiel Developer for the CBDP, reporting to the Defense Acquisition Executive (DAE) through the Army Acquisition Executive (AAE). The JPEO-CBD provides centralized program management and Joint Service acquisition program integration for all assigned medical and non-medical programs. The JPEO-CBD's eight Joint Project Managers (JPMs) execute acquisition programs in the areas of Medical, Contamination Avoidance, Biological Defense, Decontamination, Individual Protection, Collective Protection, Information Systems, and Installation Force Protection (Guardian) systems. Under the JPEO-CBD's leadership, these JPMs direct RDA, fielding, and life-cycle support of CB defense equipment and medical countermeasures in support of the *2006 National Military Strategy to Combat Weapons of Mass Destruction.*

Core Chemical and Biological Defense Program Components



Joint Chemical, Biological, Radiological, and Nuclear Defense Program Analysis and Integration Office (PAIO)

The PAIO provides independent analysis and integration functions for the CBDP. They also support JRO-CBRND-led development of the CBDP POM and lead development of budget submissions and change proposals. In addition, the PAIO develops and maintains the CBDP RDA Plan that details mid- and far-term CBDP goals, objectives, and transition of materiel within each phase of the acquisition process consistent with USD(AT&L)'s comprehensive RDA strategy in accordance with the *National Military Strategy to Combat Weapons of Mass Destruction.*

Chemical and Biological Defense Program Test and Evaluation Executive

The CBDP T&E Executive, under the Deputy Under Secretary of the Army, establishes test standards, processes, and procedures and oversees CBDP T&E infrastructure to ensure that adequate T&E is conducted for CBDP systems.

Joint Combat Developer for Experimentation for Chemical, Biological, Radiological, and Nuclear Defense (JCD-CBRND)

Under the direction of the JRO-CBRND, the JCD-CBRND coordinates and oversees Joint and multi-Service experiments used to validate the Joint integrating concept for combating WMD (CWMD) by systematically exploring new and innovative combinations of medical and non-medical DOTMLPF capabilities. Located at the U.S. Army Maneuver Support Center (MANSCEN) in Fort Leonard Wood, MO, the JCD-CBRND leverages personnel, equipment, and facilities available through each Service and other government organizations to reduce costs, shorten timelines, and improve experimental designs.

Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD)

The JSTO-CBD manages the CBDP S&T efforts in coordination with the Service laboratories, industry, academia, and other government agencies and laboratories. The JSTO-CBD develops and maintains CBDP medical and physical sciences (non-medical) S&T plans, and develops, coordinates, and transitions CBDP S&T medical and physical sciences technologies and associated CBDP T&E technology needs in response to validated and approved Joint military capability needs. The JSTO-CBD also manages the CBDP Advanced Concept Technology Demonstration (ACTD), Advanced Technology Demonstration (ATD), and Joint Capability Technology Demonstration (JCTD) processes and individual ACTDs/JCTDs as assigned by the USD(AT&L).

Defense Threat Reduction Agency (DTRA)

The DTRA serves as the accountable official, providing funds management functions for the CBDP under the direction and oversight of the ATSD(NCB).

Other Related Organizations

Military Departments

Military Departments are responsible for organizing, training, equipping, and otherwise preparing their respective forces to combat WMD, to include its means of delivery and related materiel. They also validate operational concepts and develop Military Service-sponsored CBRN defense capabilities documentation consistent with the Joint Capabilities Integration and Development System (JCIDS) process and the Joint CBRN Defense Modernization Plan. In addition, they support development of Military Service annexes to joint CBRN defense capability documents as appropriate.

Coordination with Related Programs and Initiatives

The DoD CBDP activities are coordinated with other government agencies and international partnerships to gain the benefit of knowledge, laboratory and test capabilities, and funding available within the interagency community. The National Security Council Policy Coordination Committee for Proliferation, Counterproliferation, and Homeland Defense coordinates the management, development, and implementation of national security policies related to CB defense activities. Several United States Government (USG) organizations are developing CBRN defense technologies. The CBDP currently has formal coordination efforts with the Defense Advanced Research Projects Agency (DARPA), Counterproliferation Program Review Committee (CPRC), Technical Support Working Group (TSWG), DHS S&T Directorate, and DHHS.

The table below discusses these organizations' CBRN activities. In addition to organizations with formal coordination, the CBDP coordinates CBRN defense efforts with other federal organizations.

Chemical, Biological, Radiological and Nuclear Related Activities	
Organization	**Description of CBRN Related Activities**
DARPA	CBW defense program develops revolutionary new detection, diagnostics, decontamination, and medical therapies that are active against a broad spectrum of CB threats.
CPRC	Interagency executive committee that reports on activities and programs to combat WMD.
TSWG	Interagency forum that identifies, prioritizes, and coordinates interagency and international R&D requirements for combating terrorism.
DHS (S&T Directorate)	Primary R&D arm of DHS that guides and organizes research efforts to meet emerging and predicted needs.
DHHS	The DHHS family of agencies are involved in the research, development, and procurement of safe and effective medical countermeasures including Project Bioshield.

Highlights of these coordination efforts include:

- The Interagency Board for Equipment Standardization and Interoperability (known as the IAB) is a partnership of federal, state, and local agencies focused on the capabilities necessary for fire, medical, and law enforcement responses to WMD terrorism
- Interagency agreements with the DHS Office of Grants and Training to purchase equipment in support of the DHS Grant Program
- The White House Office of S&T Policy chairs the WMD Program, R&D Subgroup
- Continuous coordination with the National Security Council; U.S. Department of Agriculture; U.S. Department of Justice; and U.S. Environmental Protection Agency
- Partnering with DHHS in the development, licensure, and procurement of biodefense vaccines.

A recent notable example of interagency infrastructure coordination is the construction of the Sample Receipt Facility (SRF), a uniquely specialized sample handling, analysis, and forensics facility at the Edgewood Chemical Biological Center (ECBC) on the Edgewood Area – Aberdeen Proving Ground, MD. The SRF is a collaborative effort, funded by the DoD, DHS, and Federal Bureau of Investigation.

A second notable example is the Chemical Biological Medical Systems (CBMS) Economy Act Purchase of Dryvax™ (smallpox vaccine) from the Strategic National Stockpile. CBMS is now coordinating for the Economy Act Purchases of Anthrax Vaccine Adsorbed (BioThrax™) and for ACAM2000™, the newly licensed smallpox vaccine that will replace Dryvax™.

International Cooperation

The two main objectives of international cooperative CBRN defense programs are to reduce defense system acquisition costs through collaboration in the areas of development, production, and support, and to enhance interoperability with coalition partners. The CBDP leverages international programs to gain access to foreign technology and infrastructure; mitigate risk in the R&D process; and establish multinational standardized test procedures and common data.

Various international agreements and programs provide a legal and procedural framework for international cooperation in CBRN defense. These agreements and programs include the Information Exchange Program, International Cooperative RDA programs, Foreign Comparative Testing Program, personnel exchanges and assignments, and foreign military sales. DoD's network of international cooperative CBRN defense programs and agreements now extends to more than 20 allied nations.

In September 2007, the CBDP broadened its international reach by drafting a multilateral Strategic Implementation Plan and Roadmap to the year 2025 for the Australia, Canada, United Kingdom, and the United States Memorandum of Understanding on Research, Development, and Acquisition of Chemical, Biological and Radiological Defence Materiel (CBR MOU). This effort will allow expanded CBDP information exchange with Australia, Canada, and the United Kingdom. As part of the international CBR MOU, the CBDP participated in a series of meetings, working groups, and an Interagency Task Force (ITF), interacting with Israel, Singapore, Poland, Sweden, Japan, Thailand, and North Atlantic Treaty Organization (NATO) nations. These interactions allow for increasing information exchange, developing cooperative relationships, and ensuring program efficiencies.

STATUS OF RESEARCH, DEVELOPMENT, AND ACQUISITION

Joint CBRN defense materiel acquisition includes basic research, applied research, advanced technology development, concept refinement, system development and demonstration (SDD), production, and deployment. The following describes the status of Joint Service CBRN defense requirements and RDA programs from the S&T base through procurement. This information is organized within the framework of the operationally oriented commodity areas outlined in a capabilities-based assessment (CBA) prepared by the JRO-CBRND. Also addressed are CBDP activities supporting homeland security, as well as force protection. T&E program-specific activities are provided in each area, and overall T&E infrastructure activities are highlighted at the end of this section.

Overall, the FY 2008 President's Budget achieves a structured and integrated medical and non-medical Joint CBDP. The Budget balances urgent short-term procurement needs, including securing the homeland from terrorist attacks and long-term S&T efforts for mitigating future CBRN attacks.

Schedules and resources drive the pace of technology demonstrations and transitions to systems acquisition, ensuring a fully executable program. Acquisition milestones are driven by the availability of financial resources, technology, and T&E resources needed for program execution.

The RDA programs within the DoD CBDP will provide U.S. Armed Forces with the best equipment to enhance survivability and mission accomplishment on any future battlefield where CBRN threats are employed. Planned RDA activities focus on supporting the seamless integration of technologies into an integrated systems architecture across the spectrum of combat and support missions. In addition to traditional medical countermeasure research, the CBDP RDA programs invest in innovative and transformational technologies that will further enhance and enable the Joint Force's ability to survive, fight, and win in CBRN-contaminated environments.

The JPEO-CBD made significant progress toward providing operational capabilities to the Joint Force to ensure they are prepared to successfully operate in potentially contaminated CBRN environments. During 2007, the JPEO-CBD fielded 20 different systems (consisting of over one million individual pieces of equipment) to the Army, Navy, Air Force, Marine Corps, and Special Operations Command.

The JPEO-CBD also made significant progress toward defining and developing capabilities that enable the Joint Force to successfully operate in future CBRN threat environments. All JPEO-CBD cost, schedule, and performance parameters were met within this period, with the exception of the Joint Service Lightweight Standoff Chemical Agent Detector (JSLSCAD).

While not meeting all Acquisition Program Baseline (APB) key performance parameters, the Vice Chief of Staff, Army established that the JSLSCAD demonstrated performance does provide a militarily significant increment of capability. The Stryker Nuclear, Biological, Chemical, and Radiological Reconnaissance Vehicle (NBCRV) will put the ability to detect a critical class of chemical agents at substantial standoff distances into operation. The Stryker NBCRV employment and concept of operations (CONOPS) has been tested and is supported by the Director, Operational Test and Evaluation. The Joint Requirements Oversight Council (JROC) endorsed the Army position to modify the JSLSCAD key performance parameters for use on the Stryker NBCRV. Alternative technical and integrated systems solutions will be explored to expand the fielded chemical standoff/early warning capability and overcome current JSLSCAD limitations.

Required Capabilities

The JRO-CBRND completed a CBRN passive defense CBA in December 2005; an update is scheduled to begin in March 2008. Other ongoing combating WMD CBAs include: National Technical Nuclear Forensics, WMD Consequence Management, Threat Reduction Cooperation, Security Cooperation and Partner Activities, and Homeland Defense and Civil Support.

When a valid operational need is identified, the Services first examine the range of non-materiel solutions to identify whether an effective capability for operating in a CBRN environment exists. If it is determined that none of the non-materiel options fully meet the required need, then equipment or materiel solutions are pursued through the defense acquisition framework. The R&D modernization process identifies technological approaches that may result in a new operational capability or an upgrade to an existing operational capability.

In FY 2007, the majority of budget activity (BA) 2 and 3 S&T efforts were well aligned in their transition to system acquisition. Additionally, T&E is being challenged due to lack of funding available to transition products and technologies to systems acquisition.

Process improvements are being undertaken to ensure the timely development of capability documents across the CBDP. For example, per the 2007 revision to the CBDP Implementation Plan for the Management of the CBDP, the JRO-CBRND will provide operational requirements metrics. The metrics should provide a current listing and status of JCIDS documents that have been approved, those pending approval, and those that need to be developed with an estimated development timeline.

Contamination Avoidance

The CBRN contamination avoidance capability area develops and integrates CBRN sensors for point, standoff, and early-warning applications for use in reconnaissance, detection, and identification. For missions requiring operations in a contaminated environment, these capabilities are critical to the continuation and accomplishment of the mission. With these capabilities, forces can assume the optimal protective posture; avoid CBRN hazards and contamination; and rapidly identify and properly decontaminate affected personnel, equipment, and areas. These capabilities also are called for in the *National Strategy to Combat Weapons of Mass Destruction*, the *National Military Strategy to Combat Weapons of Mass Destruction*, and the *2006 QDR*.

The present goal of the detection technology area is to provide a real-time capability to detect, identify, characterize, quantify, locate, and warn against all potential or validated CBRN threats, including TIC/TIM, NTA, and emerging biological threats. The ultimate goal is direct integration of CBRN detectors as a single combined system into various platforms and command, control, communication, computer, intelligence, surveillance, and reconnaissance (C4ISR) networks, allowing for near instantaneous situational awareness.

To meet near-term needs, numerous sensor technologies are being optimized while alternative detection technologies mature. Much of the S&T effort is being applied to reducing the size, power requirements, and logistics impact of current detectors; reducing false alarm rates, reducing detection times, and increasing the database and interpretive knowledge of agent signatures.

Mid-term efforts will focus on improving tactical detection and identification capabilities for CBRN threats and hazards. Developing these items will ensure that detectors provide capability for NTAs, low-volatility agents (LVA), TICs/TIMs, liquids, and solid CWAs. Efforts also are being initiated to develop post-decontamination technologies that will detect residual surface contamination.

Early detection and warning are keys to avoiding BW hazards.

Far-term S&T efforts will incorporate spectroscopy, electro-optics, and molecular sequence-based sensing to produce multi-agent sensors for CBRN agent detection and remote/early warning detection. Advances in these areas will enable remote sensing, networking with non-CBRN sensors, full situational awareness in the CBRN environment, and low-level toxicological risk assessments. Far-term efforts will capitalize on emerging advances in nanotechnology, biotechnology, information technology, and cognitive sciences (NBIC).

Future CBRN detection capability will detect, identify in near real-time, map, quantify, and track all known CBRN contamination within a theater of operations. This will enable commanders to avoid CBRN contamination, determine the need for and verification of effective reconstitution procedures, and assume an appropriate protective posture to continue their mission with minimal performance degradation and casualties. CBRN sensing and detection technologies have dual-use potential in occupational environmental health surveillance for monitoring air pollution, noxious fumes inside enclosed areas, and municipal water supplies.

Biological Defense Programs

The biological defense capability area develops point, standoff, and tactical sensors for the Joint Services. This capability is critical to U.S. Armed Forces operations in regions where the threat of BW use is a concern. Further, *The National Security Strategy of the United States of America*, the *2006 QDR*, and Homeland Security Presidential Directive 10 highlight the need for a genuine capability to detect biological agents.

Sensors in the current DoD inventory are integrated on fixed sites, surface ships, and wheeled vehicles and provide detect-to-treat capability for point and long-line releases of biological warfare agent (BWA). The current biological defense modernization strategy provides DoD with a roadmap for incrementally improving current capabilities and detect-to-treat and detect-to-warn capabilities in the near-, mid-, and far-term.

The S&T program is investing considerable resources to make state-of-the-art advances in biological defense. The S&T investment will exploit new DARPA and Homeland Security Advanced Research Projects Agency (HSARPA) technology to advance the state-of-the-art in small, light, and low power sensing technologies to achieve a first time tactical biological detection suitable for use by expeditionary forces. These investments will also enhance the selectivity and discrimination capabilities of current standoff technologies in both day and night time conditions. Investments by way of the Defense Acquisition Challenge and Foreign Cooperative Test Programs have been made to advance point detection and identification technology to increase performance and reduce the operational and sustainment costs of existing systems.

Several critical issues continue to challenge biological sensor development efforts, but the foremost concern relates to the offensive capability and intent of our adversaries. Mid- to far-term S&T and acquisition efforts are focused to provide wide spectrum capabilities to counter traditional and NTAs, employed against U.S. interests in both conventional and non-conventional methods. The strategy also aims to counter the evolving threat through data fusion from disparate sensors fielded across the battle space.

A second challenge for biological defense relates to the speed in which actionable information from the sensors can be provided to commanders. Early detection and warning are keys to countering a BW attack. Since real-time biological agent detection is the ultimate goal, investment is focused on reducing detection times. To meet mid-term needs, S&T and acquisition efforts endeavor to provide an integrated system of reliable detect-to-warn standoff sensors and detect-to-treat point detectors with wide spectrum threat and confirmatory identification capabilities.

A third challenge is in the area of standoff biological detection. To meet near- and mid-term needs in biological agent detection and discrimination, S&T is under way to:

- Acquire fundamental physical and spectral property data of BWAs
- Correlate these data to clinical and health effects to specific threat data
- Correlate detection phenomenology against atmospheric absorption and spectral properties of common battle space interferents.

A fourth challenge facing the biological defense capability area relates to the logistics footprint of current sensors. Current standoff systems are large, consume considerable power, and cannot be operated on-the-move. Similarly, fielded point sensors are large and require a considerable amount of reagent consumables to function. As a result, technology development efforts venture to find small, light, and low power consumption sensor components for both point and standoff sensor systems. Additionally, development efforts are ongoing to find identification technologies that offer greater sensitivity and specificity and fewer false alarms and consumables to reduce sensor operational and sustainment costs. Near-term efforts focus on the use of electrochemical luminescence (ECL) while mid- to far-term efforts are investing in genomic sequencing and a variety of spectroscopy technologies.

Information Systems

Warning and reporting provide a critical link between CBRN detection and protection. They also provide situational awareness to the commander, enhance hazard forecasting and assessment, and improve operational decision-making. Major technical challenges for information systems include:

- Characterizing CBRN hazards on complex urban terrain and fixed sites
- Characterizing human effects, small unit behaviors, and low-level and long-term exposures
- Rapidly assimilating CBRN-related data to support tactical and T&E applications
- Developing engineering-level models of CBRN and DoD equipment in hazard scenarios
- Obtaining CBW relevant data to facilitate M&S and information technology (IT) development
- Integrating CBRN-related IT with other emerging technology initiatives (e.g., TMTI requirements) and Major Defense Acquisition Programs (MDAP).

Information system technology capabilities, combined with new threat agent data and increased research into performance degradation effects of protective equipment on units, will address many of these challenges in the mid-term.

CBRN information systems will evolve to enable automatic collection and fusion of information from all CBRN defense assets throughout the battle space, and integrate that data with other relevant information and C4ISR systems. The end result of this capability is rapid decision-making support in the CBRN environment, improving Joint Force protection, restoration of operational tempo, and casualty care treatment.

S&T efforts around information systems consist of four thrust areas:

1. Advanced warning, analysis, and reporting (AWAR)
2. Hazard transport and dispersion
3. Simulation analysis and planning
4. System performance modeling.

Efforts are continuing to provide advanced hazard-assessment methodologies, address specific environmental flow regime issues (e.g., high-altitude and urban transport and diffusion methodologies), and support first-principle physics, chemistry, and meteorology efforts.

Current modeling capabilities are designed to support warfighter efforts to conduct scenario simulations before engagements and to train realistically. Recent advances allow CBRN defense planning to be folded into larger conflict simulation

and consequence management tools, including battle space management, hazard environment prediction, effects on operations, and acquisition decision support tools. Simulation-based acquisition (SBA) tools will be used for CBRN agent detectors in conjunction with other environmental models to assess the adequacy of acquisition strategies and identify future critical enhancements.

The next generation (mid-term) T&E methodologies will ensure CBRN defense equipment provide a multi-fidelity capability, affording the warfighter increased flexibility and greater responsiveness to threat and hazard predictions. Testing operational models with COCOMs will allow for direct user input and improvements in the fidelity of the models, which will address high-altitude intercepts, urban, littoral, and coastal environments, and interior contamination scenarios.

The far-term capabilities will include near real-time operational hazard prediction capability. The incorporation of specific advances in the characteristics of contamination avoidance, decontamination, medical, and protection systems into models is an ongoing effort that will enable warfighters to evaluate and plan for specific modernization efforts. Integrated conflict simulation capabilities will meet theater and strategic simulation requirements.

The key payoffs of improved information systems are as follows:

- Commanders and battle staff who are better trained and able to analyze alternate courses of action with advanced simulations
- The use of integrated analytical and real-time CBRN defense situational awareness tools results in less confusion and more consistent decision-making
- CBRN defense systems and operational concepts match requirements more closely because warfighter feedback is captured earlier in the development cycle under the tenets of SBA
- Advanced hazard prediction and human effects modeling has dual-use potential in aiding civilian responders or planners to prepare for or respond to terrorist attacks and industrial accidents.

The DoD anticipates more than 30 technology transitions by FY 2009, including improvements in real-time hazard prediction capability, improvements in operational effects modeling, and maturation of a CB "Sim Suite" for testing data fusion tools. In accordance with the net-centric future focus of the Department, by 2013 the Services will have improved information systems technologies that support information sharing and situational awareness of CBRN hazards in the battle space.

Future T&E capabilities will focus on virtual simulation with or without a small actual test unit in play. The emphasis will be on digitizing the environment and performance of systems to allow thousands of scenarios to be run quickly for identifying major focus areas and combinations of conditions best suited for actual live testing. Time sequenced and aligned efforts to support RDA activities in information systems include:

- Development of high-speed ground-truth and test environment monitoring to improve model comparisons
- Development of portable testing capabilities
- Implementation of improved data fusion techniques
- Improvement of test data collection capabilities
- Development of synthetic test capabilities
- Development and implementation of real-time test data collection capabilities for field testing.

Protection

The protection capability provides an ability to shield the force from CBRN hazards by preventing or reducing individual and collective exposure. The protection program is aligned within two areas, individual and collective protection (CP). In FY 2007, the JSTO-CBD integrated the physical S&T decontamination capability area under the protection capability area to form the physical S&T protection/ hazard mitigation capability area. This addresses future capability needs dictating agent neutralization be integral to protective systems. They will be addressed individually in this report.

User issues with current protective systems focus on factors such as burden, costs, duration of performance, and effectiveness against a full range of hazards. From an S&T standpoint, these operational challenges require the development of materials and systems that capture, block, or destroy hazards more effectively than the current systems without increasing material weight or costs, while reducing logistical burden and lessening the impact on mission performance. S&T efforts also address the technology areas of air purification, materials science, human performance, and systems science.

The timing and goals of the protection S&T program are aligned with acquisition programs. Specific goals for CP are to:

- Reduce the weight, size, and power requirements of CP systems
- Reduce the logistical burdens associated with the maintenance of CP filters
- Improve personal and CP capabilities against current and emerging threat agents, including TICs/TIMs
- Improve the ability of transportable shelter systems to be deployed.

The individual protection (IP) goal is to reduce the physiological/psychological burden associated with wearing protective equipment while maintaining and improving the already high level of protection against CBRN warfare hazards.

To achieve these goals, improvements to system components are being investigated along with improvements to the current vapor and particulate filtration media. Advanced air purification technologies are being investigated to eliminate the need for filter changes and improve the capabilities against battle space CBRN hazards.

The mid-term focus will be on improved materials for protective equipment and shelters. Among these materials are lightweight, low-cost materials for shelters and reactive materials for self-detoxifying clothing. For example, the Joint Service Chemical Environment Survivability Mask (JSCESM) uses lightweight materials for a situation-specific application.

Far-term efforts will involve integrated multiple threat modular protection, self-detoxifying clothing, and automated sensing devices and indicators that signal when protection is no longer required. Focus also will be placed on developing less burdensome, but still highly protective, clothing with reduced heat burden.

Presently, DARPA programs support protection capabilities by focusing on destroying or neutralizing pathogens and toxins before they come into contact with the body. Projects in the decontamination and neutralization areas include the Self Decontaminating Surfaces Program that seeks to explore, identify, and develop creative new material technologies to provide a surface treatment that is biocidal and exhibits self-cleaning/renewal behavior. The initial phase will demonstrate applications for military vehicle exteriors and coatings that are compatible with sensitive electronics.

Filtration technologies will be improved to reduce breathing resistance, thus enhancing the ability to survive and complete mission tasks. Future respiratory systems will require enhanced compatibility with life support equipment and tactical systems as well as the capability to protect against NTAs and TICs/TIMs. Future focus will be on integrated respiratory protective ensembles, which offer optimal compatibility with personal, tactical, and crew systems.

Collective protection equipment (CPE) development efforts are focused on CBRN protection systems at the crew, unit, and platform levels. New CPE systems will be smaller, lighter, cheaper, and more easily supported logistically. New systems are required to provide clean environments for critical operations (e.g., in situations where individual protective equipment (IPE) might otherwise place an unacceptable burden on the warfighter in performing duties) and for essential rest and relief. Modernization efforts will concentrate on:

- Improvements to current vapor and particulate filtration media to extend filter life and to offer improved performance against current and/or emerging threats
- Advanced air purification (vapor and particulate) technologies to reduce the logistical burden and offer improved performance against current and postulated threats
- Increased application of CP systems onto mobile and transportable platforms and fixed facilities
- Improved transportable shelter systems with integrated power/environmental control and filtration
- Improvements to current systems to reduce weight, volume, and power requirements
- Standardization of filters within the Joint Services to address storage and procurement concerns.

Future T&E capabilities for protection will include the ability to relate data to casualty models by providing a wider range of threat representation in the testing and system M&S. Time-sequenced and aligned efforts to support RDA activities in individual and CP programs include:

- Improved chamber-testing
- Expanded capability to test advanced protective materials
- Hazard-assessment models and situational-analysis methods
- Capabilities to test next-generation materials against TICs/TIMs
- Development of next-generation materials tests that incorporate expanded threat and operational conditions
- Dynamic system simulant tests that provide near real-time sampling data and a wider range of simulated agent challenge types.

Decontamination

The decontamination capability area develops technologies to reduce CB hazards by removing and neutralizing contamination and detoxifying contaminated material without damaging combat equipment, personnel, or the environment. Technology advances in sorbents, vapor dispersion methodologies, coatings, catalysts, and physical removal will reduce the logistics burden, manpower requirements, and lost operational capability associated with decontamination operations. The S&T efforts in this area include:

- Decontamination-enabling sciences
- Traditional approaches to decontamination
- Energetic and kinetic decontamination
- Smart system decontamination
- Self-detoxification processes.

The capability to mitigate the consequences of WMD is clearly called for in the *National Strategy to Combat Weapons of Mass Destruction.* The *2006 QDR* states that the DoD "will be prepared to respond to and help other agencies to mitigate the consequences of WMD attacks."

A range of technical challenges is associated with CBRN decontamination. Warfighters need decontaminants that are safe for sensitive equipment, able to decontaminate a broad spectrum of agents, are environmentally safe, and pose no unacceptable health hazards. Warfighters also require systems that effectively decontaminate all surfaces and materials while simultaneously reducing the manpower and logistics burden. Challenges to the development of decontamination T&E capabilities also lie in correlating simulant field performance to that of a specific threat hazard.

Existing decontaminants and decontamination systems are effective against a wide variety of threat agents, yet are slow and labor intensive and present logistical, environmental, material, and safety burdens. Existing systems are also inadequate for electronic equipment, large-area, port, and airfield decontamination. To improve capabilities in this functional area, the Joint community has emphasized new decontaminating technologies that reduce existing manpower and logistics requirements.

Current research has focused on developing a peroxide-based family of decontaminants as a replacement for corrosive high-test hypochlorite and super topical bleach. The goal of this new generation is to provide superior efficacy against all known CBWAs as a single, universal decontaminant. Work will continue on alternative formulations that improve material compatibility and allow for use in cold climates.

Research efforts will also complete development of an aerosol or vapor-based decontamination application and determine the efficacy of activated hydrogen peroxide vapor. Novel approaches to develop decontamination processes based on transformational countermeasures will be investigated. Additional research will be required to develop the next generation of personnel decontaminants. Capabilities to be pursued include wound decontamination and greater efficacy against future threats, NTAs, and TICs/TIMs.

Future T&E capabilities for decontamination programs include development of the following:

- Hazard-assessment models for decontamination
- Capabilities to assess the effects of decontamination on battlefield performance under battlefield-relevant conditions
- Decontamination test methodologies for NTAs and TICs/TIMs
- Updated methods to assess the degradative effects of the decontaminating process on equipment and systems.

The payoff from enhanced decontaminants and decontamination systems will be new non-corrosive, non-toxic, non-flammable, and environmentally safe decontamination systems suitable for timely elimination of CBRN hazards from all materials and surfaces. This ability will allow forces to quickly reconstitute personnel and equipment, increase combat efficiency, and lessen logistic burdens. In the future, reactive coatings may allow the continuation of combat operations without the need to disengage for decontamination. Potential uses for environmental remediation, especially those dealing with pesticide and TIC/TIM contamination, are being exploited as well.

Medical Defense

The CBMS Program addresses medical protection of personnel against CBRN hazards and develops medical countermeasures, including pretreatments (prophylaxis), therapeutics (treatment), and diagnostics. CBRN medical systems include all pharmaceuticals, biologics, and devices that preserve combat effectiveness by timely identification, diagnosis, and provision of medical countermeasures in response to Joint Service CBRN defense requirements. The CBMS mission of rapidly providing the warfighter with safe, effective, and affordable medical countermeasures against a broad spectrum of CBRN threats is in line with the January 21, 2007, *Homeland Security Presidential Directive (HSPD)-18.* This Presidential Directive mandates a Tier 1 effort for using existing, proven approaches to develop medical countermeasures.

The CBMS continuously advances CBRN medical defense program development by focusing on partnering with other government agencies, industry, academia, and international partners; regulatory compliance (Federal Drug Administration (FDA) approval); lifecycle management; and planning for the future. CBMS is working with the DHHS to form a national stockpile for fielded products and continued collaboration on numerous developmental products. An interagency stockpile currently exists for the smallpox vaccine and one is being developed for the anthrax vaccine. FDA approval of all CBRN medical products is required by Executive Order 13139, *Improving Health Protection of Military Personnel Participating in Particular Military Operations*, and AR 40-7, *Use of investigational Drugs and Devices in Humans.*

The CBMS continues to use industry best practices to obtain FDA approval of broad-spectrum medical countermeasures within benchmark timelines (see table below). These best practices have helped CBMS keep 80 percent of its products (approved or in development) on track in terms of safety and effectiveness. CBMS is the world leader in gaining FDA approval using the Animal Rule. Since 2000, CBMS received FDA approval, licensure, or clearance for five medical countermeasures, completed eight investigational new drug (IND) submissions, completed eight drug safety trials, and anticipates an additional six IND submissions over the next two years.

One of the INDs submitted will be in support of BioScavenger, one for an Improved Nerve Agent Treatment System (INATS), one for a dry powder inhaler Atropine (DPIA), and three for medical radiation countermeasures. The development of technology transition agreements (TTA) that allow for a seamless transition time from the S&T base to the advanced developer are paramount to the rapid approval timelines that CBMS achieved. Goals for the medical chemical, biological, and radiological (CBR) defense RDA program include:

- Providing individual-level medical protection and prevention to preserve fighting strength
- Maintaining technological capabilities to meet present requirements and counter future threats
- Providing medical management of CBR casualties to enhance survivability, as well as expedite and maximize return to duty
- Sustaining basic research that provides the knowledge upon which innovative diagnostics, prophylaxes, and therapeutics are developed.

Effective pretreatments can reduce medical requirements by reducing the medical resources required to treat CBR casualties, thereby freeing

medical assets for other types of battlefield casualties. Furthermore, vaccines and chemical pretreatments currently in the development pipeline will provide protection against a wider range of threat agents. Multi-agent vaccines will potentially provide protection against multiple agents simultaneously, and effective medical prophylaxes will ultimately combat use of WMD by limiting the operational advantage of such weapons.

Effective therapeutics, coupled with diagnostic capabilities that unambiguously demonstrate exposure to CBW agents at pre-symptomatic time points, will lead to rapid return to duty and are critical capabilities for sustaining the force in CB environments. Pre-symptomatic treatment greatly reduces strains on deployed and receiving medical assets, reducing the logistical support requirements for casualty care.

Major technical challenges in the medical pretreatments and medical therapeutics capabilities area include:

- Defining appropriate in-vitro and in-vivo models for research
- Determining threat agent mechanisms of action and countermeasures
- Identifying immunogenic protective antigens for vaccine targets
- Delineating pharmacokinetics and pharmacodynamics of pretreatments for chemical agents
- Stimulating immune responses to small molecules
- Developing new and effective adjuvants
- Selecting vector systems for recombinant products
- Evaluating preliminary safety and efficacy data
- Determining dose and route of administration
- Evaluating process/scale-up potential.

Chemical Biological Medical Systems Investigational New Drug (IND) Submission and Approval Dates/Food and Drug Administration Approval Dates

Goal	Program	IND Submission Dates	FY 2011				FY 2012				FY 2013				FY 2014				FY 2015			
Prophylaxes	Botulinum Vaccine	June 17, 2004		■																		
	Ebola / Marburg Vaccine *	1st Qtr. FY 2012																				
	Multivalent Equine Encephalitis *	1st Qtr. FY 2012																				
	Plague Vaccine	October 28, 2004				■																
	Ricin Vaccine *	3rd Qtr. FY 2009																				■
Therapeutics	Advanced Anticonvulsant System	April 18, 2006						■														
	Bioscavenger Increment 2	4th Qtr. FY 2008												■								
	Cellerant	4th Qtr. FY 2008																				
	Dry Powder Inhaler Atropine	1st Qtr. FY 2008			■																	
	Improved Nerve Agent Treatment System	3rd Qtr. FY 2008										■										
	Medical Radiation Countermeasures	2nd Qtr. FY 2008	■																			
	Medical Radiation Countermeasures 2 *	3rd Qtr. FY 2009									■											
	Orthopox *	December 8, 2005								■												

■ FDA Approval * Unfunded Program (Requesting FY 2010-2015 POM Funding)

Developing acceptable animal efficacy data is essential to obtaining FDA licensure of medical CBRN defense pretreatments because challenging humans with CBRN hazards to establish vaccine protective efficacy is unethical and prohibited.

The goal of the pretreatments capability area is to conduct basic research leading to the development of lead-candidate vaccines and chemical pretreatments and protectants that can be administered before exposure, to provide specific and broad-spectrum protection against validated chemical or biological agents. Biological pretreatments are the highest ranked medical capability on the latest CBRN Joint priority list. Vaccinating the force is a basic tenet in force health protection. Vaccinations help to decrease the logistics burden in theater, increase force readiness and combat effectiveness, and result in cost savings.

> "Medical therapeutics which allow DoD personnel to continue mission essential tasks in a [CBRN] environment are at highest priority."
>
> *The Department of Defense Strategy for Homeland Defense and Civil Support*

The goal in the therapeutics capability area is to develop lead-candidate medical treatments and pharmaceuticals that, when administered after exposure, mitigate the effects of that exposure and sustain forces operating in a CBRN hazard area. All sub-areas within the therapeutics and pretreatment capability area depend on the development of validated animal models and surrogate indicators of human efficacy, necessary preconditions for FDA approval. The *Department of Defense Strategy for Homeland Defense and Civil Support* clearly states, "Medical therapeutics which allow DoD personnel to continue mission essential tasks in a [CBRN] environment are at highest priority." Advanced development of therapeutic medical countermeasures focuses on broad-spectrum countermeasures to nerve agents and nuclear and radiological weapons. Improved oximes and anticonvulsants under development will provide the warfighter with a more rapid and robust defense against the entire spectrum of nerve agents. Medical radiation countermeasures will provide the Services with the ability to survive and operate in a radiological environment regardless of the presence of elevated levels of ionizing radiation.

Medical CB diagnostics research is focused on developing assays and evaluating technologies that meet FDA standards for clinical testing. Specifically, the goal is to employ FDA-approved systems to identify and confirm individual exposure to BWAs and quickly verify exposure to CWAs, or to identify sub-clinical indicators that might result from low-level chemical exposure. Identification and confirmation of exposure to CBW threat agents should be accomplished as soon as possible after exposure and, ideally, before symptoms develop to allow early initiation of the appropriate countermeasure and rapid return to duty. This capability area evaluates new and existing technologies to discover, identify, and monitor biomarkers of infection and/or exposure.

Major technical challenges related to diagnostics capability include developing appropriate sample processing methods for complex biological matrices, identifying pre-symptomatic host responses (early biomarkers), and translating that information into diagnostic assays to detect CBWA exposure. The Program continues to meet the challenges of developing new and more sensitive assays for threat agents and evaluating and determining the applicability of new diagnostic technologies to a warfighting environment.

The mission of the Medical Radiological Defense Program (MRDP) is to rapidly develop lead-candidate medical countermeasures against acute radiation syndrome (ARS) and mitigate the delayed effects of acute radiation exposure (DEARE). To meet these requirements, emphasis is placed on hematopoietic, respiratory, and gastrointestinal (GI) radioprotectants (prophylaxes), technologies and approaches, and broad-spectrum post-irradiation therapeutics. The development of diagnostic

genomic biodosimetry biomarkers will be addressed in FY 2009. Since ARS is a complex injury, DoD is partnering with the DHHS. Through this partnership, DoD is acquiring a therapeutic for the GI syndrome and DHHS is acquiring a therapeutic to treat the hematopoietic syndrome.

Major technical challenges in the MRDP include:

- Developing validated animal models and surrogate indicators of human efficacy
- Pharmacologic agents that neutralize highly reactive oxygen species that are generated by the deposition of ionizing radiation
- Small molecular weight synthetic agents that reversibly arrest cell division or inhibit apoptotic pathways
- Recombinant hematopoietic growth factors that stimulate the replication and maturation of bone marrow progenitor cells
- Recombinant keratinocyte growth factor that stimulates the regeneration of epithelial cells
- Improved drug delivery systems that provide non-encumbering protection during the entire period of radiation exposure.

Chemical, Biological, Radiological, and Nuclear Defense Homeland Security Programs

The JPEO-CBD (specifically, JPM Guardian) and DTRA are incorporating and managing programs to address CBRN defense homeland security, including the Installation Protection Program (IPP), Army Emergency First Responder Program (AEFRP), National Guard Bureau Weapons of Mass Destruction Civil Support Teams (NGB WMD-CST), NGB Chemical, Biological, Radiological, Nuclear, and (High-Yield) Explosives (CBRNE) Enhanced Response Force Package (CERFP), and U.S. Army Reserve (USAR) reconnaissance and decontamination companies.

The CBRN defense homeland security and force protection area seeks to provide urgently needed protection and response capabilities to DoD organizations, forces, and installations responsible for supporting the execution of critical military missions or responding to CBRN events. The programs that constitute this thrust differ from other CBRN defense areas in two ways: they address the need for integrated families of fully developed CBRN systems and they meet the needs of military and civilian CBRN response personnel. Due to the disparate and unique requirements of these programs, a flexible acquisition approach is required to provide a comprehensive and integrated CBRN detection, protection, and response capabilities. These capabilities must be provided to the 55 NGB WMD-CSTs, USAR reconnaissance and decontamination elements, other DoD CBR response units, and to continental United States (CONUS) and outside continental U.S. (OCONUS) installations. JCIDS documents must be developed that will provide comprehensive and integrated CBRN detection, protection, and response capabilities to those unique units and teams required to support the IPP and the CBRNE Consequence Management Response Force (CCMRF).

The CERFP is composed of four elements staffed from established National Guard Units. The four elements are Command and Control (C2), Search and Extraction, Decontamination, and Medical. Twelve CERFPs have been certified to date.

The CBRN defense homeland security area leverages S&T efforts of the other product areas. Where unmet requirements are identified and where S&T is required to meet cost objectives, the CBRN defense homeland security area will work with the CBRN S&T community, JPEO-CBD, and associated product area joint program managers to prioritize investments and integrate requirements. This strategy of supporting subsystem S&T will meet the vast majority of area requirements.

The goals of CBRN defense homeland security are to support the:

- Establishment and equipping of 55 NGB WMD-CSTs
- Fielding and equipping of the 20th Support Command (SUPCOM) and USAR reconnaissance and decontamination units

- Provision of integrated CBRN protection, detection, information management, and response capabilities to DoD installations.

All equipment for 55 teams has been purchased, certified, and fielded. Two additional teams were authorized in 2006 and will be fielded in 2008.

The IPP was restructured into three tiers based on the findings of the IPP OSD study completed in 2006:

1. The baseline tier includes a Website for training and reference information available to all installations
2. Tier 1 includes baseline Tier capabilities. It adds hand-held detectors, personal protective equipment, an incident management system, and a mass notification system
3. Tier 2 applies to installations hosting one-of-a-kind critical strategic missions or capabilities and includes the baseline Tier and Tier 1 capabilities. It adds fixed detectors and sensors and integrates them into a decision support system.

The CBRN IPP has completed fielding at 53 CONUS installations. The AEFRP provides installations with an additional operational capability for defense against CBRN hazards. During FY 2007, the AEFRP provided assessments, training, and fielding of equipment to 41 installations. The AEFRP and the Joint IPP also provide CBRN pharmaceutical countermeasures (CPC) to protect and treat emergency first responders and mission critical personnel who are exposed to CBRN agents as a result of a CBRN incident on a installation.

Major technical challenges include:

1. Providing affordable real-time biological event identification and warning
2. Low-cost, self-configuring communications for sensor networks
3. Expeditious transition of emerging Commercial off-the-shelf (COTS) capabilities
4. A comprehensive CBRN simulations-based analysis and decision support system.

The first two challenges are high on the DoD priority lists and are being pursued by many sources. The third challenge may require particular attention from the JPEO-CBD and JSTO-CBD communities to provide resources to readily evaluate COTS products against requirements and capabilities. Lastly, SBA and decision support system tools are currently fragmented across multiple system areas and a fully integrated system will require development.

Chemical and Biological Test and Evaluation Infrastructure

The development of CBRN defense equipment and medical countermeasures requires adequate T&E facilities. This section provides an analysis of the existing and planned non-medical T&E infrastructure to meet the requirements of current and future CBRN defense R&D programs.

The dynamic nature of the expanding CBRN threat has exceeded the capability of our current infrastructure, which has a limited ability to test and evaluate equipment against evolving threats. Current T&E facilities are not adequate in terms of either capacity or capability to meet the T&E needs of the CBDP. In addition, state-of-the-art technology and analytical methods are lacking or inadequate in some areas. However, efforts are ongoing to improve test chambers to enhance the ability to characterize and realistically represent BWA and CWA threat agent environments. Improvements in instrumentation are also ongoing to provide greater fidelity and confidence in test data for more precise evaluations.

For all functional areas, test methods are required to address emerging threats, including NTAs, TICs/TIMs, and dusty agents. The CBDP will fund a dedicated NTA chamber, along with the studies needed to provide data to safely operate it, and specific test fixtures tailored to each type of test. The CBDP will develop and validate advanced technology tests to address TIC/TIM effects on protective materials and systems.

Much of the T&E technology efforts are targeted to provide scientific source data, especially for M&S, which previously has been unavailable or is not representative of current threats of concern. Examples of requirements and test conditions for which test technology and data must be developed and validated are:

- Unique agent challenge profiles
- Jet aircraft flight conditions
- Simulated effective respiratory rates in CB mask protection agent tests
- Expanded environmental and agent challenge conditions for IP materials and systems.

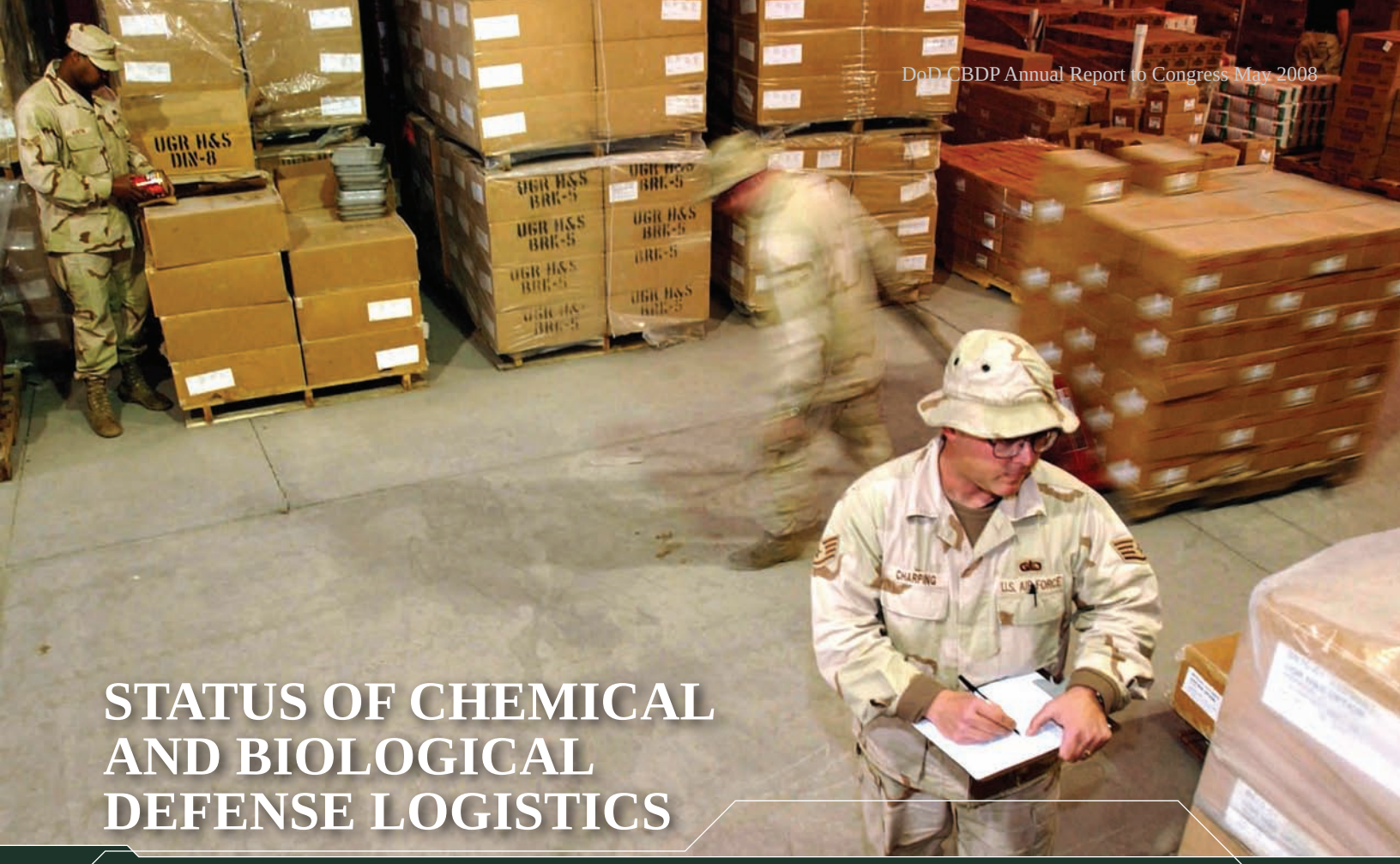
Simulant development, a key area of the S&T effort, includes developing families of simulants that can be used to predict system agent performance and that operators can use safely in outdoor environments. Mobile, deployable test capabilities are also needed to perform field simulant testing in multiple natural environments to ensure that CBRN defense systems are effective, suitable, and survivable across the range of environments. These capabilities will enable testers to provide combat developers with specific information regarding how to properly use CBRN defense systems to not only mitigate risks in the CBRN environment but also to provide system developers with the information required to adequately develop and mature the systems.

Current T&E infrastructure is severely lacking in terms of unit and system tests in realistic threat environments, simulants, and supporting data; however, funding is in place for investments to acquire these capabilities.

CBRN defense systems must be effective, suitable, and survivable across the range of environments.

The mid-term focus includes T&E infrastructure capabilities to remedy the current T&E capabilities gaps and to improve operational realism of testing. Capability improvements varying by commodity area are expected to have initial availability in FY 2008 and FY 2009. These new T&E capabilities are funded within the JPEO-CBD's Product Director for Test Equipment Strategy and Support (PD TESS) and in JSTO-CBD programs that will be integrated by PD TESS.

There is also a need for acceptance of the implementing oversight and management procedures for MILCON appropriations regarding how the DoD and the CBDP should best organize and execute MILCON projects supporting RDA activities of the CBDP. The Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs (SA(CBD&CDP)), in coordination with the Army as Executive Agent, is working on a MILCON concept paper that provides explicit guidance on MILCON prior to the start of the FY 2010 - 2015 POM.



STATUS OF CHEMICAL AND BIOLOGICAL DEFENSE LOGISTICS

The CBDP continues to progress toward the common goal of Joint logistics to ensure the overall availability of CBRN equipment for the total force, as one measure of overall readiness. This section describes the status of the CBDP logistics programs and initiatives underway to advance logistical readiness.

As the materiel developer for the CBDP, the JPEO-CBD and JPMs are responsible for Total Life Cycle Systems Management (TLCSM) and are supported by numerous government agencies as well as many industry and academia partners. These partnerships are central to the effective management of a variety of complex systems with various sustainment strategies. The JPEO-CBD maintains a cooperative engagement with the Services to ensure integration between the Title 50 responsibilities of the CBDP and the Title 10 responsibilities of the Services to train, equip, and sustain the forces.

As stated previously, the CBDP is preparing for the transition to an end state in which the total program will be managed as a "Joint Capability Portfolio." The *QDR* and the DoD strategic planning guidance emphasized the need to continue building on capability-based planning and management efforts. Joint Capability Portfolio management provides an approach to managing groups of related capabilities across the Program to improve interoperability, minimize capability redundancies and gaps, and maximize capability effectiveness.

The JPEO-CBD continues to improve the logistical readiness status of the DoD's CBRN defense equipment in three ways:

1. Improving upon several business process improvement (BPI) initiatives and institutionalizing these improvements across the JPEO-CBD
2. Enhancing the JPEO-CBD's decision support tools and communications through logistics IT solutions
3. Increasing visibility of the CBRN industrial base status in support of DoD requirements and improving understanding of the homeland defense/homeland security requirements and the risks to the industrial base from a CBRN attack on the homeland.

Chemical and Biological Defense Program Inventory Requirements

The industrial base, which has scaled down since the end of the Cold War, has stabilized. Ongoing military operations and homeland defense initiatives, as well as shelf-life expirations for stockpiles built in the 1980s, have contributed to demand for industrial base services and products. Although DoD has initiated a number of programs and outreach efforts to keep the industrial base viable, continued efforts must be maintained to ensure that readiness and sustainment requirements are not jeopardized by swings in industrial capabilities.

Inventory data for this year's ARC were, for the first time, extracted exclusively from the Joint Acquisition CBRN Knowledge System Reporting Warehouse (JACKS-RW). The data is limited to the 11 Go-to-War (GtW) items currently required to be maintained in the database. The goal for 2008 is to expand the data requirement to all CBDP equipment. The USD(AT&L) directed this reporting requirement in a formal memorandum to the Joint Services. The quantities discussed here and provided in Annex A are a snapshot of inventory for the GtW items as of September 30, 2007. Tracking inventory data is somewhat complicated because once certain equipment items are issued, they are considered expended and are not counted as on-hand inventory.

During 2008, the goal will be to expand data in the JACKS-RW to include all CBDP equipment and facilitate exact reporting on the inventory and stocks of these items. Currently, only consumable items are tracked in the JACKS-RW. The Services have been tasked to include the remainder of the CBDP equipment items for inclusion in the FY 2009 CBDP ARC and the Joint Logistics Support Plan (JLSP).

Increased requirements for CBRN defense equipment in wartime mandated a greater emphasis on the need to plan for sustainment stocks, relying on industry to surge production to meet the associated demand. As currently planned, the Services retain "deployment stocks" of CBRN defense equipment to support immediate deployments and initial operations. Each Service's doctrine determines sustainment duration for their stocks. The following table displays deployment stock requirements for each Service.

Comparison of Service Inventory Requirements

Service	Doctrine Sustainment Requirement
Army	Army divisions use a planning factor of 45 days.
Air Force	Air Force units deploy with 30 days of CBRN defense consumables.
Navy	Navy shore units use 60 days as the basis for their plans. Navy ships stock CBRN materiel to allowance equipage lists (AEL) that are 115 percent or 215 percent of the ship's manning level, depending on the equipment type and primary mission of the ship.
Marine Corps	The Marine Corps Marine Expeditionary Units (MEU) use a planning factor of 15 days, while the Marine Expeditionary Forces (MEF) use 60 days.

If required, the Joint Materiel Prioritization Allocation Board (JMPAB) CB Defense Subgroup will resolve critical issues related to joint logistical and sustainment issues for the CBDP. The completion of the analysis of the Joint Chemical and Biological Defense Expendable Equipment Combat Consumption (E2C2) study and the impact of the QDR on the force planning construct will permit the Services and the Defense Logistics Agency (DLA) to more accurately assess their readiness and sustainment status. The E2C2 study modeled the consumption rates of consumable CBRN defense assets on the battlefield. The results will provide a foundation to define requirements for a set of critical consumable items, which will aid in readiness assessment and planning.

In peacetime, quantities of CBRN defense equipment are necessary to train personnel and to build confidence among our warfighters that their equipment will provide protection when used correctly. The two most critical areas of peacetime stocks are IPE and medical chemical defense materiel. There is sufficient training equipment on hand for all Services.

In support of the Surface Warfare Enterprise (SWE) and Naval Aviation Enterprise (NAE), the Naval Sea Systems Command (NAVSEA) has implemented a new program entitled IPE Readiness Improvement Program (RIP) Lean. The program ensures minimum IPE readiness levels are achieved through the issuance of CBR defense masks and IPE kits on a cyclic basis. This cycle is tied to the 27-month fleet response plan cycle and the 36-month typical Sailor rotation cycle.

Also in support of the SWE and NAE, NAVSEA has implemented a new program entitled CBR defense Readiness Assist Visit (RAV). The RAV program provides a comprehensive CBR defense readiness evaluation within 90 days of a scheduled ship deployment. This evaluation includes decontamination, bio-consumables, IPE, CP, and detection (including medical polymerase chain reaction) systems. It will be expanded to include information systems when they are fielded.

Business Process Improvements

The Services and the JPEO-CBD coordinate and integrate Joint CBRN defense logistics. Stakeholders share information to maximize the distribution and use of limited resources, to gain total visibility of CBRN defense materiel, and to ensure a common understanding of requirements for fielding and sustaining equipment for all operational environments, including battlefield operations and homeland defense.

The JLAC-CBD (chart on the following page) was formally established by a signed charter on March 15, 2007. The JLAC-CBD operates under a set of business rules designed to allow all participants an equal voice in the process, while maintaining overall authority to recommend the issues presented to the decision-making authority under the charter's established process.

The JPEO-CBD is addressing its TLCSM responsibilities and the implementation of a Joint Capability Portfolio with a very deliberate process that recognizes the Services' authority and responsibility to sustain the force. The JLAC-CBD is composed of Military Service representatives, including the Special Operations Command, representatives from the DLA, and other supporting activities and stakeholders, as well as senior logisticians from the JPEO-CBD.

The main purpose of the JLAC-CBD is to recommend Service-wide BPIs that address best practices for the efficiency and effectiveness of the sustainment activities of the CBDP. The JLAC-CBD focuses on joint sustainment processes that:

- Increase availability, reliability, and maintainability to the warfighter
- Avoid duplication of efforts, potential excess, and unbalanced capacity for depot/contractor logistics support (CLS)
- Maintain configuration control and address supportability issues, including diminishing manufacturing sources and material suppliers (DMSMS)
- Maximize economies of scale
- Reduce life-cycle costs
- Maintain asset visibility.

Joint Logistics Advisory Council for Chemical and Biological Defense (JLAC-CBD)

- **Joint Equipment Assessment Program (JEAP)-** The JPEO-CBD chartered the JEAP in April 2006 as the single point of contact for surveillance of CBRN defense equipment throughout DoD. JEAP establishes Joint Service standards for surveillance, assessment, and reuse of fielded CB defense equipment. The JEAP initiated a study of the Joint Service Lightweight Suit Technology (JSLIST) protective suits to determine if any degradation of the suits resulted from high thermal conditions while in the theater of operations. The successful testing of 61 lots of JSLIST suits resulted in a cost avoidance of over $18 million, as good lots were returned to inventory for reissue.
- **Individual Protective Equipment Strategic Inventory Management (IPE SIM)-** explores methods and concepts designed to improve the management of IPE inventories within the DoD.
- **Joint Materiel Release (JMR) Program-** On September 25, 2007, the JMR program for the CBDP was approved and Materiel Release Authority was delegated to the MDA for the CBDP. The program integrates the separate Service fielding processes into a single process, eliminates redundancy, and streamlines acquisition efforts, while ensuring that all U.S. Armed Forces continue to receive safe, effective, suitable, and supportable materiel.
- **CBRN Joint Training Working Group-** Addresses Joint Training approaches ranging from New Equipment Training (NET) to sustainment and institutionalization of formal training for the CBDP.
- **Joint Maintenance Integrated Product Team-** investigates options to transform the current multi-Service maintenance concept to a Joint structure in order to more effectively use scarce government resources.
- **Industrial Base Working Group-** is charged with transforming its industrial base assessment from the traditional report on contractors who are actively engaged in the CBDP to a broader look into those in the industry who are capable of providing goods and services to fulfill the Departments needs.

Information Technology and Communications Improvements

IT is being used to ensure optimal communications and information sharing efficiency between the warfighter and all supporting agencies. The table below discusses specific applications of IT for logistics information management.

Information Technology
• **Joint Acquisition CBRN Knowledge System (JACKS)-** is the Web-based DoD knowledge management portal for information related to the acquisition and support of non-medical CBRN defense products.
• **JACKS-RW-** Formerly known as the Joint Total Asset Visibility Reporting Warehouse (JTAVRW), JACKS-RW was established as the central repository for CBD equipment. The JACKS-RW currently tracks 11 GtW items.
• **CBRN Information Response Center (CBRN-IRC)-** seamlessly integrates and provides responsive, relevant, and reliable CBRN information in support of warfighters' mission and the JPMs as TLCSM for the CBD community.
• **Unique Identification (UID) / Radio Frequency Identification (RFID)-** JPEO-CBD developed and implemented a plan for an UID and RFID of Tangible Property and Property in the Possession of Contractors in response to the requirements of the Acting USD(AT&L).

Industrial Base

The DLA and the Army Materiel Command (AMC) are the item managers, or National Inventory Control Points (NICP), for the vast majority of CBRN defense items in all four Services. DLA and AMC are responsible for industrial base development and storage of wholesale peacetime and sustainment wartime stocks. DLA and AMC depots store primarily Army-owned sustainment stocks, although the Air Force, Marine Corps, and Navy may provide funds to store their sustainment stocks. All Services are responsible for individually programming and funding sustainment stocks to provide the required support to their force structure.

The CBRN defense industrial base is characterized as small niche, defense-centric sectors embedded in larger commercially dominant industries such as materials, textiles, pharmaceuticals, and electronic equipment. This industrial base was robust during the Cold War era and supported a large number of producers. After the end of the Cold War excess inventory of CB defense items, coupled with evolving and ill-defined threats and declining budgets, led to lower demand for products from the CBRN defense industrial base. Mergers and acquisitions further reduced the number of firms participating in defense production.

Over the past decade, demand has grown intermittently for CBRN defense products. The increased demand is a function of ongoing operations such as Operation Enduring Freedom and Operation Iraqi Freedom, the terrorist threat at home and abroad, and DoD's increased emphasis on homeland defense for DoD installations and units. Another factor driving demand is the shelf-life expiration of inventories built up during the 1980s, such as chemical suits and masks. Although the current sector is stable, vulnerabilities still exist, particularly where sources of component materials are limited.

Private sector industries, particularly small businesses, have difficulty handling the fluctuations in production necessitated by wartime demands when peacetime demand is low or nonexistent. Once industry surges production to support a period of high demand, DoD is challenged to maintain the industrial capability after DoD requirements drop to typically lower peacetime levels. Industrial production surge capability may also be limited by the supply of essential components with long lead times. Intervention is sometimes required to maintain an active production capability, or "warm industrial base." CBRN defense items for which peacetime demand is often inadequate to maintain the industrial base include chemical protective suits and gloves and nerve agent antidote auto-injectors.

The JSLIST industrial base is of significant concern at present and warrants a categorization of "high" risk. The ramp-up of JSLIST production for Operation Iraqi Freedom and Operation Enduring Freedom led to the premature achievement of the total Service requirement (TSR) leading to the cessation of JSLIST program funding in FY 2007. The loss of this dedicated funding resulted in unstable, significantly decreased demand that continues to impact this industrial base. The JPEO-CBD, in coordination with the DLA and Defense Supply Center Philadelphia, is investigating several alternatives to ensure continued capability.

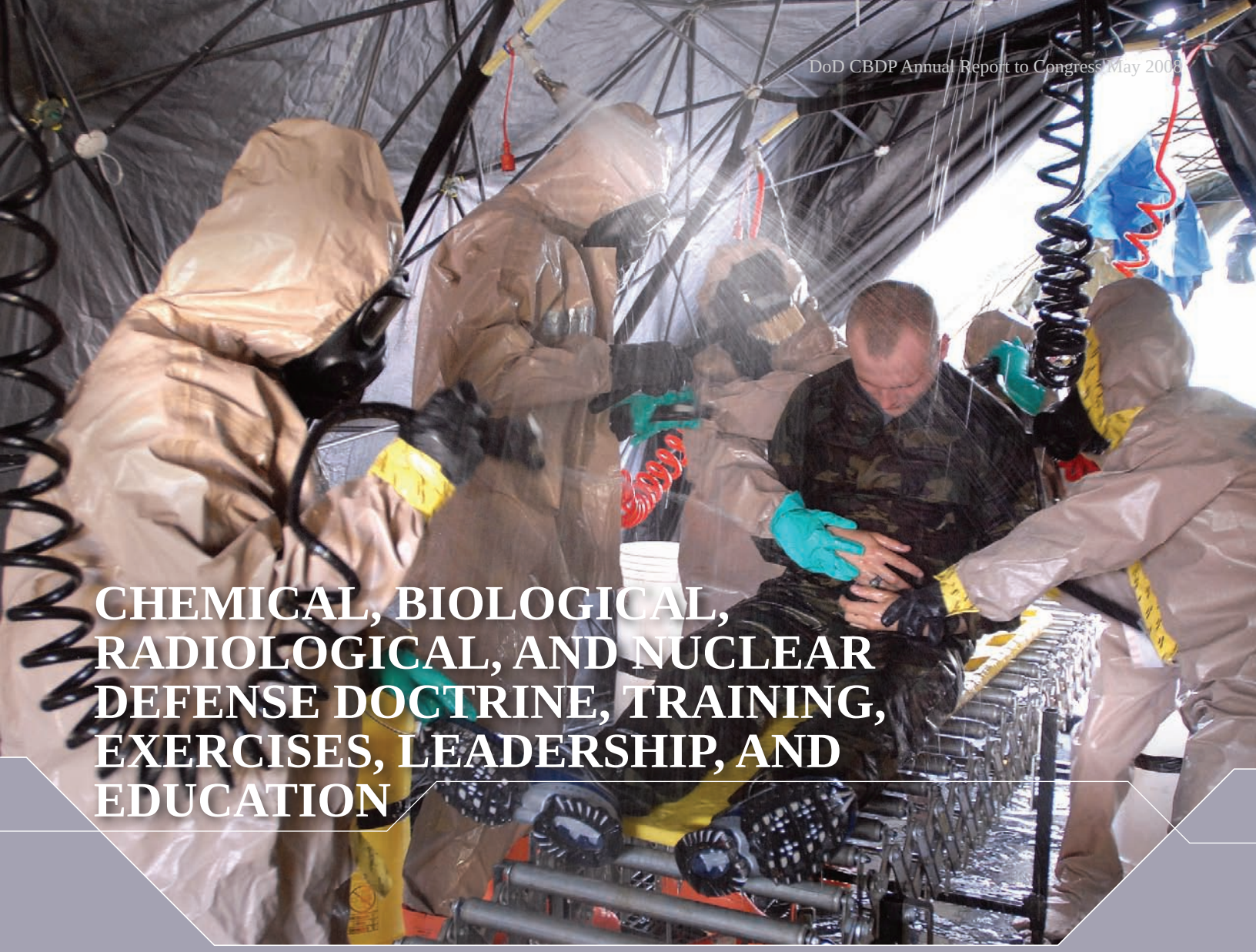
Proactive Industrial Base Sustainment Efforts

The DLA's Warstoppers Program, mandated by law (House Report (H.R.) 102-311), recognizes that preparedness measures must be taken for certain supply items, and that critical industrial capability must be preserved to support DoD's readiness and sustainment requirements. The Warstoppers Program supports the Services' GtW estimated requirements and maintains sole source of supply for the GtW surge. DoD has undertaken a number of industrial base outreach efforts as a way of expanding or obtaining new subject matter, new technologies, and CBRN equipment across the commercial sector. The CBDP relies on multiple methods and venues to leverage industry to meet program requirements. These include small business innovative research (SBIR), small business technology transfer (STTR), and technology transfer, including cooperative research and development agreements (CRADA), broad agency announcements (BAA), conferences, symposia, events, working groups, and traditional procurement activities and solicitations. The CBDP also hosts an annual Acquisition Program Brief for industry and presents the latest technology, with an emphasis on detailed competitive opportunities. Entire industry sectors are brought into a discussion of issues and events through the CB Defense Acquisition Initiatives Forum. This executive level gathering of CBDP and industry leaders meets quarterly.

Industrial Base Assessments

The JPEO-CBD is transforming its industrial base assessment from the traditional report on contractors who are actively engaged in the CBDP, to include all those who are capable of providing goods and services to fulfill the DoD's needs. This is an important paradigm shift and begins with active engagement with our industry partners, other government agencies, and the commercial sector at the global level.

This year, a voluntary risk assessment was conducted measuring data on 219 CBRN defense items from 116 contractors in seven CBRN defense sectors. Most contractors were rated low-to-moderate risk for industrial and financial viability using the Defense Contract Management Agency's (DCMA) industrial/financial analysis methodology. However, several contractors were identified as "high industrial risk" and as such, will require continued monitoring and timely communication of any factors that impact their respective programs' cost, schedule, and technical performance.



CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR DEFENSE DOCTRINE, TRAINING, EXERCISES, LEADERSHIP, AND EDUCATION

This section highlights FY 2007 DoD CBRN defense doctrine, training, exercises, leadership, and education initiatives. The Services, COCOMs, JRO-CBRND, Office of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), and the CBRN defense Education and Training Integration Council (ETIC) under the ATSD(NCB) played major roles in improving CBRN defense education, training, and doctrine. This partnership has expanded to include DTRA and the National Defense University (NDU).

Major initiatives in FY 2007 included integrating CBRN defense stovepipes, incorporating the medical community into education and training, and increasing collaboration in the CBRN defense training community. Another major CBDP accomplishment in FY 2007 was the timely completion of the H.R. 109-452, *Joint Training and Certification for Nuclear, Biological, and Chemical Defense*, at the request of Congress and as tasked to the ATSD(NCB).

Education and Training Integration Council

The CBRN defense ETIC, whose membership includes the Services, Joint Staff, and medical community representatives, provides DoD with a comprehensive approach to integrating stakeholder organizations responsible for CBRN defense education and training policies, processes, requirements, and activities. The ETIC met quarterly in FY 2007, resulting in a successful second annual conference that provided an opportunity for stakeholder organizations to participate in education and training activities that crossed Service and organization boundaries.

The ETIC continues to expand its focus and meets regularly to address specific issues in CBRN defense education and training. Accomplishments include the development of a Website, portal, and database as key resources for CBRN defense stakeholders. The Website provides community-wide notifications, a report library, and a CBRN defense course catalog. In FY 2007, Website membership increased to roughly 150 members. Plans are to populate the catalog database in 2008 by incorporating course information from the Services and other CBRN defense education and training organizations.

A major function of the ETIC is to implement the findings of H.R. 109-452, discussed below. An ETIC strategic working group met in late 2007 to designate offices of primary responsibility for the 10 gaps identified in the report. The ETIC provides the ATSD(NCB) with regular progress reports and plans to include updates in all subsequent ARCs.

H.R. 109-452, Joint Training and Certification for Nuclear, Biological, and Chemical Defense

Congressional language in H.R. 5122, October 2006, directed the ATSD(NCB) to "perform a gap analysis on [nuclear, biological and chemical [NBC]] defense training, to review NBC defense doctrine across each of the Military Services, and to make recommendations regarding the implementation of joint training, certification, and doctrinal alignment for NBC defense for both the active and reserve components." The report was submitted on October 1, 2007, as H.R. 109-452. Six themes, shown at right, emerged from the 10 gaps in CBRN defense joint training and certification identified in H.R. 109-452.

H.R. 109-452 Themes

1. Policy disconnects
2. Lengthy process or delay in doctrine updates
3. Doctrine and requirement inconsistencies
4. Need for advanced NCB defense education
5. Low priority still exists for NCB defense training
6. Need to improve realism in training

Overall Readiness

The Title 50 U.S.C., Section 1523, directs the CBDP to report on the "overall readiness of the Armed Forces to fight in a chemical-biological warfare environment and…describe steps taken and planned to be taken to improve such readiness." Non-materiel solutions, such as doctrine and training, are critical to ensuring and improving force readiness, along with the materiel solutions discussed earlier in this report.

The ATSD(NCB) provided parameters to develop a repeatable process for assessing overall Joint CBRN defense readiness. The new CBRN readiness assessment (RA) process will support Title 50 U.S.C., Section 1523 by presenting a CBRN defense assessment based on identified capabilities and capability gaps communicating current readiness to handle today's operational CBRN challenges while developing capabilities to meet future CBRN challenges.

The ATSD(NCB) assigned responsibility for the RA to the SA(CBD&CDP) to work in conjunction with the PAIO, which developed the assessment methodology and process. The assessment currently addresses the 11 GtW items, but future ARCs will also identify and assess other critical items in the CBDP.

Doctrine and Requirements

Both Title 10 U.S.C. and Joint Publication (JP) 3-11, *Joint Doctrine for Operations in Nuclear, Biological, and Chemical Environments*, state that individual training and exercises to test proficiency remain under the

New and Updated Joint Chemical, Biological, Radiological, and Nuclear Defense Doctrine and Publications	
Publication	**Type and Status**
Joint Publication 3-07.2 Antiterrorism, April 2006	Joint Doctrine–Under Revision
Joint Publication 3-11, Joint Doctrine for Operations in Nuclear, Biological, and Chemical Environments, July 2000	Joint Doctrine–Under Revision
Joint Publication 3-27, Homeland Defense, September 2007	Joint Doctrine
Joint Publication 3-28, Civil Support, July 2007	Joint Doctrine
Joint Publication 3-40, Joint Doctrine for Combating Weapons of Mass Destruction, July 2004	Joint Doctrine–Under Revision
Joint Publication 3-41, CBRNE Consequence Management, October 2006	Joint Doctrine
Multi-service Tactics, Techniques, and Procedures (MTTP) for NBC Aspects of Consequence Management, December 2001	Multi-Service Doctrine –Under Revision
Standardization Agreement (STANAG) 2463 NATO Handbook on the Medical Aspects of Defensive Operations, Edition 1, AMed P-6(C), Vol. III (Chemical)	NATO and STANAG
Allied Tactical Publication 3.8.1, Vol. I, Allied Joint Tactical Doctrine for CBRN Defense	NATO and STANAG
Allied Technical Publication 3.8.1, Vol. III, Allied Joint Technical Doctrine for Conduct of CBRN Defense Training, Exercise and Evaluation	NATO and STANAG
STANAG 2476 Medical Planning Guide for the Estimation of NBC Battle Casualties, Addendum, AMedP-8(B), Vol. II (Biological)	NATO and STANAG
NATO Planning Guide for the Estimation of CBRN Casualties, Edition 1, Study Draft 2, AMedP-8(C). AMedP-8C is the restructure, revision, and combination of STANAG 2475, Vol. I (Nuclear); STANAG 2476, Vol. II (Biological); and STANAG 2477, Vol. III (Chemical)	NATO and STANAG
MTTP for CBRN Installation Defense	Under Revision
MTTP for WMD/E Operations	Under Revision
MTTP for CBRN Operations	Under Revision
MTTP for CBRN Decontamination	Multi-Service Doctrine
MTTP for NBC Protection	Multi-Service Doctrine
MTTP for NBC Reconnaissance	Multi-Service Doctrine
MTTP for Biological Surveillance	Multi-Service Doctrine
MTTP for NBC Vulnerability	Migrated into CBRN C2 MTTP
MTTP for Aspect of CBRN Command and Control	Under Revision
MTTP for CBRN Contamination Avoidance	Multi-Service Doctrine
Potential Military Chemical/Biological Agents & Compounds	Multi-Service Reference Manual
Treatment of Biological Warfare Agents Casualties	Multi-Service Doctrine –Under Revision
Treatment of Nuclear & Radiation Casualties	Multi-Service Reference Publication
Treatment of Chemical Agent Casualties & Conventional Military Chemical Injuries	Multi-Service Reference Publication
Health Service Support in a CBRN Environment	TTP

purview of the Services. Standards of proficiency (SoP) have been codified in field manuals and joint publications, which are used as the foundation for CBRN defense training. Joint and multi-Service CBRN defense doctrine is the foundation for new and ready forces capable of operating in a CBRN environment. The review and evolution of Joint and multi-Service Doctrine continues to examine and incorporate lessons learned from continuing operations, validated CONOPS, and TTP ensuring the foundation upon which education, training, and operations is established.

The CBRN defense doctrine can be found in Joint, multi-Service, and Service-specific doctrinal publications. CBRN defense TTPs can be found in both multi-Service and Service-specific doctrine. The JRO-CBRND is tasked to support and facilitate the development of multi-Service and Joint doctrine and has recently conducted multiple CBAs that identified a need for non-materiel solutions to fill CBRN defense gaps and deficiencies. These non-materiel gaps and deficiencies are being addressed in Joint doctrine publications, including JP 3-11; JP 3-40, *Joint Doctrine for Combating Weapons of Mass Destruction*; and JP 3-41, *Chemical, Biological, Radiological, Nuclear, and High-Yield Explosives Consequence Management.*

The Services are working in conjunction with the JRO-CBRND to update and develop the following MTTPs:

- WMD-E operations
- Installation CBRN defense
- Aspects of consequence management
- CBRN C2
- CBRN Operations.

This updated guidance will improve collaboration in the Armed Forces and resolve many of the gaps identified in the CBAs.

Army Doctrine

The U.S. Army CBRN School (USACBRNS), in conjunction with the JRO-CBRND, performs lead Service functions for development of tactical MTTP. The Services jointly completed updates to existing MTTP doctrine on installation CBRN defense and CBRNE consequence management. During the year, the USACBRNS separately developed doctrine and training products for toxic chemical improvised explosive devices, technical escort operations, Weapons of Mass Destruction Civil Support Teams (WMD-CST), and specialized reconnaissance missions. The Army is in the process of developing two new doctrine publications: the *CBRN Responder Operations Handbook* and the *CBRN Handbook: Sensitive Site Exploitation and Environmental Recon Operations.*

Navy Doctrine

During 2007, the Navy promulgated a new update to its primary shipboard guidance for CBW defense, *Navy Tactical Reference Publication (NTRP) 3-20.31.470, Shipboard BW/CW Defense and Countermeasures*, and initiated the revision of the companion primary shipboard reference for nuclear and radiological defensive measures, *Naval Ships' Technical Manual (NSTM) 070.* The Navy is in the final stage of completing development of new TTP manuals for its amphibious and special warfare communities. As part of the Joint Staff

acquisition requirements process, and in response to the ongoing operations against terrorism, the Navy has commenced development of TTPs and acquisition requirements for conducting at-sea maritime interception operations when the threat or the presence of CBRN weapons or components exists. As these experimental TTPs are approved, incorporation will take place into appropriate doctrine such as Navy TTP 3-07.11, *Maritime Interception Operations.*

Air Force Doctrine

During 2007, the Air Force Doctrine Center published AF Doctrine Document 2-1.8, *Counter-CBRN Operations.* This doctrine replaced the previous approach to counter-CBRN operations with more robust Air Force-specific guidance. This document explains and links Air Force doctrine to the three pillars in the *National Strategy to Combat Weapons of Mass Destruction*: nonproliferation, counterproliferation, and consequence management. In addition, AFI 10-2501, *Air Force Emergency Management Program Planning and Operations*, was updated in 2007 to improve education and training concepts. This document outlines roles and responsibilities for Air Force personnel to accomplish planning, equipping, training, and responding to major accidents, hazardous material incidents, natural disasters, enemy attacks with CBRNE, and terrorist use of CBRNE material. The Air Force is also developing guidance and standard operating procedures for major accidents and natural disasters as well as enemy attack and terrorist use of CBRNE materials.

Marine Corps Doctrine

The Marine Corps views CBRN as an operational environment, not a specific mission. The Marine Corps Warfighting *Publication 3-37* is the capstone doctrinal publication for Marine Air Ground Task Force (MAGTF) operations in a CBRN environment. The Marine Corps is rewriting this publication to address current Marine Corps expeditionary maneuver warfare concepts, while integrating the emerging Joint and multi-Service doctrine and validated concepts of operations related to CBRN defense.

The Marine Corps is currently conducting Field User Evaluations (FUE) for the Marine Air Ground Task Force Chemical Biological Radiological Nuclear Consequence Management (MAGTF CBRN CM) Program. These FUEs are designed to develop a sustainable training and certification program enabling each MEF to conduct sensitive site exploitation (SSE) in CBRN environments specifically TIM environments outside the scope of conventional warfare agents. The program also seeks to incorporate this training into the basic CBRN course at the USACBRNS.

Status of Training

Training is essential to the CBDP's objective of ensuring U.S. Armed Forces are ready to survive and operate in a CB environment. All geographic COCOMs participated in CBRN defense training, to include table-top and full-scale exercises involving Joint and allied forces and allied first responders. Foreign CBRN consequence management and counterproliferation representatives were also included in this training. Although the Services are statutorily responsible for individual training and exercises, the CBDP provides oversight and coordination, especially regarding realism in exercises and training. In 2007, the USACBRNS completed a state-of-the-art CBRN Responder Training Facility, which provides a realistic CBRN hazard training environment. The USACBRNS also hosts the Chemical Defense Training Facility (CDTF), which provides all Services the opportunity to practice planning, monitoring, and sampling skills in a toxic environment. Although these facilities are available to all Services, the USACBRNS courses remain primarily Service-specific in a collocated environment.

Service and Combatant Command Achievements

Advances in CBRN defense training across the Services in 2007 reflect an effort to integrate the medical community, increase collaboration, and capitalize on different methods of learning. The Joint Staff conducts exercises as part of the Chairman's Sponsored Exercise Program. These

exercises contain CBRN themes and include Services, COCOM, and interagency participation. In May 2007, exercise *Positive Response* was linked to the Northern Command (NORTHCOM) exercise *ARDENT SENTRY.* This effort focused on testing the response to a U.S. domestic incident involving CBRN. In October 2007, *Positive Response* was linked to *National Level Exercise 1-08*, testing top officials' response to CBRN incidents. In 2008, *Positive Response* will link to *National Level Exercise 2-08* with CBRN themes.

Army Training and Exercises

The Army's policy is to train all Soldiers on individual CBRN defense tasks to ensure their survival and mission continuation under any conditions. CBRN defense training is integrated into all phases of professional development.

The MANSCEN serves as the center for co-located Service CBRN defense specialist training including the Army, Navy, Marine Corps and Air Force. The USACBRNS CBRN specialists' training consists of courses designed to support instruction in CBR agents, hazardous material characteristics, decontamination operations, individual protective clothing and equipment, combating WMD to include CBRN consequence management, as well as live/toxic agent training in the CDTF. Toxic agent training is mandatory for all Chemical Corps Specialist initial entry and professional courses. These schools graduated more than 5,000 students across all Services during FY 2007.

In 2007, the USACBRNS received delegated authority to certify students at the HAZMAT

Awareness, Operations, and Technicians levels, from the International Fire Services Accreditation Congress through the Air Force Civil Engineer Support Agency. These standards are already integrated into consequence management courses with plans for future integration into existing CBRN professional military education, such as the CBRN Captain's Career Course.

The USACBRNS continues to provide initial and advance courses in support of the WMD-Civil Support Team Program. More than 300 students from the Army and Air National Guard graduated in FY 2007. This cutting edge education and training program continues to draw interest from all the services and many civilian agencies responsible for CBRNE response related activities. In addition, new courses developed to support the US Army Reserve Domestic Reconnaissance and Mass Casualty Decontamination mission have evolved to provide key CBRN reconnaissance and decontamination skills to support other DoD CBRNE consequence management programs, including CERFP and CCMRF.

Navy Training and Exercises

The U.S. Navy significantly increased the number and quality of CBRN defense-type exercises, as forecasted in last year's report. Exercises included the U.S. Third Fleet's roundtable exercise with Navy and civilian units addressing a pandemic influenza outbreak. All U.S. Navy bases, installations, and civilian personnel participated in Exercise *Solid Curtain*, which focused on training and readiness

of the Navy's security personnel. The Navy also participated in Exercise *Vigilant Shield 08*, designed to train personnel in homeland defense, homeland security, and defense support to civil authorities.

To integrate the medical community with education and training, the National Naval Medical Center, along with local authorities, conducted the fourth annual *Emergency Preparedness Partnership* exercise, focused on two near-simultaneous events and coordination with first responders. In addition, ships deploying overseas must demonstrate counter-CBRN proficiency.

Air Force Training and Exercises

The Air Force developed new CBRN defense training courses using a blended learning format consisting of Web-based training (WBT) courses. The WBT format allows academic self-paced learning and provides students with increased access to course materials. New courses developed in 2007 included the:

- CBRNE Awareness Course
- CBRNE Key Leaders Course
- CBRNE Survival Skills Course
- CBRNE Defense Emergency Management Course
- Exercise Evaluation Team Course
- Emergency Response Operations Course.

The Air Force Field Training Flight CBRNE Element Basic Military Training trains 45,000 students annually. Their facility has the largest non-lethal gas chamber in the Air Force inventory and supports Army and Marine CBRNE training requirements as well.

The Air Force All-Hazard Response Training (AHRT) merged the Medical Response Exercise and Training Program with the WMD Incident Response Training Program to streamline installation exercises and training requirements. The initiative resulted in quality training and exercises for Air Force installations, along with a comprehensive training and exercise program focused on Exercise Evaluation Team members, key Air Force leaders, installation Disaster Control Group members, and local community leaders with emergency management responsibilities.

Marine Corps Training

Awareness of CBRN is incorporated into all levels of training and operational planning in the Marine Corps. CBRN training is specifically addressed at the small unit level to maximize force protection and unit survivability. The Marine Corps institutionalized CBRN training at its Combined Arms Exercise Facility in Twentynine Palms, CA, with a plan to incorporate CBRN training requirements into MEU training. The Marines are currently conducting FUEs for the MAGTF CBRN CM Program to develop a sustainable training and certification program.

The Marines' Chemical Biological Incident Response Force (CBIRF) regularly trains with local, state, and federal responders. In the past year, these exercises included rapid deployment drills, pre-staged deployment events, and live agent training. The CBIRF capabilities include mass decontamination, casualty decontamination, explosive ordnance disposal, and CBRN reconnaissance and technical rescue.

Joint Training and Exercises

In 2007, the JRO-CBRND provided support to six COCOM and Joint Task Force (JTF)-level exercises and three JTF-level tabletop exercises. They also conducted five iterations of the Joint Chemical, Biological, Radiological, and Nuclear Mobile Training Team (JCBRNFC MTT) Course and sponsored CWMD Professional Military Education (PME) sessions at the COCOMs.

Medical Training

In 2007, the Defense Medical Readiness Training Institute (DMRTI) developed a new SoP that identifies actions the Services should take to prevent, protect against, respond to, and recover from a CBRNE threat. This process resulted in approval from the Services to certify and validate medical CBRNE courses in their SoPs. All military, civilian,

and contract personnel assigned to the military health care system must complete the required initial CBRNE training, and sustainment training will be required every three years. The original DMRTI SoP training levels were consolidated into a single core knowledge level, and the advanced knowledge standards were redefined. Both levels of knowledge use education and training to meet the requirements.

Joint Professional Military Education (JPME)

The Chairman of the Joint Chiefs of Staff Instruction (CJCSI) 1800.01C, *Officer Professional Military Education Policy*, and the CJCSI 1805.01, *Enlisted Professional Military Education Policy*, emphasized the increasing priority of the CBDP. It is essential that all Services personnel understand the CBRN threat, are familiar with U.S. capabilities to detect and mitigate the threat, and comprehend their roles and responsibilities in handling any future CBRN defense issues.

The JRO-CBRND plays a key role in JPME. The JRO-CBRND uses their CBAs to:

- Identify gaps in leadership education
- Develop plans to address the gaps with education programs at all levels
- Provide technical support to War College games
- Provide subject matter experts (SME).

FY 2007 JPME accomplishments include:

- Weapons of mass destruction/effects (WMD/E) accreditation at all four Service senior-level colleges
- Guest speakers at five Joint senior colleges
- Codification of JPME/PME annual review process (CJCSI 180.01C)
- CWMD course at the Joint Advanced Warfighting School
- Recognition of countering WMD as one of the "Chairman's High Interest Training Issues" in the Chairman of the Joint Chiefs of Staff (CJCS) Joint Training Guidance, Joint Chiefs of Staff Notice (CJCSN) 3500.01.

In 2007, NDU assumed an increased role in JPME. As the WMD education focal point for JPME, the Center hosted organizational meetings, conferences, and workshops on WMD while focusing on curriculum development.

JFCOM is a lead integrator in Joint education and training and developed the Joint Knowledge Development and Distribution Capability (JKDDC). The JKDDC's Joint Knowledge Online provides Web-based CBRNE training products and services. FY 2007 accomplishments include WMD/E accreditation at all four Service senior-level colleges and a CWMD course at the Joint Advanced Warfighting School. This initiative is coordinated with the online training and course catalog discussed earlier in this section and JFCOM's development of a Live Virtual Constructive CBRNE Environment to facilitate more realistic training.

Challenges and Solutions

The H.R. 109-452 was an important tool for identifying gaps and highlighting deficiencies. The CBDP training community continues to be challenged by deficiencies in consistency, realism, and collaboration. Some methods to address these issues include sharing lessons learned and best practices from Joint training events, integrating CBRN training objectives into Joint training events, and ensuring all CBRN defense training stakeholders work closely together in a common venue and advocate communication and collaboration.

ADDITIONAL REPORTING REQUIREMENTS

The Title 50 U.S.C., Section 1523, requires the CBDP to provide a comprehensive overview of CB defense activities, including overall readiness, requirements, and ongoing initiatives to improve the ability of the U.S. Armed Forces to survive and operate in a CBW environment. In addition, there are very specific requirements to report on the TMTI, the status of efforts for the CWC, and a statement reconfirming compliance regarding testing involving human subjects.

Transformational Medical Technologies Initiative Fiscal Year 2007

The mission of the TMTI is to protect the warfighter from conventional or genetically engineered biological threats, known or emerging, by accelerating the discovery and development of broad-spectrum medical countermeasures using novel technology platforms and innovative management approaches. TMTI aims to develop countermeasures that are truly "broad spectrum" and effective against a range of pathogens.

The TMTI is managed through the Program Office (PO), with direct program guidance provided by the Executive Office (EO). Program oversight is provided by the SA(CBD&CDP).

The JPEO-CBD and JSTO-CBD established a PO to exercise day to day management of the ongoing execution of the projects under the TMTI. The PO will manage contracting and the funds to be obligated under contracts. The PO will also develop and implement the detailed acquisition strategies needed to transition mature technologies to products.

The PO is responsible for managing and executing the program, including:

- Portfolio management
- Strategic planning
- Individual project support
- Program staffing and contract support
- Contracting Officer Representative and program management
- Day to day supervision to the TMTI team
- Reporting and rating
- Issue resolution
- Performer relationships.

The EO is comprised of the JPEO-CBD and JSTO-CBD. The SA(CBD&CDP) Deputy/Medical Advisor is an invited guest to formal EO reviews. The EO holds a review on a monthly basis to assess the overall progress and success of TMTI, provide direction to the PO, and coordinate communications to key stakeholders, including PO reports provided to the SA(CBD&CDP).

The TMTI stakeholders provide oversight of the program in accordance with Title 50 U.S.C. 1522, the *Chemical and Biological Defense Program Implementation Plan*, October 2007, and the *Chemical and Biological Defense Program Medical RDT&E Plan*, December 2006. The size and complexity of the TMTI program requires frequent and in-depth oversight. Quarterly Overarching Integrated Product Team (OIPT) meetings, chaired by the SA(CBD&CDP) provide a forum to review program results and identify next steps to accomplish this effort. The first OIPT convened in March 2007.

Two advisory boards assist the OSD offices with TMTI oversight responsibilities. The Threat Reduction Advisory Committee (TRAC) panel, whose membership is drawn from government agencies and industry, meets quarterly at the OIPT to review program performance, incorporation of FDA guidance, coordination of research efforts among the agencies, alignments and planning of technology transitions toward product development, and other matters related to achieving the goals of the program. In addition, a group of selected peers, chaired by the ATSD(NCB), meets semi-annually to monitor progress and provide guidance.

A deliverable expected from many TMTI performers is the submission of an IND application. The most promising candidate products will continue through the development process toward FDA licensure, potentially with industry partners, to meet warfighter requirements. Maturity of the most promising products and enabling technologies in each portfolio from the S&T phase will determine the investments made in systems acquisition. The TMTI goals are as follows:

- Within five years of program's inception (i.e., by 2011), develop two or more platform technologies that can be used to identify unknown pathogens and rapidly develop countermeasures to newly identified threats
- By 2011, identify the genetic sequences for all pertinent threat agents against which to screen, characterize, and identify potential biodefense threats

- By 2011, develop and submit two or more IND broad-spectrum countermeasures
  - One product will be active against hemorrhagic fever viruses (HFV)
  - One product will be active against intercellular bacterial pathogens (IBP).

The TMTI Program Office (PO) uses project level metrics to track the progress of the individual efforts within TMTI and concentrates on cost, schedule, and performance. The TMTI PO collects progress data for these metrics via quarterly reports from the performers, site visits by the TMTI team, and payment invoices. In addition, the TMTI PO will use a project assessment (PA) metric, a qualitative review by a panel of experts composed of TMTI staff and SMEs, to determine a project's scientific merit and contribution to program goals.

The TMTI PO will conduct annual evaluations of program progress with regard to the following metrics:

- Program overview of cost, schedule, performance, and PA as a summation of the three goal areas
- Progression through technology readiness levels (TRL)
- Program risk assessment
- Portfolio funding and project distribution.

TMTI represents a new paradigm for rapid development of medical countermeasures. This paradigm has been developed, in part, by benchmarking the program's structure, metrics, and goals against DoD program management best practices and successful practices of the pharmaceutical industry.

Transformational Medical Technologies Initiative Program Funding and Objectives through FY 2009

	FY 2006	FY 2007	FY 2008	FY 2009
Funding ($M) Total Funding in Budget Activities	74	124	147	301
Annual Program Objectives	• Broad project selection across BA1-BA3 • Define potential products, platforms, and enabling technologies	• Determine approved products for label expansion • Identify near-approval products (e.g., shelved products) • Identify projects expecting to reach IND filing status within 1-2 years	• Identify products expected to transition at the end of FY 2010 or early FY 2011 • Realign investments per thrust area as determined by gap analysis • Continuance of current products' progression	• Identify performers for enhanced development capabilities • Continuance of selected current products' progression
Contracting Mechanism	Broad Agency Announcement (BAA) for new projects	Multiple (BAA and others)	Multiple	Multiple
Timing	October 2005	December 2006	October 2007	TBD
Targeted Performer	Industry, Academia, Government	Industry and Government	Industry and Government	Industry (if needed)
Size of Program Portfolio	25 projects	35 projects	33-37 projects (projected)	12-19 projects (projected)

The following benchmarks of successful DoD programs have been incorporated into the management and oversight of the TMTI program:

- Funding and program stability
- Program responsibility of the system's entire life cycle from systems acquisition through operations support
- Continuity of key personnel and technical expertise
- Milestone gated reviews of projects
- Good management practices as evidenced by open communications, independent internal evaluations, and a contracting environment that values innovation.

The Executive Office (EO) conducts periodic reviews of the program with the PO. These reviews include a project status that reflects updates on metrics and a discussion of potential issues based on cost, schedule, and performance. This metrics analysis facilitates a program gap analysis that will assist in the development of future BAAs, requests for proposals (RFP), requests for information (RFI), and other contracting mechanisms that the PO will employ to ensure successful program accomplishment.

The TMTI PO, EO, and DoD oversight will continually assess program direction and alignment with the benchmarks and associated metrics. All TMTI stakeholders will communicate a constant and transparent program status through informal and formal program reviews at all levels. This effort will enable the PO to reallocate funding within the TMTI portfolio as required to achieve product goals faster and to develop early corrective action for off-track projects. The table below shows TMTI program funding and objectives through FY 2009.

Transformational Medical Technologies Initiative Program Funding and Objectives through FY 2009

The figure below shows TMTI IND submission target dates. The PO grouped the projects by primary goal area. As per the statements of work

Transformational Medical Technologies Initiative Investigational New Drug Submission Dates

Goal	Project	Description	FY Project Inception Dates	FY 2008				FY 2009				FY 2010				FY 2011			
HFV Therapeutics	AVI	Conserved viral genes	2006				■												
	F Gen 06 (2)	TSG101mAb, small molecule inh	2006									■							
	F Gen 07	Small molecule inh-host targets	2007						■										
	SRI	Screened library of licensed drugs	2007									O							
	Alynylam	RNAi to host genes-viral infection	2007							■									
IBP Therapeutics	Microbiotix	Bisimidazolinylindoles	2006				■												
	PTC	T-RNA hydrolase inhibitors	2006									■							
	Achaogen	Bacterial resistance	2007												■				
	Achaogen	Lipid synthesis inhibitors	2007										■						
	GSK	Gyrase inhibitors	2007												■				
	Implicit	Immunomodulator dipeptide	2007									■							
	USAMRIID	Licensed FQ, immunomodulators	2007					O											
	Evolva	Small molecules targeting TLRs	2006							■						■			
	SRI	Screened library of licensed drugs	2007									O							

■ Expected IND filing (14) O Expected Abbreviated New Drug Application (ANDA) filing (≥3)

(SOW), the PO expects initial IND submissions to occur in the third and fourth quarters of calendar year 2008. After IND submission, TMTI has an option of renegotiating contracts or soliciting for RFPs to advance promising candidates into systems acquisition. Conducting systems acquisition post-IND submission is capital intensive and requires a steady stream of funding. However, the attrition rate seen in pipeline management (as seen in the pharmaceutical industry) will force TMTI to mitigate risk by making careful assessments about the probability of success before making decisions to cut performers. The TMTI PO has developed portfolio and pipeline management processes that will allow go/no go decisions based on the review of three elements of a candidate product: TRLs, target product profile (TPP), and programmatic criteria.

Platform Project Timelines

The figure below shows the platform product timelines associated with sequencing projects or technology platforms. At the completion of these projects, the information that is gleaned will reside within the DoD and be shared with other federal agencies. For example, the government may use information resulting from these projects to identify targets (pathogens or host genes) that are likely to be susceptible to treatment with drugs.

In FY 2007, the PO added an additional 10 projects to the TMTI portfolio. Of those 10, one is in negotiation, and seven others have been awarded or provided funds via military interdepartmental purchase request (MIPR). The two remaining proposals are the result of leveraging existing agreements with other government agencies and are in contract negotiations. The program has obligated 100 percent of FY 2006 funds and 49 percent of FY 2007 funds (as of September 30, 2007). The PO expects that TMTI will be 100 percent obligated for FY 2007 by July 2008. The FY 2008 TMTI spending plan accounts for all of the $147 million in the Defense Appropriations Bill for TMTI, a reduction of $100 million from the President's Budget Request. Funding cuts may jeopardize the ability of TMTI to progress candidates into advanced development to fill program gaps and develop a future capability.

Several performers in the TMTI portfolio have reported early success and are anticipating successful IND submissions as early as the third quarter of FY 2008. This success has advanced the need for critical decisions that are necessary in the portfolio management process. TMTI is writing a guideline for developing TTPs with assistance from the FDA, JRO-CBRND, JPEO-CBD, and OSD. This document will guide performers in developing therapeutics and clearly state performance thresholds

Platform Project Timelines

Thrust	Performer	Description	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Genomic Sequencing	NMRC	Genomic Sequencing of Bacterial Pathogens						
Platform Technologies	Brookhaven	Toxin Database						
	Ingenuity	Bioinformatics						
	USAMRIID	Construct interactome for Y. Pestis						
	Harvard	Develop library of host macrophage genes						
	Stanford	Host genes exploited by pathogens						

and objectives required for systems acquisition. The PO will develop product specific TPP for therapeutics developed against HFVs and IBPs.

TMTI initiated and participated in several focus groups that are of value to its program goals. The development of validated animal efficacy models against BWAs is critically important to TMTI. TMTI has participated in, and is continuing to participate in, interagency meetings to coordinate the development of new animal models for pathogens of interest. To attract the attention of industry and other partners, TMTI is working with OSD to prepare a Website to communicate with the public. The Website will contain program highlights and upcoming RFIs, RFPs, and BAAs.

The TMTI PO released a multi-year BAA in October 2007 aimed at attracting performers across industry, academia, and government capable of providing rapid and effective medical countermeasures against genetically engineered or emerging BW threat agents. The BAA focuses on products within two to three years of filing an IND application and initiating a Phase 1 clinical study or on products already licensed for another indication. The BAA also listed plans for the development of animal models for the FDA's Animal Rule exception, platform technologies for drug screening and drug development, and early detection of threat agents in patient or environmental samples exposed to BWAs as suitable projects. The source selection authority will review these proposals and will make award decisions in April 2008. In addition, TMTI will perform a complete technology sweep and use the multi-year BAA to supplement gaps in the portfolio, if the pipeline of therapeutics demonstrates an attrition rate (as expected) that would expose the program to a greater risk.

FY 2007 funding reductions forced the program to focus on more mature technologies to reduce risk of failure. In addition, the reductions forced a shift in emphasis to near-term gains versus a more balanced portfolio of early and late stage technologies. To meet program goals successfully, TMTI must contain a portfolio of projects that represent diverse technological approaches to each thrust area. To accomplish the goals expeditiously, the TMTI must conduct the approaches in parallel instead of sequentially. Reductions in the funding stream have hindered the program's efforts at risk mitigation.

This year, the TMTI moved closer to achieving its mission of protecting the warfighter from known, emerging, and genetically engineered biological threats by leveraging interagency coordination and collaboration to develop a TPP for HFV and IBP therapeutics and developing a focus group to aid in the development of new animal models for pathogens of interest.

Statement Regarding Chemical and Biological Defense Programs Involving Human Subjects

The reporting requirement (Title 50 U.S.C. 1523) for the ARC on the CBDP was modified by Section 1086 of the FY 1998 National Defense Authorization Act (NDAA). The amendment requires the following information:

> "A description of any program involving the testing of biological or chemical agents on human subjects that was carried out by the DoD during the period covered by the report, together with a detailed justification for the testing, a detailed explanation of the purposes of the testing, the chemical or biological agents tested, and the Secretary's certification that informed consent to the testing was obtained from each human subject in advance of the testing on that subject."

The United States formally renounced the "use of lethal biological agents and weapons, and all other methods of biological warfare" in *National Security Decision 35*, November 25, 1969. Human testing with lethal BWAs never occurred, and testing with incapacitating BWAs was ceased in 1969.

Although DoD conducted tests involving the exposure of human subjects to CB agents in the past, all such tests and programs have been halted and disbanded. Tests involving the exposure of human

subjects to chemical agents began in the 1940s and continued following World War II through the Cold War until the early 1970s. Such testing has been documented and reported to Congress (e.g., Department of the Army Inspector General Report (DAIG-IN) 21-75, *Use of Volunteers in Chemical Agent Research*, March 1976). In addition, extensive congressional testimony was given on this subject during 1975 and 1976. The last human testing of CWAs occurred on July 25, 1975. Acting Secretary of the Army Norman Augustine suspended testing of chemical compounds on human volunteers on July 28, 1975. DoD has not conducted any experimentation since that time involving the exposure of human subjects to CWAs.

The table below summarizes prior tests conducted by the DoD, directly and under contract, which involve the use of human subjects for the testing of chemical or biological agents. In summary, there has been no such testing since 1969 with biological agents, no such testing since 1975 with chemical agents, and no testing is planned.

Summary of Experiments and Studies With Human Subjects Involving the Use of Chemical and Biological Agents	
November 25, 1969	Human biological agent testing ended
July 28, 1975	Human chemical agent testing ended
Since 1969/1975	No activities with human subjects involving exposure to biological agents nor chemical agents have occurred since testing

The Department is in full compliance with the requirements of all laws regarding the use of human subjects involving CB agents. DoD is not involved in experimentation or any other efforts that involve the exposure of unprotected human subjects to CB agents. All individuals involved in training or RDT&E activities concerning live CB agents are fully protected and carefully monitored.
As part of the CBDP, DoD requires the use of small quantities of CB agents in the RDT&E of detection, protection, and decontamination equipment and systems. CB agents also are used in small quantities in training U.S. Armed Forces to operate protective equipment and detection and decontamination systems in a CB environment. However, no RDT&E involves the exposure of unprotected human subjects to CB agents.

The medical CB defense programs conduct controlled clinical trials to test and evaluate the safety, immunogenicity, and other effects of medical products (e.g., drugs, vaccines, therapeutics) to protect against CB agents. Using human subjects in these trials involves volunteers who have provided informed consent. All use of human subjects in these trials is in full compliance with the "Common Rule," Federal Policy for the Protection of Human Subjects, FDA Regulations, Federal Acquisition Regulations (FAR), DoDDs and DoDIs, and all other applicable laws, regulations, issuances, and requirements. The FDA's July 1, 2002 rule, *New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible*, is the final version of the proposed October 5, 1999, rule cited in previous reports. No medical CB defense program involving human subjects involves the exposure of these subjects to CB agents.

Simulants are sometimes used to enhance the realism of operations in a CB-contaminated environment as part of some training and RDT&E activities. Although simulants are not CB agents, they may simulate some of their properties (e.g., particle size, surface absorption). The following are requirements for testing involving simulants:

- All personnel are informed of any hazards, if any, associated with the simulant
- All personnel are provided with appropriate protective equipment
- All names of testing participants are carefully recorded.

If at some point in the future it is determined that a simulant used in testing presents a potential health hazard, the Department will notify personnel of potential risks to their health.

Status of Department of Defense Efforts to Implement the Chemical Weapons Convention

The CWC opened for signature on January 13, 1993. The Convention entered into force on April 29, 1997. As of November 1, 2007, 182 countries including the United States are signatories of the CWC, and in 2007 one country ratified or acceded to the CWC. The 12th session of the Conference of the States Parties, the highest policy-making organ of the Organization for the Prohibition of Chemical Weapons (OPCW), convened in The Hague, Netherlands from November 5-9, 2007.

Department of Defense Implementation of the Chemical Weapons Convention

In 2007, DoD hosted 102 inspections and visits at CW storage, former production, destruction, and Schedule 1 facilities. The Army (the Service most directly affected by CWC implementation activities) and DTRA continue to host and escort inspectors from the OPCW Technical Secretariat (TS). The OPCW is charged with overseeing worldwide implementation of the CWC. TS inspectors conduct continuous and non-continuous monitoring at DoD CW destruction facilities and systematic inspections at DoD CW storage, former production, and Schedule 1 facilities. DoD completed the destruction of the last of its former CW production facilities in 2007, thus terminating TS systematic inspections for former production facilities in the United States.

The DTRA provides CWC orientation training and associated mission-support training (i.e., treaty escort, HAZMAT, and hazardous waste operations and emergency response (HAZWOPER) training) to USG national escorts and other treaty compliance personnel. DTRA ensures that all escorts are trained and ready to receive OPCW TS inspection teams.

In addition to supporting inspections at DoD facilities, DTRA assisted the Department of Commerce (DOC) with CWC escort training pursuant to a memorandum of agreement (MOA). The DOC is the lead agency for chemical industry inspections. DTRA continues to support DOC with expedited customs and immigration processing at the point of entry into the United States and with inspections of OPCW technical equipment. U.S. chemical industry inspections began in May 2000. The OPCW TS conducted seven chemical industry inspections in 2007.

The DoD conducts a Chemical Weapons Implementation Working Group (CWIWG), chaired by the CW/BW Treaty Manager, and the ATSD(NCB), to implement the CWC. Through

regularly recurring meetings, representatives of the OSD, the Joint Staff, Services, and DoD agencies and activities coordinate planning efforts to ensure proper implementation of the CWC. Formal meetings of the CWIWG are scheduled quarterly, and small group meetings are held as needed to address specific requirements in support of the CWIWG.

A Compliance Review Group (CRG), also chaired by the CW/BW Treaty Manager, was established within DoD to address CWC compliance concerns as needed. The OSD, the Joint Staff, Services, and DTRA provide technical experts to support activity at the U.S. Delegation to the OPCW at The Hague.

The Army is the Executive Agent for the Chemical Demilitarization Program, which has the mission to destroy all U.S. CW material while ensuring maximum protection of the public, personnel involved in the destruction effort, and the environment. The Army works through OSD to ensure that this program is compliant with CWC provisions.

Safety Orientation for Inspectors

All OPCW inspectors who conduct continuous monitoring at U.S. CW demilitarization facilities are required to attend a 32-hour safety orientation. This orientation, presented by the Army, is divided into two sections: a 24-hour health and safety orientation (HSO) course, which is a USG requirement of all personnel who must be present on a more than short-term basis at U.S. chemical demilitarization facilities; and an eight-hour ammunition safety course. A 48-hour demilitarization protective ensemble (DPE) procedures course is required only for those inspectors designated by the OPCW TS, whose responsibilities would include the use of such protective equipment.

Roughly 172 OPCW TS inspectors have attended initial HSO training and 14 inspectors have attended the DPE course. The training is conducted either at the CDTF or at The Hague. In addition, an annual eight-hour HSO refresher course is also required of TS inspectors. The Army teaches this course at The Hague. DTRA provides USG national escort support for OPCW inspectors while attending required training in the United States. DTRA ensures that all inspectors receive the required training.

Preparation of Defense Installations

The Services and DTRA have developed individual implementation and compliance plans to provide guidance for their commands and activities under the CWC. The Services have individually established implementation support offices, which participate actively at the DoD CWIWG, provide Service policy direction, and liaise with their major commands to ensure that all military elements are fully prepared for inspections under the CWC.

The Services continue to coordinate actively with OSD and DTRA to prepare DoD installations for inspections under the CWC. All defense installations are subject to declarations under CWC requirements. Installations that are subject to challenge inspections, even though not declarable, have been visited by Service representatives and DTRA technical experts. DTRA will continue to support site assistance visits and Army treaty implementation and compliance meetings.

All Services have held exercises to test their preparedness for short-notice CWC challenge inspections. Such exercises involve the active participation of Service, OSD, DTRA, and other DoD representatives in the roles they would assume during a challenge inspection. DoD and the Services have exercised written DoD guidance and procedures to test the operational readiness of personnel and facilities. The Services have 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 coordination with the Navy, DoD sponsored a six-day tabletop challenge inspection exercise in 2007, using the Naval Support Facility, Dahlgren, VA, as the challenge site. DoD's overall objective

was to validate the latest DoD compliance guidance, exercise the CRG process, address and validate public affairs guidance, and exercise the host team subgroup process.

Defense Treaty Inspection Readiness Program

The Defense Treaty Inspection Readiness Program (DTIRP), for which DTRA is the executive agent, provides arms control implementation advice and assistance to sites subject to onsite inspection using specially trained personnel, analyses, and educational activities. In 2007, DTIRP supported the U.S. Army Chemical Materials Agency, Defense Security Service Academy, and other Services to provide arms control security advice and tailored training for new personnel. The DTIRP has provided, and will continue to provide, arms control vulnerability assessment teams in support of any requirement to assess risks to critical national security assets, U.S. industry, and research institutions. Program personnel are actively engaged throughout the arms control and security arenas to remain current and focused on present arms control security challenges.

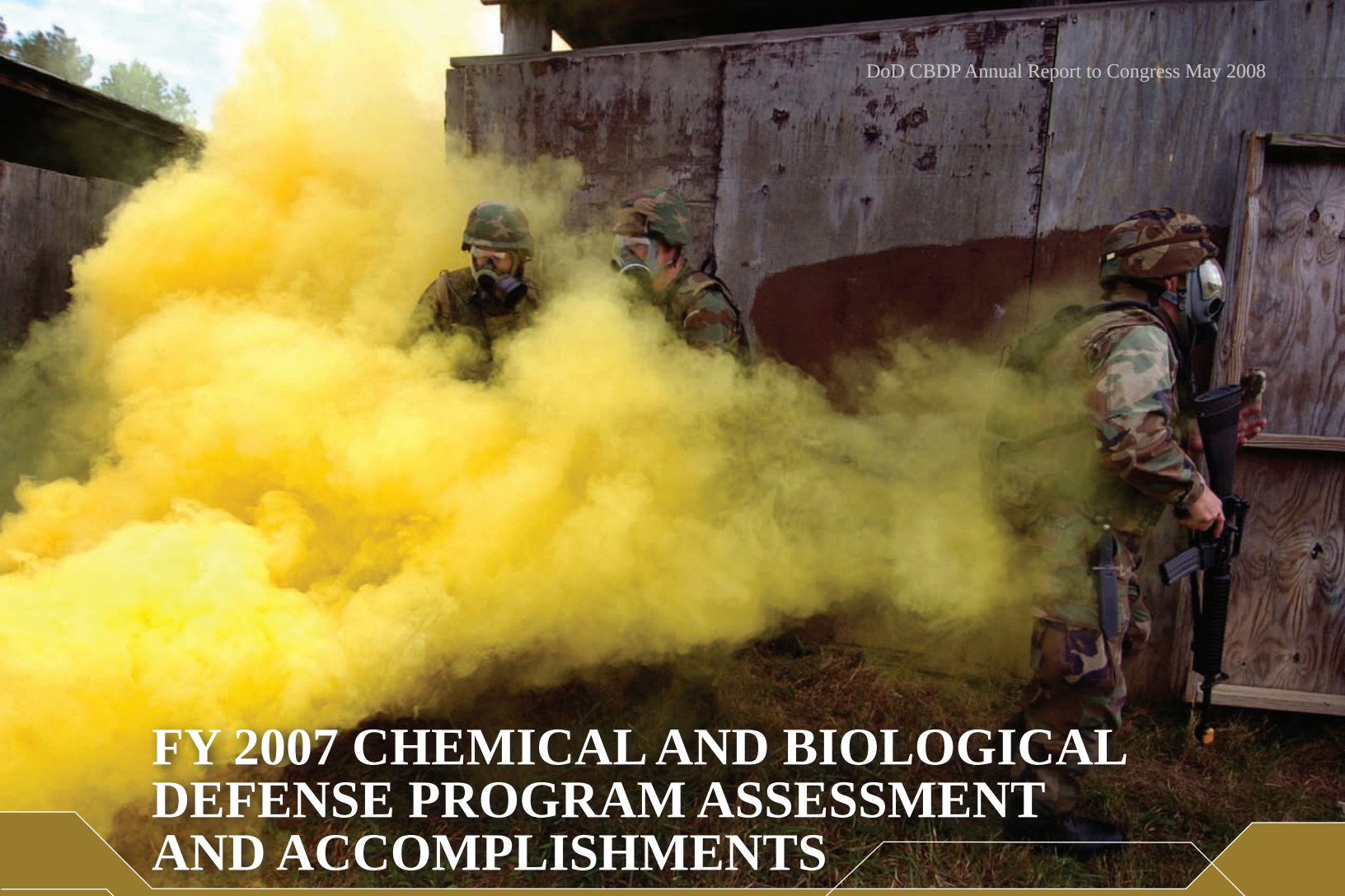
Technical Equipment Inspection Program

The Technical Equipment Inspection (TEI) Program ensures that OPCW TS verification equipment meets U.S. safety, environmental, and security requirements through a familiarization process authorized by the OPCW Conference of States Parties. Familiarization results are documented in the U.S. Certification Report of Chemical Weapons Convention Organization for the Prohibition of Chemical Weapons Technical Secretariat Equipment. In addition, TEI verifies and confirms OPCW equipment entering and exiting the United States and performs chemical agent monitoring of inbound equipment for all inspection teams at the point of entry. Chemical agent monitoring is conducted to protect U.S. and OPCW personnel and prevent inaccurate findings resulting from preexisting contaminants on the OPCW verification equipment.

Article X Assistance and Other Assistance

Under Article X of the CWC, a State Party to the treaty may make an appeal for assistance through the Director-General of the TS. In accordance with a condition established in the U.S. Senate's Advice and Consent to the Ratification of the CWC, the United States will provide "no assistance…other than medical antidotes and treatment," which the USG deems are necessary, to those CWC States Parties that have requested assistance under Article X of the CWC.

Under the CWC, DoD has provided neither CW detection equipment nor assistance in the transportation, storage, and destruction of CW to other States Parties, except that being provided to Russia and Albania under DoD's Cooperative Threat Reduction (CTR) program.



FY 2007 CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM ASSESSMENT AND ACCOMPLISHMENTS

Assessment

The following provides a review of the CBDP from capability needs to readiness. This assessment captures program-wide successes and issues impacting the CBDP's overall health across operational requirements, S&T, acquisition, and T&E infrastructure.

The assessment uses existing DoD/CBDP processes and leverages existing data and information to the greatest extent possible. The process summarizes and integrates information of record from numerous data sources, and the results are verifiable by internal and external organizations and agencies, where applicable, and as required. The assessment supports the SA(CBD&CDP) efforts to accurately assess CBDP health and progress and summarizes program status, overall CBDP performance, and cross-cutting and significant issues identified (but not resolved) by the CBDP OIPT in FY 2007.

In addition, the assessment supports the requirements of Section 4.2.1 of the 2007 Revision to the CBDP Implementation Plan for the ATSD(NCB) to provide the DAE with an integrated program assessment on a quarterly basis to support the semi-annual OIPT schedule.

Within each category, an assessment metric rating is based on the following criteria:

- GREEN: No cross-cutting issues
- YELLOW: Cross-cutting issues with identified resolution within established processes
- RED: Critical issues that require Flag Officer/ General Officer (FO/GO) resolution.

Chemical and Biological Defense Program Operational Requirements Assessment

The following information can also be found in the JRO-CBRND Quarterly Report, December 2007.

In FY 2007, when evaluating JRO-CBRND JCIDS documents, 44 of 45 (98 percent) of the documents in place have either no issues or an issue that can be resolved within an established process. Only one program of record (POR) (two percent) has a JCIDS document with a critical issue that requires FO/GO resolution efforts.

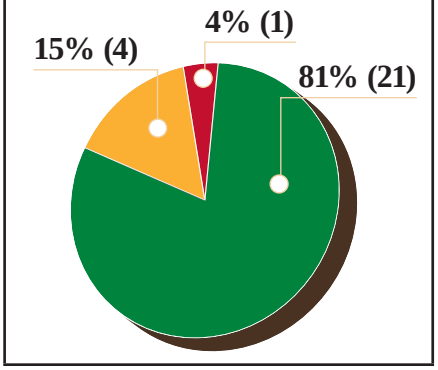
The POR that is rated red due to a critical issue, Joint Service Transportable Decontamination System – Small Scale (JSTDS-SS) Increment 1, is in the process of resolving Air Force performance issues and currently has a capabilities production document (CPD) in draft.

The overall health of the JRO-CBRND JCIDS documents are assessed within three Operational Requirement categories; Approved JCIDS Documents, Pending JCIDS Documents, and JCIDS Documents in Development. As of FY 2007, of the 45 POR JCIDS documents in place, 26 were approved, six were pending approval, and 13 were in development.

Approved Joint Capabilities Integration and Development System Documents

Of the 26 approved documents, 21 (81 percent) had no issues; four (15 percent) had substantial issues having a resolution within the established processes; and one (four percent) had a critical issue requiring FO/GO resolution.

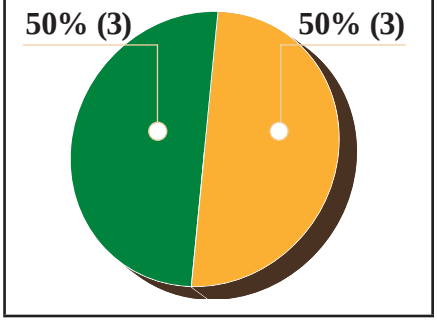
Approved Joint Capabilities Integration and Development System Documents (26)



Pending Joint Capabilities Integration and Development System Documents

Of the six pending documents, three (50 percent) had no issues; three (50 percent) had substantial issues having a resolution within the established processes; and none had critical issues requiring FO/GO resolution.

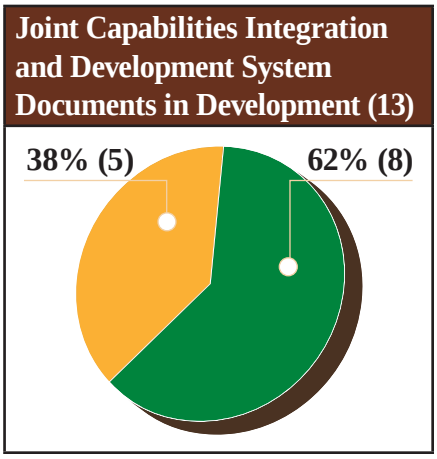
Pending Joint Capabilities Integration and Development System Documents (6)



Joint Capabilities Integration and Development System Documents in Development

Of the 13 POR documents in development, 8 (62 percent) had no issues and five (38 percent) had substantial issues having a resolution within the established processes; and none had critical issues requiring FO/GO resolution.

Joint Capabilities Integration and Development System Documents in Development (13)

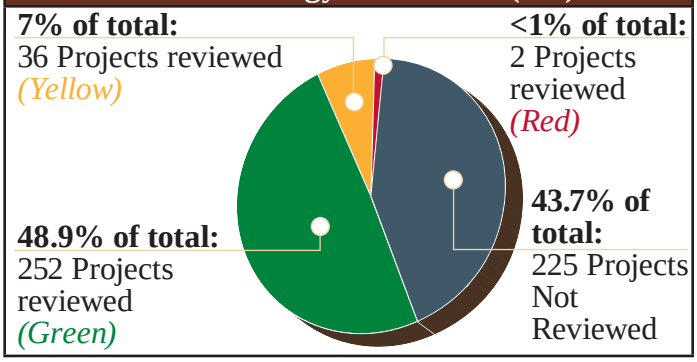


Chemical and Biological Defense Program Science and Technology Assessment

The CBDP S&T Program validates that appropriate science is being applied to address validated capability needs. In FY 2007, the S&T Program had a total of 515 projects. Of those 515 projects, 290 (56 percent) physical and medical projects

were reviewed. Of the 290, 252 (86.9 percent) were assessed as green, 36 (seven percent) were assessed as yellow, and two (0.69 percent) were assessed as red.

Chemical and Biological Defense Program Science and Technology Assessment (515)



For the two projects that require significant management attention, the Capability Area Program Officers (CAPO) are developing and implementing sound risk management strategies that are innovative, proactive, and revolutionary.

CAPOs are taking aggressive action to develop and implement sound risk management strategies to address those projects that require intervention and to develop a future program that is innovative, proactive, and revolutionary and takes advantage of innovations in science and incorporates technology from outside of the program. The program measured and evaluated each projects' progress by using metrics in three evaluation areas:

1. Explanation of the science
2. Utilization of the state-of-the-art science
3. Outcome of the approach to warrant continuation.

The Medical S&T Program continues on track and represents both a comprehensive and balanced portfolio with an emphasis on mutually beneficial and synergistic research collaborations. These collaborations between industry, academia, other government agencies, and international entities increased greatly during FY 2007 and are expected to continue increasing in FY 2008 and beyond. The Medical S&T Program leveraged established collaborations and funded programs, which will enhance the potential for the development of newer, safe, and effective methods for medical S&T transition to Advanced Technology Development and to the warfighter. Medical transitions remain a priority for the Medical S&T program, and a number of S&T programs have recently transitioned to the advanced developer. Six additional medical transitions are scheduled from FY 2008 through FY 2011. The Medical S&T Program successfully utilized its Product Development Office to achieve success in enhancing transitions and alignments with TTAs between S&T efforts and advanced developers.

Particularly noteworthy Medical S&T successes in FY 2007 included the establishment of assay standards and the focus on knowledge-based publications, which resulted in over 150 peer-reviewed publications and 33 patents.

The CBDP S&T Program is on track and soundly positioned with a forward-facing orientation to deal with emerging technologies and threats.

Chemical and Biological Defense Program Acquisition Programs Assessment

Overall success of acquisition programs are measured by outcomes in terms of fielding additional or new capability to the warfighters. Within the Defense Acquisition System, the JPEO-CBD is the designated MDA for all CB Defense Acquisition PORs. Currently, there are 43 PORs with 23 active APBs. The APBs are used to manage the cost, schedule, and performance throughout the SDD, to the full-rate production decision review. During 2007, the JPEO-CBD modified the monthly Acquisition Status Reports to implement the new DAE Summary format for all programs. Relevant information is reviewed monthly for all 43 programs under JPEO-CBD purview, to include those in full-rate production and pre-system acquisition where APBs are not pertinent. During 2007, nine APBs were changed; of these nine, six were updated as required during decision reviews; two were updated to reflect fact-of-life changes in quantities; and one reflected a restructured program schedule to align an information system with associated external C2 system developments.

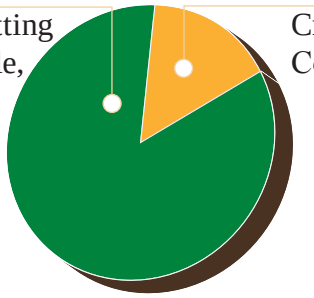
During 2007, the JPEO-CBD fielded 20 different systems to the Army, Navy, Air Force, and Marine Corps. These total package fieldings included 173 training events totaling 10,447 students, and approximately 1.2 million individual pieces of equipment fielded at 106 fielding locations. Overall satisfaction of these training and fielding events was above 4.5 with 5.0 being the best on a scale of one to five.

Overall Acquisition Program Assessment – Green to Yellow: *Cross-cutting issues have been identified that can be resolved by the agencies included in the CBDP. The table above illustrates the ratio of green programs – 36, to the number of yellow programs – seven.*

Chemical and Biological Defense Program Acquisition Programs (43)

84% (36): No Cross-Cutting Cost, Schedule, or Performance Issues

16% (7): Cross-Cutting Cost Issues*



* Seven programs in the medical portfolio are affected by programmatic cost growth resulting from new FDA Requirements for earlier full-scale production process prove out and costly implementation of DoD unique biosurety policies.

Cost

During 2007, technology challenges resulting in program cost growth have been resolved within the CBDP under the control of the JPEO-CBD and its JPMs. These resolutions are reflected in revised APBs during milestone reviews and when revising fact-of-life changes in APB quantities. Seven programs in the medical portfolio are affected by programmatic cost growth resulting from new FDA requirements for earlier full-scale production process prove-out and costly implementation of DoD unique biosurety policies. Most programs will experience some cost growth to implement mandatory unique item identification mandates. This cost growth has been addressed at the CBDP OIPT level, and the associated costs with these mandates will be included in the FY 2010 - 2015 POM.

Cost Assessment - Yellow: *The CBDP identified cross-cutting issues that can be resolved by the agencies included in the program.*

Schedule
Schedules have been updated in MDA approved APB revisions during decision reviews to reflect technology challenges, contractor progress during development and demonstration, and the one APB program restructure. In addition, cross-cutting schedule impacts due to delays in JCIDS capabilities document approvals are being addressed within the CBDP.

Schedule Assessment - Yellow: *The CBDP identified cross-cutting issues that can be resolved by the agencies included in the program.*

Performance
The CBDP continues to field militarily significant increments of capability, with no performance issues that cut across the acquisition POR. Individual acquisition program specific performance challenges have been addressed within the CBDP and reflected in APB updates during decision reviews.

Performance Assessment - Green: *No cross-cutting issues identified. On track.*

CBDP Test & Evaluation Infrastructure Assessment

CBDP T&E infrastructure remains challenged, but is improving as a result of investments in FY 2006 - 2007. T&E efforts are assessed as green because no cross cutting issues have been identified and efforts to address T&E infrastructure limitations are ongoing. Funding for T&E infrastructure supports the Joint Project Manager for Nuclear, Biological, and Chemical Contamination Avoidance (JPM NBC CA) PD TESS efforts.

Sense - Chemical Detection System Test & Evaluation Infrastructure
Current capabilities for chemical detector testing are limited to a standoff CWA chamber (simulant only) and field simulant capability for CWA standoff detection performance tests. Current CWA point detection performance test chambers (agent) can provide common static challenge concentration profiles with limited environmental conditions and interferents. Efforts to improve this area include a NTA Test Facility, Dynamic Test Chamber (DTC), and the renovation of a Chemical Surety Laboratory. The NTA Facility provides a capability to conduct emerging, highly toxic threat materials testing. The DTC provides a new capability for testing chemical point detection systems against chemical agents in various environmental conditions.

Sense - Biological Detection System Test & Evaluation Infrastructure
Current capabilities for biological detector testing are limited to component level of point detection systems. Efforts to improve the biological detection testing infrastructure include a Whole System Live Agent Test (WSLAT) Chamber and a Biological Standoff System Test Chamber. The WSLAT Test Chamber will support testing of all biological point detection systems in production configuration in BWA environments. The Biological Standoff System Test Chamber will provide a contained BWA environment on a larger scale for testing biological standoff detection systems.

Sense - Field Simulant Test & Evaluation Infrastructure
Current capabilities for field simulant testing are limited to antiquated referee instrumentation and dissemination devices. Efforts to improve this area include a fully instrumented 1km X 1km resolution fixed test grid and three 5km X 5km medium resolution relocatable test grids that integrate cloud tracking equipment, meteorological equipment, Test Data Network, C4ISR network, and operations center.

Additional efforts include instrumentation and characterization of the existing Joint Ambient Breeze Tunnel (JABT) and Active Standoff Chamber (ASC) Facilities. The JABT/ASC effort will provide facilities for controlled chemical simulant cloud and standoff detector testing.

Shield/Sustain - Individual Protection, Collective Protection, and Decontamination Test & Evaluation Infrastructure

Current test capabilities comprise chemical agent materials swatch tests which allow for comparative performance assessment under limited conditions and test environments, vapor and aerosol Man-in-Simulant Test (MIST), Simulant Agent Resistant Test Mannequin (SMARTMAN) to test CB masks, and protection factor mask tests.

Efforts to improve this area include: a decontamination chamber; IPE Mannequin System; MIST instrumentation; IPE Grid; Chemical, Biological Agent Resistance Test (CBART) equipment; and CP instrumentation and chamber. The decontamination chamber provides an enhanced ability to conduct decontamination and residual agent off-gas testing. The IPE Mannequin System provides an articulated robotic mannequin that simulates war fighter activities for evaluating IPE performance against CWA challenges. The MIST instrumentation provides a near real-time simulant sensor system to monitor penetration of simulant vapor and aerosols during testing. The IPE Grid provides test procedures to establish commonality measurements for IPE system level performance tests.

CBART equipment provides a near real-time testing capability under a range of environmental conditions for individual and collective protection materials. CP instrumentation upgrades provide improved test capabilities for the evaluation of entire CP systems, subsystems, and individual components.

Shape - Modeling & Simulation Test & Evaluation Infrastructure

Current M&S test capabilities do not exist for many acquisition programs. Efforts to make improvements in this area include the synthetic test environment library of real world environmental and interferent physical characteristics that affect chemical/biological system performance. The environmental signatures will be integrated into models to generate synthetic environments to allow material performance assessment under various conditions. A key focus of S&T T&E supporting efforts is to develop T&E models for prediction of system performance using material and component data for each commodity area.

> Because of the combined efforts of all CBDP partners, our U.S. Armed Forces are better organized, trained, equipped, and resourced to deal with all aspects of the WMD threat.

Summary

The CBDP initiated improvements in T&E infrastructure in FY 2006. These improvements are ongoing through the POM, and are aligned with the S&T and acquisition programs that they support. These test capability and methodology development projects are planned and executed in multi-year increments and are absolutely dependent upon the funding levels in each year.

Accomplishments

As detailed in this report, during FY 2007, the CBDP completed several initiatives to improve overall management and coordination of the CBDP within the Services and within other government agencies. In addition, the CBDP expanded its contacts within the international community through the CBR MOU and bilateral contacts with numerous other governments.

Because of the combined efforts of all CBDP partners, our Armed Forces are better organized, trained, equipped, and resourced to deal with all aspects of WMD threats. The following table lists CBDP key accomplishments in FY 2007.

FY 2007 Accomplishments	
Management & Oversight	• Developed the CBDP Strategic Plan • Issued the April 2007 DoDD 2060.02, *DoD Combating Weapons of Mass Destruction Policy* • DoDI 3150.cc, *The CBRN Survivability Program* (currently in draft). DoDI 3150.cc • Reissued DoDD 5160.05E, *Responsibilities for Research, Development, and Acquisition of Chemical Weapons and Chemical and Biological Defense* • Successful interagency coordination for the construction of the SRF at ECBC • DMRTI developed a new SoP to identify actions to prevent, protect against, respond to, and recover from a CBRNE threat • Drafted a multilateral Strategic Implementation Plan and Roadmap to the year 2025 for the CBR MOU which broadened international reach
Research, Development, and Acquisition	• Approved seven acquisition decision memoranda in the second half of 2007 (17 total) • Completed an interagency stockpile for the smallpox vaccine and began development for the anthrax vaccine • CBMS achieved an 80 percent FDA approval success rate • JSTO-CBD integrated the physical S&T decontamination capability area under the protection capability area to form the physical S&T Protection/ Hazard Mitigation capability area
Chemical Biological Defense Logistics	• Extracted inventory data for the first time using exclusively JACKS-RW • Formally established JLAC-CBD • Approved and delegated Materiel Release Authority to the MDA for CBDP • The successful testing of 61 lots of JSLIST suits resulted in a cost avoidance of over $18 million, as good lots were returned to inventory for reissue

Continued on following page

FY 2007 Accomplishments	
Education, Training, and Doctrine	• Completed *Joint Training and Certification for NBC Defense* report requirement as mandated by H.R. 109-452 • WMD/E accreditation at all four Service senior-level colleges, and a combating WMD course at the Joint Advanced Warfighting School • Trained 45,000 students at the Air Force Field Training Flight CBRNE Element Basic Military Training • More than 5,000 students graduated from Army CBRN specialist training courses • More than 300 students graduated from the USACBRNS individual training in support of the WMD-CST program • Purchased, certified, and fielded equipment for 55 WMD-CSTs • IPP completed fielding at 53 CONUS installations • AEFRP provided assessments, training, and fielding of equipment to 41 installations • USACBRNS received delegated authority to certify students at the HAZMAT Awareness, Operations, and Technicians levels • Published Air Force Doctrine Document 2-1.8, *Counter-CBRN Operations* • Conducted multiple capabilities-based assessments to assess the Armed Forces' CM and CBRND capabilities
Transformational Medical Technologies Initiative	• Developed a TPP for HFV and IBP therapeutics • Added 10 new projects to portfolio of 25 • Developed new animal models for TMTI pathogens of interest by leveraging interagency coordination • Approved the medical radiation countermeasures GI project for entry into concept and technology development
Chemical Weapons Convention Efforts	• CRG was established to address CWC compliance concerns • Hosted 102 inspections and visits at CW storage, former production, destruction, and Schedule 1 facilities • Completed destruction of last former CW production facilities • 172 OPCW TS inspectors attended initial HSO training and 14 inspectors attended the DPE course • Conducted seven chemical industry inspections • Sponsored a six day tabletop challenge inspection exercise

SUMMARY

Overall, the CBDP accomplished many initiatives towards achieving their vision and strategic goals. To achieve CBDP's strategic goals and provide the warfighter with the best technologies and support, the CBDP provides integrated, coordinated, and sustainable CBRN defense materiel and non-materiel solutions to the joint warfighter. All program efforts are focused on achieving the four CBDP strategic goals:

- ***Goal 1:*** Provide operational capabilities to the Joint Force to ensure they are prepared to operate successfully within all COCOM's area of responsibility in current CBRN threat environments to include support to civil authorities within the Homeland Defense Mission.
- ***Goal 2:*** Define and develop transformational capabilities to increase significantly our ability to dissuade, deter, defend, and defeat any future adversary in any CBRN threat environment.
- ***Goal 3:*** Sustain the capability of the Joint Force to operate jointly and provide an effective response in any CBRN crisis.
- ***Goal 4:*** Improve management practices to fulfill enterprise strategic roles and missions, meet the letter and intent of Title 50 U.S.C. 1522/23, and ensure effective and efficient use of Department resources in accordance with the priorities established in our national military strategies.

The CBDP seeks to ensure that DoD operations are unconstrained by CBRN threats by providing CBRN defense capabilities to build readiness for current and future challenges. The CBDP depends on continued congressional support in three priority areas to maintain the forward momentum of the program:

1. Stable funding for TMTI to fully exploit advanced S&T innovation necessary to successfully counter future genetically engineered biological weapons

2. Adequate long-term investment in infrastructure to enhance RDT&E capabilities, including modernization and construction of laboratories and test facilities to ensure development of advanced countermeasures against current and emerging CBRN threats
3. Adequate resources to ensure procurement and fielding of improved defensive capabilities essential to the Armed Forces' ability to operate in any environment, unconstrained by CB weapons.

Program Management and Oversight

Using the CBDP strategy, goals, and implementation plan, the CBDP will continue to optimize management and oversight methodologies and resources to ensure mission success in an increasingly dynamic environment. The CBDP will continue to coordinate and leverage efforts with other related programs and initiatives, including other USG organizations, and will continue international cooperation and information exchange with initiatives such as the CBR MOU and the ITF with NATO nations. In addition, the CBDP plans to rely more on M&S tools and continuous process improvement (CPI) to enhance oversight methodologies to bring proven technology to the field as rapidly as possible.

Status of Research, Development, and Acquisition

Joint Service CBRN defense RDA programs aim to meet current and future needs by leveraging Department-level strategies, joint operational and functional concepts, and architectures that emphasize common capabilities across the entire military operating continuum. RDA investments are achieved through a structured, executable, and integrated medical and non-medical joint CBDP that balances urgent near-term procurement needs to equip the warfighter and secure the homeland from a terrorist attack and far-term S&T efforts to mitigate future CBRN threats. These investments establish a foundation to meet the *National Military Strategy to Combat Weapons of Mass Destruction* passive defense, force protection, homeland defense, and consequence management CBRN defense requirements.

To prepare for the future, the CBDP is focused on actively coordinating with DoD components and other government agencies. Leveraging opportunities through coordination will ensure that RDA programs demonstrate acquisition stability, adhere to modernization strategies and priorities, and provide a defensible program to the OSD. Overall success of CB defense RDA programs and equipment can be achieved through the development of transformational capabilities and fielding the proper mix of capabilities that enable military operations to continue unabated by CBRN threats.

The goals of the R&D efforts for the capability areas described in this report include:

- Improving IP and CP capabilities against current and emerging threat agents
- Integrating real-time capabilities to detect, characterize, and communicate CBRN threats
- Improving neutralization and decontamination technologies
- Providing expanded individual medical protection.

To achieve these goals, the CBDP is investigating technology transitions to personal and CP system components, along with the integration of CB detectors into personal warfighter gear and the expansion of CBRN detector platforms. Full integration of automated warning and reporting networks will be prioritized to characterize CBRN hazards and battlefield environments. Congressional support for maintaining the R&D infrastructure related to these initiatives will enable continued forward momentum in the expansion of CBDP capabilities.

Status of Chemical and Biological Defense Logistics

The CBDP has continued to make progress toward the strategic objective of an integrated and efficient Joint logistics system. JPEO-CBD is implementing BPIs, decision support tools, and communications technologies and is increasing the visibility of the CBRN defense industrial base in an effort to further the goal of efficient and coordinated availability of CBRN equipment across all Armed Forces.

Chemical, Biological, Radiological, and Nuclear Defense Doctrine, Training, Exercises, Leadership, and Education

The CBDP is working in conjunction with the Services and other DoD agencies to explore new methods of improving realism in training, breaching stovepipes, and integrating the medical community in CBRN defense education and training. However, the CBDP training community continues to be challenged by deficiencies in consistency, realism, and Jointness. The H.R. 109-452 was an important tool in identifying gaps and highlighting deficiencies.

The CBDP is actively working to address these issues to include sharing lessons learned and best practices from Joint training events, integrating CBRN training objectives into Joint training events, and ensuring all CBRN defense training stakeholders work closely together in a common venue to advocate communication and collaboration.

Conclusion

The CBDP will continue to develop new defensive capabilities in anticipation of the continued evolution of WMD threats and potential threats, including genetically engineered biological pathogens and next-generation chemical agents, to ensure that our Soldiers, Sailors, Airmen, and Marines are prepared to operate in CBRN environments. To continue countering the existing and emerging CBRN threats and to gain a competitive advantage, continued congressional support for the CBDP's FY 2009 President's Budget Request is essential to sustain progress and to meet the critical operational needs of our warfighters and homeland defense requirements.

This report was coordinated and prepared by the office of the Under Secretary of Defense for Acquisition, Technology and Logistics and the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs in accordance with Title 50 U.S.C. 1523 and related requirements.

Copies of this report may be downloaded from the World Wide Web through the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs Website at http://www.acq.osd.mil/cp under the reports section as an Adobe Acrobat (.pdf) file.

Annex A: Go-to-War (GtW) Items

The data in this Annex was automatically generated from the JACKS-RW. It reflects Service and DLA on-hand inventories as of September 30, 2007 (see table below). JACKS-RW is the joint repository of initial inventory and tracking for 11 chemical defense equipment GtW items. In addition to the Reporting Warehouse module, the JACKS is the JPEO-CBD centralized and authoritative portal for logistics information such as shelf-life, training resources, equipment search, fact sheets, publications, and other items of interest including the CBRN-IRC.

The JACKS-RW was implemented in response to Government Accountability Office (GAO) Reports No. 04-334, *(For Official Use Only (FOUO)) Chemical and Biological Defense: Department of Defense Needs to Reduce Protective Ensemble Operational Risk*, April 30, 2004 and GAO-01-667, *Chemical and Biological Defense: Improved Risk Assessment and Inventory Management are Needed* that highlighted critical deficiencies with the Department's ability to monitor inventory levels and serviceability conditions. The Department plans to expand JACKS-RW to include all CB defense equipment for future reports.

Additional detailed equipment information about condition, shelf life, and detailed quantities within each of the categories in the roll up above can be viewed by accessing the JACKS at: https://jacks.jpeocbd.osd.mil/secure/default.aspx. Non-users must request access to this Website, as this information is FOUO. Approval is normally granted within 24 hours.

Joint Acquisition Chemical, Biological, Radiological, and Nuclear Knowledge System Reporting Warehouse On-hand Inventory of 11 Go-to-War Items as of September 30, 2007

Category	Nomenclature	Total Rollup Stocks on-hand as of September 30, 2007
Sense – Point Detection	Point Detection M256A1 – Chemical Agent Detector Kit	231,750
	M8 – Chemical Agent Detector Paper	4,506,900
	M9 – Chemical Agent Detector Paper	3,165,307
Shield – Individual Protection	Chemical Protective Overgarments	5,803,535
	Chemical Protective Boots	1,881,100
	Chemical Protection Gloves	4,025,295
	Filter, Canister C2/C2A1	3,554,090
	Cover Helmet, Chemical Protective	1,098,919
	Hood, M40/M45 (Air Force MCU-2/P)	544,875
Sustain – Decontamination	M295 Decontamination Kit, Individual Equipment	1,266,214
	M291 Skin Decontaminating Kit	1,681,094

Annex B: Joint Medical, Chemical, and Biological Defense Research, Development, and Acquisition Programs

Annex B discusses the joint medical CB defense RDA programs. This annex is organized into three sections that correspond to the organization of budget documents. This report will supplement the President's Budget Request submission in accordance with Title 50 U.S.C. 1523. The table below shows the relationship between this Annex and the budget documents.

Within S&T, research ranges from basic research to more mature applied and advanced research efforts designed to ensure that countermeasure candidate data not only meets the requirements for entry into the technology development phase but also is consistent with technical information required for an IND application. Maturing technologies will be integrated into the product development team process to plan for appropriate systems acquisition.

- ***Basic Research.*** Research that produces new knowledge in a S&T area of interest and encompasses a broad versus specific area of application. Basic research does not need to transition to more advanced studies.
- ***Applied Research.*** An expansion and application of knowledge to develop useful technologies to meet an identified need. Applied research may translate promising basic research into solutions for broadly defined military needs. This type of effort is typically inclusive of efforts that establish the initial feasibility and practicality of proposed solutions to technological challenges.
- ***Advanced Technology Development.*** Research with direct relevance to identified military needs. The aim for projects in this category is to move out of S&T and into the acquisition process in the near-term. This strategy will convey an understanding of FDA requirements for IND and new drug application (NDA) submissions.

Medical Research Description and Budget Documents *(Project Numbers are shown in body of chart)*

	Budget Activity (Program Element)				
	1. Basic Research (0601384BP)	**2. Applied Research (0602384BP)**	**3. Advanced Technology Development (0603384BP)**	**4. Advanced Concept Development and Prototypes (0603884BP)**	**5. System Development and Demonstration (0604384BP)**
Report Section	**Science and Technology Base**			**Advanced Development**	
Medical Chemical (MC) Defense (B.1)	TC1	TC2	TC3	MC4	MC5
Medical Biological (MB) Defense (B.2)	TB1	TB2	TB3	MB4	MB5
Medical Radiological (MR) Defense (B.3)	-	TR2	TR3	MR4	MR5

- TC= Technology Base Chemical
- TB= Technology Base Biological
- TR= Technology Base Radiological

Studies are required to have a plan to advance the technology from proof-of-concept through advanced animal studies in support of an FDA data package. This research will include a strategy for meeting Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP) requirements for product development, as appropriate.

Within systems acquisition, activities focus on the conduct of clinical trials with the goal of obtaining FDA approval for technologies developed under the CBDP technology base or transitioned to DoD from other organizations, including industry, academia, and other government agencies. The Advanced Component Development and Prototypes (ACD&P) phase includes R&D of vaccines, drugs, and diagnostic medical devices that are directed against CBR threats, with a focus on activities that are in Phase 2 of FDA clinical trials. Results of these efforts and those conducted during the SDD phase will be used to submit a Biologic License Application (BLA) to the FDA for product licensure. Upon FDA licensure, the product will transition to full-scale licensed production.

Medical Chemical Defense Research

Overcoming medical threats and extending human performance has provided a significant increase in military effectiveness in the past, and presents a potential for future enhancement in military operational effectiveness. The focus of the chemical countermeasures research area is to develop medical pretreatments and therapeutics to protect and treat the warfighter against exposure to traditional chemical threats (i.e., nerve, vesicant). The table at right summarizes key research task areas for providing pretreatment, therapeutic, and diagnostic capabilities.

Science and Technology Base

Although some investigation into the mechanisms of injury is merited, the testing and development of pretreatments, therapeutics, and adjuncts will be considered a priority. Compounds not currently under evaluation will be prioritized over those already under investigation or those studied in the past. The approach to meeting these objectives will address one of the following research focus areas. These research focus areas include those started or continuing in FY 2008 and those planned for FY 2009.

- ***Nerve Agent BioScavengers.*** Develop catalytic BioScavenger (cBioScavenger) or other than butylcholinesterase BioScavenger pretreatments that provide protection against all organophosphate nerve agents in several animal models, including non-human primates (NHP). The research will focus on developing compounds that should be devoid of physiological and psychological side effects when used alone (that is, in absence of nerve agent poisoning).
- ***Neurologic Therapeutics.*** Develop medical countermeasures for protection of the nervous system from nerve agent threats. Compound classes meriting research under this task area include neuroprotectants, anticonvulsants, and improved reactivators.

Chemical Countermeasures: Key Research Task Areas

Pretreatment	Therapeutic	Diagnostic
• Nerve Agent BioScavengers	• Neurologic Therapeutics • Cutaneous and Ocular Therapeutics • Respiratory and Systemic Therapeutics • Medical Toxicology Research (including sub-task: CWA Operational Exposure Hazard Assessment Research) • NTA Therapeutics • Medicinal Core Chemistry	• Chemical Medical Diagnostics • Medical countermeasures for NTAs

- ***Cutaneous and Ocular Therapeutics.*** Develop therapeutic strategies to effectively minimize the injuries to the integument and ocular tissues resulting from exposure to CWAs. This effort will involve developing effective practical field and clinic management strategies and physical and pharmacological interventions to treat the injury.
- ***Respiratory and Systemic Therapeutics.*** Investigate the systemic host response to CWA injury via all routes of exposure, emphasizing respiratory system and chronic effects to exposure. The primary goal will be to develop effective practical field and clinic management strategies, and physical and pharmacological interventions to treat the injury.
- ***Medical Toxicology Research.*** Determine toxic effects of NTAs by probable routes of field exposure, as well as standard experimental routes. Physiological parameters and pathological assessment will be used to establish the mode and mechanism(s) of toxicity. Determination of mode and mechanism will support the validation for a collateral objective of this area to investigate new advances in predictive tools such as Quantitative Structure Activity Relationship (QSAR) models. Research studies in this topic area will range from basic research to identify the mode and mechanism of action of NTAs, to more advanced computational and animal model development. Research will enable identification of molecular targets for next-generation therapeutics. Data generated in this thrust area will be used to guide the testing and development of therapeutics targeting NTAs. A specific sub-task within this research area is a defense technology objective (DTO) titled, "Chemical Warfare Agent Operational Exposure Hazard Assessment Research." This DTO aims to deliver data sets on operationally relevant health effects of low-level exposure to NTAs. The emphasis will be on assessing health hazards from the contact (percutaneous) route of exposure— although some selected compounds will be assessed for their respiratory (inhaled) hazard as appropriate. These data sets will support the refinement of fielded risk assessment tools. Specific objectives are to measure relevant experimental effects and to predict health problems in exposed military personnel that may affect mission performance and operational readiness. This program will design and execute studies that generate scientifically valid data to be used as a basis for reducing the error in health risk assessments useful for military operational risk management (ORM) decisions.
- ***NTA Therapeutics.*** Develop and test therapies against all NTA classes via all routes of exposure. Research will focus on de novo drug development and on testing of available countermeasures and FDA-licensed products. Studies, which will use appropriate in silico, in vitro, and in vivo animal models, will be designed to support eventual FDA licensure of new non-licensed compounds or new indications for licensed products for use in the treatment of chemical warfare casualties.
- ***Chemical Medical Diagnostics.*** Develop state-of-the-art laboratory/fieldable methods that detect exposure to CWAs (e.g., nerve agents and vesicants) in clinical samples. The task area also targets identifying biomolecular targets that can be leveraged as analytical methodologies as well as in vitro and in vivo studies characterizing time-course and longevity of a particular analyte/biomarker.

Medical Chemical Defense Research Accomplishments

Pre-treatments

Research thrust: Nerve agent BioScavenger (chemical warfare agent prophylactic)

- Recombinant BioScavenger pre-treatment of guinea pigs followed by exposure to Soman or VX resulted in 100-percent survival, with no signs of toxicity or behavioral impairment
- Developed and validated Physiologically Based Pharmacokinetic/Pharmacodynamic (PBPK) models for intravenous, subcutaneous, and inhalational administration of Soman in three animal models
- Further refined and analyzed X-ray structure of candidate BioScavenger yCE
- Cloned, sequenced, expressed, purified, and kinetically characterized greater than eight mutants of yCE to increase organophosphorous acid anhydrase (OPAA)
- Achieved up to a 20-fold increase in the specificity constant for carboxyl acid ester (pNPA) hydrolysis, and at least 200-fold increase in paraoxon reactivity through site directed mutagenesis of candidate BioScavengers
- Continued characterization of human serum paraoxonase (PON1) as a third-generation cBioScavenger.

Therapeutics

Research thrust: Neurologic therapeutic development, including advanced anticonvulsants, improved neuroprotectants, and next-generation acetylcholinesterase (AChE) reactivators

- Developed a mathematical molecular model to clarify the reactivation of inhibited AChE, as well as the effect of substituent groups on the reactivation event
- Initiated research into technologies to enhance blood brain barrier penetration for nerve agent countermeasures
- Used site-directed mutagenesis to better identify the role of the key amino acids in the reactivation event
- Used proteomic analysis to identify changes to proteome and genome of neuronal tissue following exposure to nerve agent
- Evaluated effects of nerve agents on mitochondrial function and tested efficacy of cyclosporine A and its analogs at mitigating damage
- Continued investigation of gross, cellular, and subcellular alterations of central nervous system tissue following exposure. Identified temporal and spatial progression of damage in small animal models
- Evaluated galantamine and huperzine A as potential replacements for pyridostigmine bromide
- Testing putative compounds to ameliorate seizures and reduce lethality using established animal models—tested compounds include FDA-licensed drugs and proprietary compounds obtained through CRADA.

Diagnostics

Research thrust: Develop chemical diagnostic technologies

- Completed development of robotic whole blood diagnostic system for nerve agent exposure
- Continued comparative research into field sampling techniques and technologies for post-exposure diagnosis.

Research thrust: Medical countermeasures for NTAs

- Identified and tested several potential compounds in small animal seizure models
- Investigated basic mode and mechanism of injury for NTAs.

Advanced Development Products

In advanced development, the goal is to obtain FDA approval and licensure of drugs, vaccines, and devices. The JPEO-CBD, through the Joint Project Manager for Chemical and Biological Medical Systems (JPM-CBMS), is the materiel developer. The following medical chemical defense products are now in the systems acquisition phase:

- ***Advanced Anticonvulsant System (AAS).*** After development and FDA approval, the AAS will provide an intra-muscular administration of midazolam, a drug for treatment against nerve agent induced seizures and subsequent neurologic damage. Exposure to nerve agents may produce long-lasting convulsions, even after treatment with atropine and 2-PAM. Untreated, these convulsions will produce permanent neurological damage in survivors. The AAS will be a replacement for the currently fielded Convulsant Antidote Nerve Agent (CANA) that uses diazepam. Midazolam is more water-soluble than diazepam (for quicker absorption into the blood stream). In animal models, midazolam terminates nerve agent-induced seizures more quickly than diazepam. AAS will not eliminate the need for other protective and therapeutic systems. During FY 2006, IND application was submitted and Phase I clinical trials were initiated.
- ***Chemical Agent Prophylaxes (BioScavenger).*** No prophylaxis against nerve agent poisoning exists. Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP) is the current FDA-approved pretreatment for Soman poisoning. To be effective, SNAPP must be administered every eight hours as a pretreatment and requires administration of atropine sulfate and 2-pralidoxime after exposure. The BioScavenger system is a prophylactic regimen that will protect the warfighter from incapacitation and death caused by organophosphorus nerve agents (e.g., Soman, Sarin, and VX). The plasma-derived form of human butyrylcholinesterase (HuBChE), a protein that can bind organo-phosphorus nerve agents, is the current candidate for BioScavenger Increment I. The BioScavenger Increment I Phase I clinical trial is ongoing and will be complete in FY 2008. The BioScavenger Increment II achieved a Milestone A decision in FY 2006. Contracts for BioScavenger Increment II were awarded in late FY 2006. The strategy included a proof-of-concept study followed by an initial down-selection between two different technologies: Recombinant human butyrylcholinesterase (rHuBChE) and small synthetic molecule. The chosen technology, rHuBChE, will continue to a formal down-selection with the plasma-derived BioScavenger at Milestone B prior to transition to the SDD phase.
- ***Improved Nerve Agent Treatment System.*** INATS is an enhanced treatment regimen against the devastating effects of nerve agent poisoning. INATS components are a new oxime to replace the currently fielded oxime (2 pralidoxime chloride or 2-PAM) and use of pyridostigmine bromide (PB), the component of SNAPP, against additional nerve agents. Nerve agents inhibit the enzyme, AChE, disrupting the routine transmission of messages. PB protects some of the AChE against nerve agent-induced inhibition. Oximes are compounds that reactivate nerve agent-inhibited AChE to restore normal enzymatic activity. INATS will develop a treatment system that offers optimal protection against a broad spectrum of nerve agents. INATS, which the FDA will license, will be issued to Service members who are performing military operations in which there is a risk of nerve agent attack. The new oxime component of INATS will replace the currently fielded oxime (2-PAM) in the Antidote Treatment Nerve Agent Autoinjector (ATNAA), but it will not eliminate the need for other protective and therapeutic systems. The oxime candidate (MMB4) transitioned to advanced development in FY 2005.

Medical Biological Defense Research

Advances in DoD medical R&D improve the warfighting mission by sustaining unit effectiveness through conserving the fighting strength of our forces and supporting the nation's global military strategy, which requires an ability to effectively deploy and operate in all environments. Medical R&D products (materiel and non-materiel solutions) provide the foundation to ensure the fielding of a flexible, sustainable, modernized force across the spectrum of conflict and in the full breadth and

depth of the battlefield. Overcoming medical threats and extending human performance has resulted in a significant increase in military effectiveness in the past and present, as well as the potential for future enhancement of military operational effectiveness.

The FDA has three licensed biological defense vaccines: Anthrax Vaccine Adsorbed, sold under the trade name BioThrax™, the smallpox vaccine called Dryvax™, and the smallpox vaccine ACAM 2000®. A prime systems contract, which supports the Joint Vaccine Acquisition Program (JVAP) component of the CBMS Office, is responsible for moving vaccine candidates from the technology base, through advanced development, to FDA licensure and procurement of baseline stockpiles. The following currently licensed, IND, or S&T vaccines and biologicals are for use in medical biological defense R&D (vaccines and antisera):

Vaccines:

- Anthrax Vaccine Adsorbed (licensed) (sold under the commercial name BioThrax ™)
- Smallpox Vaccine (limited stockpile of licensed vaccine, Dryvax™)
- Smallpox vaccine ACAM 2000®
- Botulinum Pentavalent Toxoid Vaccine Adsorbed (IND #3723)
- Botulinum Type F Toxoid Vaccine (IND #5077)
- Q Fever Vaccine, Formalin Inactivated, CM Extract, Gamma Irradiated (Henzerling Strain) (IND #3516)
- National Drug Company (NDC) (Salk) LVS Tularemia Vaccine (IND #157)
- The Salk Institute (TSI) Smallpox Vaccine (Vaccinia Virus, Cell Culture-derived) (IND #4984)
- Venezuelan Equine Encephalitis (VEE) Virus Vaccine (Attenuated), TC-83 (IND #142)
- Venezuelan Equine Encephalitis (VEE) Virus Vaccine (Inactivated), C-84 (IND #914)
- Eastern Equine Encephalitis (EEE) Virus Vaccine (IND #266)

- Western Equine Encephalitis (WEE) Virus Vaccine (IND #2013)
- Recombinant Botulinum Toxin Vaccine Serotypes A and B (BB-IND #11756)
- Recombinant Plague Vaccine—Fusion (BB-IND #12031)
- Recombinant Plague Vaccine—Bivalent (BB-IND #11378)

Therapeutics:

- Vaccinia Immune Globulin (licensed 2005) Therapeutic
- Equine Heptavalent F(ab')2 Botulinum Antitoxin (Types A, B, C, D, E, F, and G) (IND #3703)
- Botulism Immune Globulin, Human (IND #1332)
- Botulism Antitoxin Heptavalent Equine, Types A, B, C, D, E, F, and G (IND #7451)
- Vaccinia Immune Globulin, Intramuscular (IND #8429)
- Vaccinia Immune Globulin, Intravenous (IND #9141)
- Vaccinia Immune Globulin, Intravenous (IND#10351, emergency use protocol)
- Cidofovir Smallpox Therapeutic, Intravenous (S&T)
- Cidofovir Smallpox Therapeutic, Oral (S&T)
- SIGA-246 Smallpox Therapeutic, Oral (fast track status (S&T))

Biological Defense Science and Technology Base

Research focuses on developing medical countermeasures effective against BW threat agents. Research activities focus on reducing the lethal and functional incapacitating effects of an agent and/or complement vaccination strategies and being amenable to use in field operations. Research also will range from basic research to more mature research efforts. Basic research will aim to identify common targets among multiple threat agents. More mature research will aim to evaluate novel therapeutic and vaccine technologies, therapeutics, and vaccine candidates at an advanced stage of development, or therapeutics designed to reduce the morbidity and mortality associated with threat agent infection. Studies will use appropriate in silico, in vitro, and in vivo animal models and will be designed to support eventual FDA licensure of new non-licensed antimicrobial compounds and vaccines, or new indications for licensed products for use in the treatment and prophylaxis of BW casualties. The table on the following page lists key research task areas for providing pretreatment, therapeutic, and diagnostic capabilities.

The approach to meeting these objectives will address one of the following research focus areas, including those started or continuing in FY 2008 and those planned for FY 2009:

- ***Vaccines for Bacterial Agents.*** The long-term objective of this program is to conduct studies leading to the development of FDA-approved vaccines for the warfighter's protection against the Centers for Disease Control and Prevention (CDC) Category A and B biothreat agents. Studies that identify, characterize, and evaluate improved single-agent or multi-agent countermeasures against Category A or B bacterial select agent threats—in particular, the development of next-generation vaccines that represent improvements in immunogenicity, efficacy, and economy to the existing vaccine candidates—are encouraged. Further testing and evaluation of secondary leads and identification/characterization of adjunct candidate vaccines should be conducted. A second objective is to identify protective antigenic epitopes against bacterial Category A and B biothreat agents that eventually could be incorporated into a multi-agent vaccine platform. A third objective is to search for common mechanisms of bacterial pathogenesis in bacterial Category A and B biothreat agents that could be useful as common prophylactic targets. The emphasis of the program will be to identify and/or down-select vaccine candidates for advanced development.
- ***Vaccines for Toxin Agents.*** The overall objective of this task area is research, leading to the development of candidate prophylactic medical countermeasures (vaccines and pre-treatments), using appropriate laboratory and animal models, and demonstration of their capability for preventing or reducing mortality and morbidity in animals exposed to predicted or presumed battlefield doses of aerosolized toxin biological threat agents.
- ***Vaccines for Viral Agents.*** The long-term objective of this program is to conduct studies leading to the development of FDA-approved vaccines against Category A or B viral biothreat agents for the warfighter's protection. Studies that identify, characterize, and evaluate improved single-agent or multi-agent countermeasures against viral select agent threats—in particular, the development of next-generation vaccines that represent improvements in immunogenicity, efficacy, and economy to existing vaccine candidates—are encouraged. The program will focus on identifying and/or down-selecting vaccine candidates for advanced development. The overarching goal of this task area is to identify and characterize candidate vaccines using appropriate laboratory and animal models to demonstrate their capability to protect or significantly reduce morbidity in animals exposed to predicted or presumed battlefield doses of aerosolized viral BW threat agents. The major thrust in this area is in filoviruses (e.g., Ebola and Marburg viruses) and alphaviruses (e.g., VEE, WEE, and EEE viruses). This program is committed to developing a vaccine

against each viral agent class, either as single or preferably multi-agent (e.g., VEE/WEE/EEE) vaccines. Focus is in molecular virology, applied immunology, and pathogenesis. The scientific data on candidate vaccine technologies/constructs should be consistent with the technical information requirements that the advanced developer needs for an IND application.

- ***Multi-agent Vaccines.*** The long-range objective of this task area is to shift strategic focus from developing single-agent vaccines to emphasizing research leading to the development of multi-agent vaccines that simultaneously target multiple selected biothreat pathogens through a single immunization series. The goal of this task area is to develop an FDA-licensed multivalent biodefense vaccine by examining vaccine constructs that would be appropriate to combine into a single vaccine employing well-defined lead vaccine candidate immunogens. At a minimum, the vaccine will protect against anthrax, plague, and one other bio-threat agent. Rather than identifying new vaccine target antigens, this task area seeks to develop platforms and formulations capable of expressing previously identified vaccine target antigens in a manner that confers protection against these agents. Vaccine modalities that facilitate needle-free delivery remain of particular interest. A further objective under this task area will be to identify and develop common, relevant animal models to assess the immunogenicity and efficacy of the proposed multivalent vaccines.
  - ***Multi-agent Vaccine Against Three Alphaviruses***. A specific sub-task under multi-agent vaccines is the development of multi-agent vaccine against three alphaviruses. The goal is to develop a candidate for an FDA licensed combined VEE/WEE/EEE vaccine.
  - ***Multi-agent (Molecular) Vaccines for Bio-Warfare and Genetically Engineered Agents.*** A specific sub-task under multi-agent vaccines is the development of multi-agent (molecular) vaccines for bio-warfare and genetically engineered agents.
- ***Vaccine Technology Development.*** This research area is composed of two key sub-tasks: Molecular Vaccine Development and Molecular Immunology. Molecular Vaccine Development seeks to better identify, characterize, and

Biological Countermeasures: Key Research Task Areas		
Pretreatment	**Therapeutic**	**Diagnostic**
• Vaccines for Bacterial Agents • Vaccines for Toxin Agents • Vaccines for Viral Agents • Multi-agent Vaccine Development, including sub-tasks: ▪ WEE and EEE Vaccine Constructs for a Combined Equine Encephalitis Vaccine ▪ Multiagent (Molecular) Vaccines for Bio-Warfare and Genetically Engineered Agents • Vaccine Technology Development, including sub-tasks: ▪ Molecular Vaccine Development, and ▪ Molecular Immunology	• Therapeutics for Bacterial Agents • Therapeutics for Toxin Agents • Therapeutics for Viral Agents, including sub-task: ▪ Therapeutics for Ebola and Marburg Virus Infections	• Diagnostic Technologies, including sub-task: Rapid Detection, Threat Assessment and Attribution of Genetically Engineered Biothreat Organisms Using Microarray-Based Resequencing Technologies

evaluate countermeasures against bacterial, viral, and/or toxin select agent threats through the use of genomic, molecular, and bioinformatics-based approaches, and evaluate vaccine delivery platforms and adjuvant research that may enhance the efficacy of genetic-based approaches used to immunize an individual against a range of biothreat agents. This research includes innovative approaches, including emphasis on: projects dealing directly with specified bio-threat agents, as opposed to model systems; projects directed toward the induction of a specific immune response leading to the development of a multi-targeted vaccine as opposed to those designed to stimulate a broad, non-specific response eliciting brief immunity to a number of pathogens (e.g., CpG-induced prophylaxis); and projects incorporating high-throughput genomics/ bioinformatics-based approaches to identify and evaluate potential antigens common to a class of pathogens. The long-range objective is to develop vaccines targeted against multiple pathogens using current and novel biotechnological approaches that exploit the use of novel platform technologies such as genetic (molecular) immunization, recombinant viral constructs, or mixed platform immunization strategies.

- ***Molecular Immunology.*** This sub-task seeks to: investigate various aspects of the immune response, with particular interest in the human immune response, after immunization against bio-threat agent target antigens; further identify, characterize, and evaluate the human immune response against bacterial, viral, and/or toxin select agent threats through the use of genomic, molecular, and bioinformatics-based approaches through the examination of samples from immunized donors; examine the use of transgenic animal models in determining the molecular basis of the human immune response; and incorporate studies related to the enhancement of the innate immune system. The long-range objective of this research is an ability to design more effective vaccines by better understanding the details of the human immune response at the molecular level.
- ***Therapeutics for Bacterial Agents.*** The objective of this task area is to develop therapeutic modalities that reduce the lethal and functional incapacitating effects of bacterial BW threat agents of interest, and are amenable to use in field operations. Agents of interest include Yersinia pestis, Francisella tularensis, Burkholderia mallei, Burkholderia pseudomallei, and Bacillus anthracis.
- ***Therapeutics for Toxin Agents.*** This task area will support development of therapeutic modalities that protect against toxins or complement vaccination strategies and are amenable to use in field operations. Protection that a given medical countermeasure provides implies amelioration of the lethal and functional incapacitating effects of an agent. Resources will be applied primarily toward discovery and therapeutic development efforts directed against botulinum neurotoxins (BoNT) serotypes A-G.
- ***Therapeutics for Viral Agents.*** Research in this task area will focus on developing therapeutic modalities effective against aerosolized viral BW threat agents. Modalities will reduce the lethal and functional incapacitating effects of an agent and/or complement vaccination strategies and will be amenable to use in field operations. Resources will be applied primarily toward the advanced development of therapeutics effective against filovirus and orthopox virus infection, as previously demonstrated in non-human primate animal models. Research also will explore proof-of-concept of therapeutic development efforts directed against CDC category A and B viral biothreat agents, especially hemorrhagic fever viruses and viral encephalitis. This research area includes a specific sub-task to develop therapeutics for Ebola and Marburg virus infections. This subtask will develop antiviral therapeutics and treatments against one strain of Ebola virus and one strain of Marburg virus and will provide supporting data that the FDA can use to facilitate licensure under the animal efficacy rule.

- ***Diagnostic Technologies.*** This research effort is focused on diagnostic technology assessment and assay development, with the ancillary developmental areas given high priority. The ultimate goal is to field complete diagnostic systems (e.g., test platform, assays, and reagents) that will confirm health threats and rapidly diagnose exposure to, or disease caused by, BWAs. The current program provides ongoing support for an established program of record, Joint Biological Agent Identification and Diagnostic System (JBAIDS), as well as the Critical Reagents Program. Guidelines have been established and standardized for assessing nucleic acid assays and immunoassays developed in DoD laboratories that provide a decision point for transition out of the tech base to the advanced developer, who coordinates the FDA approval process.

Medical Biological Defense Research Accomplishments

Pre-treatments

- The DoD recombinant ricin vaccine was demonstrated to be safe and effective in NHPs. The IND application is expected in 2008.
- Four candidate vaccine platforms demonstrated protection against both Ebola and Marburg viruses in NHP, down-selection is expected in 2008.

Diagnostics

- FDA cleared the Q-flow kit for Deoxyribonucleic acid (DNA) extraction from blood, and it is currently being fielded in the JBAIDS, Block I deployment package. This kit answers the main user complaints against the previous kit by eliminating the need for a large tabletop centrifuge and decreasing the sample volume required by ~1,000-fold.
- Established standards for reporting data on assay design, optimization, and performance. These are also being adopted for use by the environmental and infectious disease communities and have been presented to our international partners.

Therapeutics

- Sponsored the establishment of a clinical field site for Orthopox virus in the Democratic Republic of Congo.
  - Enrolls >100 Monkeypox patients annually—these patients are provided the current standard of care for this disease
  - Collects human pathogenesis data, which is compared with similar data generated in current animal models
  - Advanced clinical developers, the National Institute of Allergies and Infectious Diseases (NIAID) and SIGA Technologies, will manage the site in the future.
- ST-246 (SIGA Technologies)—an oral antiviral therapeutic drug.
  - Demonstrated 100-percent protection against monkeypox and human smallpox virus in NHP trials—first drug to do so
  - Developed an IV monkeypox animal model that is being used as the pivotal animal model in the FDA licensure process
  - At the CDC's request, it was used recently to successfully treat a child having significant atopic dermatitis and a disseminated case of the disease acquired from contact with a parent's smallpox vaccination.

Advanced Development Accomplishments

Joint Vaccine Acquisition Program Prime Systems Contract

- DynPort Vaccine Company continued to expand its operations, finding appropriate commercial subcontractors to engage in the advanced development of biological defense vaccines (recombinant botulinum vaccine and recombinant plague vaccine).

Contingency Stockpile of Biological Defense Vaccines

- Testing potency and other characteristics continues for legacy VEE, WEE, EEE, Tularemia, and Q-Fever vaccines
- Advanced Development of the Tularemia Vaccine
- Program terminated as a result of removal of funding
- NIAID will continue vaccine development through IND application submission.

Advanced Development of the Plague Vaccine

- Achieved Milestone B in FY 2006 for plague vaccine program that consists of two vaccine candidates (United States and United Kingdom) that will be jointly developed through an event driven down-select, planned for 2008
- Initiated Phase II clinical trials in FY 2006
- Began manufacturing process development and scale up in FY 2007
- Complete process validation in FY 2008.

Advanced Development Recombinant Botulinum Toxin Vaccine

- Finalized and submitted IND
- Continued Phase 1 clinical trial, vaccination of cohorts resulted in no serious adverse events
- Finalized manufacturing scale-up and initiated process validation for serotypes A and B
- Received Fast-Track designation by the FDA
- Initiated Phase 1B clinical trial.

International Cooperative Research and Development

- The original CBR MOU among the United States, United Kingdom, and Canada (CANUKUS) was signed and implemented on June 1, 2000. The United States and Canada signed a bilateral Project Arrangement (PA) under the CBR MOU on March 27, 2003 to cooperatively develop a smallpox vaccine system with the United States as the lead nation. PA objectives include development and licensure in the United States and Canada of a smallpox vaccine and a VIG to treat rare cases of adverse reactions. In light of the DHHS's efforts to develop a smallpox vaccine, both nations have the smallpox vaccine portion of the PA under review. In April 2005, the CANUKUS signed the PA for developing the United Kingdom plague vaccine.
- In September 2007 a Strategic Implementation Plan and Roadmap to the year 2025 was drafted for the CBR MOU. This effort will allow expanded information exchange with Australia, Canada, and the United Kingdom.

Advanced Development Products-Terminated

Advanced Development of the Smallpox Vaccine

- Filed an annual report with the FDA under IND #9141 to ensure the continued availability of VIG
- DynPort Vaccine Company achieved licensure for its new VIG product for intravenous administration in February 2005. The current manufacturer has ceased all plasma-derived processing, and the Prime Systems Contractor (PSC) was unable to locate a new manufacturer to perform the technology transfer. Consequently, VIGIV will be procured from an alternate producer, Cangene Corporation
- DoD has migrated to ACAM2000® as the Dryvax™ license has expired.

Advanced Development of the Tularemia Vaccine

- No longer a POR
- NIAID will continue vaccine development through IND application submission.

Medical Radiological Defense

No medical countermeasure exists against radiological and nuclear threats within the DoD stockpile. As such, appropriately applied advances in medical radiological countermeasures will significantly affect the warfighting mission by sustaining unit effectiveness and conserving the warfighters' fighting strength. The warfighter is significantly more likely to become a traumatic casualty as a result of radiation injury and illness.

No licensed non-toxic pharmaceutical agents or diagnostic capabilities are suitable for use in military operational environments. An aminothiol compound, amifostine, is FDA approved for use in patients receiving chemotherapy or radiation therapy, but amifostine's performance degrading toxic side effects prohibit its use in a fit-fighting force. A physician may use other pharmacologic agents off label on a case-by-case basis (e.g., hematopoietic cytokines for treating bone marrow injury), but regulatory restrictions for such use make it impractical for treating large numbers of casualties during battlefield operations. Antibiotics are commonly used to treat the infectious sequelae of radiological injuries, but they must be selected appropriately to effectively treat exogenous and endogenous systemic infections while not affecting beneficial intestinal normal microfluora.

Medical Radiological Defense Research & Development Accomplishments

The MRDP at JSTO-CBD began in FY 2006 with one project. The program expanded beyond this initial effort, and new starts were initiated in FY 2007 and FY 2008. Candidate countermeasures have been identified for possible transition to advanced development. (Note: Research activities described in this section are limited to MRD efforts funded by the DoD CBDP. Excluded are the radiological research efforts conducted by Armed Forces Radiobiology Research Institute (AFRRI) sponsored by the Defense Health Program, which falls under the oversight of the Assistant Secretary of Defense for Health Affairs.)

The focus of the medical radiological defense research area is to develop broad-spectrum medical radioprotectants (prophylactic) and post-irradiation therapeutics effective against ARS and DEARE leading to chronic radiation damage (e.g., fibrosis and mutagenesis). The program seeks to expand the medical options available to prevent or mitigate radiation-induced injury with an emphasis on work at the advanced research level (6.3). Countermeasures under development should focus on the effective treatment of respiratory and GI systems against radiological and nuclear exposures, which will support anticipated future FDA requirements. The approaches include medical countermeasures such as anti-oxidants, anti-apoptotic agents, decorporation agents, and lung/GI rescue of cellular components against ARS and DEARE. Although the use of novel approaches is encouraged, more mature, promising product candidates at late stages of development clearly demonstrating the feasibility of a given approach will be more favorably considered. In addition, an advanced technology development effort for genomic biomarkers will be supported. These genetic biomarkers will improve the biodosimetry assessment of whether an individual has received a significant whole body irradiation exposure, what dose range was received, and the time following the exposure during mass casualty triage scenario.

Medical Radiological Defense Advanced Development Accomplishments

The Medical Radiation Countermeasure Advanced Development program achieved a Milestone A in FY 2007 under JPEO-CBD/CBMS-Medical Identification and Treatment Systems (MITS). DoD is collaborating with DHHS to develop a comprehensive medical countermeasure solution to treat ARS. DHHS is pursuing development of a treatment for the hematopoietic (blood disorder) sub syndrome of ARS while DoD is developing a treatment for the GI sub syndrome of ARS. CBMS-MITS anticipates a contract award in January 2008 through a small business competitive set aside and is engaging large pharmaceutical companies through Other Transaction Authority in developing a GI treatment for ARS. A down-select is planned in FY 2009 to one candidate.

Annex C: Joint Non-Medical, Chemical, and Biological Defense Research, Development, and Acquisition Programs

Annex C discusses Joint non-medical CB defense RDA programs. This Annex is organized into six sections that correspond to the organization of budget documents in the adjacent table. This report will supplement the President's Budget Request submission in accordance with Title 50 U.S.C. 1523. The table below shows the relationship between this Annex and the budget documents.

CBRN threats continue to evolve worldwide. The WMD programs undertaken by nation-states remain the primary focus of the DoD CBRN defense program. The potential for opponents to use CBRN weapons in overseas operations continues to drive development, acquisition, and integration of a new generation of military CBRN defense materiel.

Simultaneously, a significant effort is also under way to anticipate and develop countermeasures to asymmetric attacks by foreign and domestic non-state entities. This evolution in CBRN defense measures is a response to an expanding set of potential attack scenarios and the need to develop the tools to defend against such attacks more rapidly.

Non-Medical Research Description and Budget Documents
(Project Numbers are shown in body of chart)

	Budget Activity (Program Element)				
	1. Basic Research (0601384BP)	**2. Applied Research (0602384BP)**	**3. Advanced Technology Development (0603384BP)**	**4. Advanced Concept Development and Protoytypes (0603884BP)**	**5. System Development and Demonstration (0604384BP)**
Report Section	**Science and Technology Base**			**Advanced Development**	
Chemical/ Biological (CB) Defense	CB1	CB2	CB3	-	-
Contamination Avoidance (CA)	-	-	-	CA4	CA5
Individual Protection (IP)	-	-	-	-	IP5
Collective Protection (CP)	-	-	-	-	CO5
Decontamination Systems (DE)	-	-	-	DE4	DE5
Information Systems (IS)	-	-	-	IS4	IS5

Non-Medical Chemical and Biological Defense Program

- ***Physical Science and Technology Capability Areas***. The JSTO-CBD Physical Science and Technology Division (CBT) research emphasizes innovation in managing multi-disciplinary basic and applied research to meet the technology needs and capability gaps defined and prioritized by the JRO-CBRND. The CBT also ensures the effective transition of resulting technologies to Joint acquisition programs and new insights into policy and doctrine.
- ***Basic Research.*** The mission of the Basic Research Program is to fund critical research with broad long-term potential applications in CB defense. The program is aligned with the DoD definition of basic research and the recommendations of the 2005 Report from the National Research Council's Committee on DoD Basic Research Division on Engineering and Physical Science, "Assessment of Basic Research." Per Recommendation 1 in that assessment, "Basic research is systematic study directed toward greater knowledge or understanding the fundamental aspects of phenomena, and has the potential for broad rather than specific, application." The Basic Research Program funds innovative scientific efforts across the physical sciences in government, industry, and academia that could lead to high payoff for CB defense applications in the physical S&T functional capability areas' core program. It seeks to develop a balanced investment across the scientific disciplines for long-term and short-term impact on CB defense.

The investment includes need-based, basic research supporting the underlying fundamental science relevant to CB defense and opportunities-based research to develop revolutionary new S&T that may significantly enhance warfighter protection and survivability through the following:

  - The development of molecular-level self assembly and directed assembly to obtain exceptionally stable, useful, and highly functional abiotic supramolecules, systems, and materials that can behave as true artificial enzymes and give living-system-like responses
  - Fundamental studies on the formation of metal oxide particles precipitated together with biocidal agents and agent reactive enzymes using a biomimetic-based synthesis; potential applications exist in decontamination and protection
  - Development of a fundamental understanding of biophysical fluid dynamics at nanosensor surfaces in microfluidic systems, including how biomolecules and labels interact with functionalized surfaces under laminar flow, which could lead to develop sensors with enhanced performance.

- The goal of this program is to maintain a diverse basic research program supporting both needs-based and opportunity-based research with applicability across multiple capability areas.
- ***Detection Capability Area***. The Detection Capability Area develops CB sensor components and systems for standoff applications; BWA point identification; lightweight, integrated identification; and detection of CB agents in water to enable contamination avoidance. Emphasis is placed on early-warning applications, which include capabilities for CB reconnaissance, detection, and identification to provide situational awareness of the total battle space CB threat. For fixed sites where contamination cannot be avoided or for missions requiring operations in a contaminated environment, reconnaissance, detection, and identification are necessary for forces to assume the appropriate protective posture. This is necessary to sustain operations and rapidly identify affected areas, equipment, and personnel to initiate decontamination and medical intervention, if possible or necessary. This capability area is also developing sensors for the individual Service member and systems capable of detecting multiple agents and characterizing new agents to provide situational awareness for battle space management decisions. The heightened operational tempo of future

battle spaces demands responsive detection and warning capabilities to reduce force degradation caused by CB contaminated environments. The DoD community will continue to emphasize these capabilities, which encompass reconnaissance, detection, identification, and reporting, in the near- and far-term. Early detection and warning are keys to avoiding CB hazards. The Detection Capability Area is divided into thrust areas to manage efforts that address specific aspects of CB detection:

- Point detection
- Standoff detection
- CBRN reconnaissance

- ***Protection and Hazard Reduction Capability Area.*** The Protection and Hazard Reduction Capability Area provides the capability to shield the force from harm caused by CBRN hazards by preventing or reducing individual and collective exposures to prevent or mitigate negative physiological effects, protecting critical equipment, and reducing hazards after employment of CBRN weapons to restore the capability of units that become contaminated.
- ***Threat Agent Science (TAS) Capability Area.*** The TAS Capability Area identifies and addresses gaps in the understanding of CBRN and TIM threat agents and materials, including their physical and chemical behavior, environmental stability and transport, and toxicological properties. These studies facilitate detection, protection, and decontamination countermeasures; improve warfighter decision support tools; and provide a sound scientific basis for doctrine and policy development.
- ***Information Systems Capability Area.*** In support of battle space information and related systems, the Information Systems Technology (IST) Capability Area provides information collection, fusion, and rapid knowledge generation for all CB defense assets throughout the battle space. Collaborating with the CBDP's Joint Effects Model (JEM), Joint Operational Effects Federation (JOEF), Joint Warning And Reporting Network (JWARN), and other PORs, IST provides scientific knowledge, technology insights, data, and a variety of software products. IST delivers capabilities that enable CB situational awareness and hazard warning and prediction within the battle space. IST S&T efforts support the integration of threat information, CB sensor and reconnaissance data, protective-posture data, environmental conditions, medical surveillance, and related data capabilities. These capabilities rapidly provide the warfighter and decision-makers with the ability to quickly analyze courses of action prior to or during operations. Aspects of decision support IST capabilities for CB defense include Joint Force protection, restoration of operational tempo, casualty care treatment, and intelligent resource-allocation support. Warning and reporting IST capabilities provide the hardware and software to connect detection systems into the overall C2 architecture. IST also aids in the assessment of Joint- and multi-Service doctrine, materiel development, and equipment design (simulation-based acquisition). IST supports warfighter and battle staff training by employing larger conflict simulations. IST can perform support analyses of CB defense operations within the context of larger military operations. These efforts also support simulation-based acquisition in the development of critical CB defense capabilities.

Sense: Contamination Avoidance - Advanced Development Products - Near-Term

- ***Chemical Point Detection.*** The current fielded chemical point detection systems are M8 and M9 paper, M8A1 Automatic Chemical Agent Alarm (ACAA), M256A1 kit, M18A2 and M18A3 kits, M72 water testing kit, Improved Chemical Agent Monitor (ICAM), Improved Point Detection System (IPDS), M22 Automatic Chemical Agent Detector and Alarm (ACADA), and Joint Chemical Agent Detector (JCAD).
  - The JCAD is an automatic, lightweight, man-portable, CWA detection and warning system. It is a small, pocket-sized, detector

capable of automatically detecting (nerve, blister, and blood), identifying, and quantifying chemical agents in aircraft, vehicles, and fixed sites. It also provides hand-held monitoring capabilities for the individual warfighter. The JCAD will replace the ICAM, M8A1 ACAA, and M22 ACADA. JCAD Increment 2 will expand upon the Increment 1 capability by providing the ability to detect low-level cumulative exposure, increasing utility aboard ship and rotary wing aircraft, and expanding the number and types of chemicals detected.

- Fielded legacy systems are maintained by the Services through their operations and maintenance (O&M) accounts. In addition, the JPM-NBC CA is developing upgrades to fielded detectors against nontraditional chemical threats and TICs.
- ***Biological Point Detection***. Point detection systems are deployed worldwide to counter the threat of BW.
  - The Joint Portal Shield (JPS) is used to protect high-value fixed assets. The system consists of an automated trigger, detector, identifier, and sampler, and is networked to a centralized command post. The sensor can presumptively identify 10 agents simultaneously in 25 minutes. The system also includes a chemical sensor interface for the M22 ACADA and a radiological sensor interface for the AN/VDR-2 (portable dose rate gamma/beta radiation meter). To date, over 250 JPSs have been fielded to fixed sites in Korea and Southwest Asia.

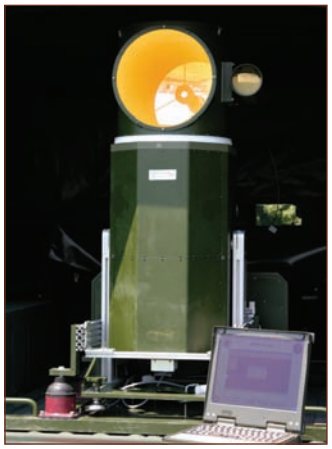
  - M31A1 Biological Integrated Detection System (BIDS) is a collectively protected, S788 shelter suite mounted on a dedicated vehicle (M1097 High Mobility Multi-purpose Wheeled Vehicle (HMMWV)) and equipped with a biological detection suite employing complementary technologies to detect large area biological attacks. The system includes a trailer-mounted 15-kw generator (PU-801) to provide electrical power. The BIDS is C130 aircraft transportable, has roll-on/roll-off capability, and can operate in a dismounted role separate from its dedicated HMMWV. The suite semi-automatically detects and samples, and simultaneously identifies eight biological agents in the environment in less than 30 minutes. There are four Active Army BIDS companies with total assets of 70 M31A1s.
  - M31E2 BIDS is a collectively protected, S788 shelter suite equipped with the Joint Biological Point Detection System (JBPDS) and mounted on a dedicated vehicle (HMMWV). The M31E2 BIDS utilizes the Force XXI Battle Command, Brigade and Below (FBCB2) for digital communication, and an on-board 10kw generator for power. The Army fielded the first 35 M31E2 BIDS to the 375th Chemical Company from the third quarter of FY 2003 to the first quarter of FY 2004. Through the fourth quarter of FY 2007, the Army fielded over 250 M31E2 BIDS to over 20 reserve and active Army sites, at CONUS and OCONUS locations. Fielding is scheduled to continue through FY 2013.

  - The JBPDS provides a common point detection capability for individual Service

platforms and offers joint interoperability and supportability. It continuously monitors, automatically detects and samples, and simultaneously identifies 10 biological agents in the environment in less than 20 minutes. It is equipped with on-board global positioning and meteorological systems, and can be operated locally or remotely for up to 12 hours. The system is common across multiple configurations (i.e., the XM96 Portable; the XM97 Shelter; the XM98 Shipboard; and the XM102 Trailer Mounted for airbase, vehicle, surface combatant, Stryker, and Joint Nuclear, Biological, and Chemical Reconnaissance System (JNBCRS)). The JBPDS provides increased detection and presumptive identification capabilities for an increased number of agents when compared to the Army's M31A1 BIDS and the Navy's Interim Biological Agent Detection Systems and provides a first time point biological detection capability for the Air Force and Marine Corps. The acquisition strategy and modular design facilitates incremental system improvements with the advanced biological detection, collection, identification, and information technology.

- Joint Biological Tactical Detection System (JBTDS) will provide warfighters a small, light, battery-operable detection capability for use during tactical or expeditionary operations. It consists of an automated biological aerosol detector, sampler, and a hand-held identifier to warn and provide a presumptive identification capability to Joint Expeditionary Forces (JEF). The system will be small enough to support unmanned, manned, and man-portable applications. The JBTDS will be networked to increase the probability of detection and reduce the probability of false alarm. The size and mission of the warfighting unit will determine the quantity and composition of systems needed within a network. JBTDS will be employed remotely or in an unattended configuration on platforms to include vehicles and aircraft and by foot-mobile forces. Its network will support both hardwire and wireless interfaces for maximum flexibility. It will warn automatically or with manual intervention and its sample isolation feature will collect a sample for presumptive identification and for confirmatory analysis. The JBTDS program is executing an incremental acquisition approach and is leveraging the Expeditionary Biological Detection Advanced Technology Demonstration. The JBTDS Increment 0 is scheduled for Milestone C in the first quarter of FY 2009 and JBTDS Increment 1 is scheduled for Milestone B in the second quarter of FY 2009.
- The Dry Filter Unit (DFU) is a stand-alone collector that collects internal and external ambient air samples for subsequent analysis. The system provides a sample that is compatible with both Hand-Held Assay and Polymerase Chain Reaction (PCR) technology. To date, over 1,700 DFUs are fielded to expeditionary units, fixed sites, and ships.
- The Joint Chemical, Biological, and Radiological Agent Water Monitor (JCBRAWM) will provide the ability to detect, identify, and quantify CBR contamination during water-monitoring missions. Increment 1 will provide the capability to detect two biological agents and radiation using immunoassays and components of the fielded AN/PDR-77 system and accessory package. Future increments will also detect chemical agents to the Tri-Service standard, provide a new detection system to replace the M272 Water Test Kit, and detect NTAs and TICs.

- ***Chemical Standoff Detection.*** The current fielded chemical standoff detection capability is the JSLSCAD. The JSLSCAD, which will improve on the capabilities of the current M21 Remote Sensing Chemical Agent Alarm (RSCAAL), will detect, locate (azimuth and elevation), identify, confirm, display, and transmit detection information for CWA vapors and provide the commander with operational situation awareness when integrated on the Stryker NBCRV. The JSLSCAD Increment I is a small, fully automatic, passive standoff chemical agent vapor detector. The JSLSCAD is equipped for visual and audible alarm and can display the chemical agent class and relative position of the detected chemical agent. Future plans for JSLSCAD include capabilities for fixed site surveillance applications.
- ***Biological Standoff Detection.*** The Joint Biological Standoff Detection System (JBSDS) is the first Joint standoff early warning biological detection system. The system will be capable of providing near real-time detection of biological attacks/incidents and standoff early warning of BWAs at fixed sites or mounted on vehicles. It will be capable of providing standoff detection, ranging, tracking, and discrimination (manmade versus natural occurring aerosols) of BW aerosol clouds for advanced warning, reporting, and protection. It provides a first time detect-to-warn capability for both Army and Air Force.



- ***Nuclear, Biological, and Chemical Reconnaissance.*** The current fielded reconnaissance capability is the M93A1 FOX NBC Reconnaissance System, which contains an enhanced and fully integrated NBC sensor suite consisting of the M21 RSCAAL, MM1 Mobile Mass Spectrometer, Chemical Agent Monitor (CAM)/ICAM, Radiation Detection, Indication, and Computation (RADIAC) detector, AN/VDR-2, and M22 ACADA. The NBC sensor suite is digitally linked with the communications and navigation subsystems by a dual-purpose central processor system known as the Multi-purpose Integrated Chemical Agent Detector (MICAD). The M93A1 is also equipped with an advanced position navigation system that enables the system to accurately locate and report agent contamination. In addition, M93A1P1 provides enhanced survivability capability to the base system. The M93 FOX NBC Reconnaissance System remains fielded with Army and Marine Corps forces.

  - ***Joint Nuclear, Biological, and Chemical Reconnaissance System (JNBCRS).*** The JNBCRS Increment I will provide a CBRN detection and identification reconnaissance system. This vehicle mounted suite of equipment and software designed to detect, collect, analyze, mark, and disseminate CBRN data allows for real-time field assessment of CBRN hazards. Timely provision of automated, digital information meshed with meteorological and positioning information will provide commanders with more options in merging CBRN information with tactical, operational, and strategic plans. The JNBCRS is intended for independent operations (e.g., main supply routes, airfield perimeter) or with reconnaissance elements in tactical environments. The JNBCRS Increment 2 will provide a dismounted reconnaissance capability to the warfighter. The following equipment will be integrated into the JNBCRS suite: Chemical/Biological Mass Spectrometer Block II (CBMS II), ACADA, AN/VDR-2, ADM-300 series, ICAM, and proven commercially available equipment. The JNBCRS also will be fitted

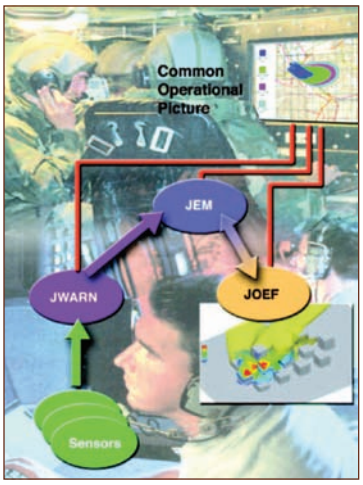
with an automated biological detection capability via JBPDS. JNBCRS Increment 2 will consist of mission essential kits with both Commercial and Government off-the-shelf handheld equipment to provide detection, presumptive identification, sample collection, marking, and immediate reporting of standard NBC hazards, to include hazardous industrial materials.

- ***Stryker Nuclear, Biological, Chemical Reconnaissance Vehicle.*** Also in the near-term, the Stryker NBCRV will be fielded to the Army consistent with transformation. The NBCRV is a dedicated system of nuclear and chemical detection and warning equipment, and biological sampling equipment integrated into a high-speed, high-mobility, armored carrier capable of performing CBRN reconnaissance on primary, secondary, or cross-country routes throughout the battlefield. The NBCRV will be able to detect and collect CB contamination in its immediate environment, on-the-move, through point detection CBMS and JBPDS, and at a distance through the use of a standoff detector, the JSLSCAD. It automatically integrates contamination information from detectors with input from on-board navigation and meteorological systems and automatically transmits digital CBRN warning messages through the Maneuver Control System (MCS) to warn follow-on forces. The Stryker NBCRV is planned to be transportable on C-130 aircraft.

Shape: Information Systems - Advanced Development Products

- ***Integrated Early Warning.*** Integrated early warning is a critical capability. Warning and reporting systems combine hardware and information systems to automatically provide sensor system data to the information system and consequently to provide the resulting information in an effective manner to the warfighter.
  - ***Joint Warning And Reporting Network***. The aforementioned JWARN will provide the warfighter with a comprehensive warning and reporting capability that will collect, analyze, identify, locate, report, disseminate, and minimize the effects of hostile CBRN attacks, accidents, and incidents. JWARN will be compatible and integrated with Joint Service C4ISR systems. JWARN will be located in C2 centers at the appropriate echelon level and employed by CBRN defense specialists and other designated personnel. JWARN will provide additional data processing, production of plans and reports, and access to specific CBRN information to improve the efficiency of limited NBC personnel assets. JWARN 1F has been fielded to warfighters in support of operational requirements from a Central Command (CENTCOM) Urgent Needs Statement (UNS), dated July 29, 2006. JWARN 1F provides software networked to Service C2 platforms and MCS for automated CBRN and TIC/TIM warning and reporting. JWARN 1F allows CBRN and TIC/TIM hazard areas to be displayed on the Common Operational Picture (COP), providing standardized CBRN warning and reporting across Service boundaries. JWARN 1F also provides for integration of Joint Portal Shield sensor data, medical surveillance data, and Explosive Ordnance Disposal data in order to develop a CBRN-E common operational picture. Finally, JWARN 1F contains electronic references and decision aids, including incident response checklists, to support consequence management operations.
- ***Battle Space Analysis.*** Legacy hazard analysis models including the Vapor, Liquid, and Solid Tracking (VLSTRACK) hazard assessment model and the Hazard Prediction and Assessment Capability (HPAC) were successfully transitioned to the JEM in FY 2007.

- ***Joint Effects Model.*** JEM provides a single DoD-approved methodology and model that provides common representation of CBRN hazard areas and effects resulting from CBRN weapons and TIC/TIM. Operationally, JEM supports operational and crisis action planning to mitigate the effects of WMD. JEM also provides the ability to display to the COP and operates in an integrated fashion with operational and tactical C4ISR systems as well as in a stand-alone mode. JEM will interface and communicate with JWARN and the JOEF, weather systems, intelligence systems, and various databases. JEM will be fielded in FY 2008.



- ***Battle Space Management.*** Battle Space Management provides the capability to assess the overall impact of the CBRN hazard. It is a decision support tool which can be used in either the deliberate or crisis action planning phase.
- ***Joint Operational Effects Federation.*** JOEF is an operational and strategic planning and decision support tool for deliberate and crisis planning and will include tactical level incident management and consequence management capabilities in future increments. It will enable joint warfighters and planners to assess CBRN effects on operations, personnel, and equipment to minimize or eliminate the CBRN threat. JOEF pre-crisis planning capabilities will improve strategic and operational analysis of a potential CBRN incident and enhance preparation for operations during the incident. JOEF decision support tools will enable strategic, operational, and tactical warfighters to quickly and efficiently assess risk and vulnerability to protect critical assets, optimize decontamination processes, restore operational tempo, and minimize exposure of personnel to hazards.

Shield: Individual Protection - Advanced Development Products

In the near-term, the CBDP will begin to replace Service-unique protective items with modernized protective equipment.

- ***Respiratory and Ocular Protection***
  - ***Joint Service General Purpose Mask (JSGPM).*** A lightweight, protective mask with 24-hour CBRN protection, lower breathing resistance, and reduced weight and bulk will become the sole respiratory protection system for ground, shipboard, and combat vehicle environments.

  - ***Joint Service Mask Leakage Tester (JSMLT).*** JSMLT is a Joint Service COTS item that alleviates the need for various test devices. JSMLT will be a portable unit level device capable of determining proper fit and identifying defective or unserviceable components of current and future negative pressure NBC protective masks.

- ***Joint Service Aircrew Mask (JSAM).*** JSAM is a lightweight CB-protective mask that will be worn as CB protection for all Army, Air Force, Navy, and Marine rotary and fixed-wing aircrew.

- ***Percutaneous Protection***
  - ***Joint Protective Aircrew Ensemble (JPACE).*** JPACE is a CB and fire resistant protective clothing ensemble for use by aviators and aircrew members for all fixed wing and rotary wing requirements. JPACE will provide aviators, aircrew members, and combat vehicle crewmen the same advantages and improved protection that JSLIST provides combat forces. JPACE was approved for full rate production on August 21, 2006, and was approved for deployment and fielding on June 8, 2007. First production deliveries began in June 2007.

  - ***Joint Service Lightweight Integrated Suit Technology***. To date, approximately 3.8 million JSLIST protective clothing ensembles consisting of an overgarment, boots, and gloves have been produced and delivered. The JSLIST Block 1 Glove Upgrade (JB1GU) is geared toward satisfying the urgent SOCOM CB protective glove requirement. The alternative footwear solutions (AFS) and integrated footwear system (IFS) programs also satisfy the need for a CB protective overboot and a sock/liner. Future protective ensembles will continue to evolve as technology matures.

- ***Collective Protection – Advanced Development Products.*** Near-term collective protection efforts are focused on increasing the quantity of collectively protected shelters and platforms in C2, medical, and rest and relief areas. In addition, new technologies are being used to make incremental improvements in currently fielded CPE to correct deficiencies and to reduce costs by using new materials or manufacturing processes to reduce logistics impact to the users. Several systems were fielded to increase the quantity of collectively protected shelters and platforms. The M20A1 Simplified Collective Protection Equipment (SCPE) is currently fielded to the Services. It provides CP to existing structures by providing resistance to liquid and vapor agents and allowing expansion of protection areas.
- ***Fixed/Transportable Collective Protection***
  - ***Collectively Protected Field Hospital (CPFH).*** The CPFH program was established in FY 2006 to manage the CB defense activities of the Services' collectively protected deployable field hospitals. This includes the Army's Chemically Protected Deployable Medical System

(CP DEPMEDS), the Air Force's Collectively Protected Expeditionary Medical Support (CP EMEDS), and the Navy's Chemically Protected Expeditionary Medical Facility (CP EMF). CPFH will convert the field hospitals into fully operational, environmentally controlled, and collectively protected medical treatment facilities designed to sustain medical operations in a CB contaminated environment for a requirement of 72 hours.

- ***Chemical and Biological Protective Shelter (CBPS).*** CBPS is a highly mobile, rapidly deployable shelter system designed to be used for Level I and II forward area medical treatment facilities and surgical teams. As a result of reliability concerns during an urgent operational need to support Operation Iraqi Freedom, an engineering change was developed to eliminate the hydraulic sub-system and replace it with a more reliable self-powered (electrical) environment control system. The CBPS Program is reviewing design options to integrate CBPS systems onto an up-armored Medium Tactical Vehicle platform to meet the Army's armor requirements.

- ***Joint Expeditionary Collective Protection (JECP).*** JECP is a new start Acquisition Category (ACAT) III program that is pre-Milestone B. JECP will provide a CP capability to shield the Joint Expeditionary Forces during potential CBR/TIM attacks. JECP is intended to provide CP for the rest and relief, command and control, and medical functions in support of expeditionary missions/operations. Possible materiel solutions include a stand-alone shelter system and/or kit(s) for use with selected portable shelters or within permanent structures.

- ***Mobile Collective Protection***
  - ***Mobile Collective Protection Systems (MCPS).*** MCPS provide collective protection against CBR contamination to vehicles and aircraft. MCPS allow the warfighter to perform mission critical tactics by filtering all the air that is supplied to the vehicle and aircraft by over pressurization to prevent contamination from penetrating or leaking into the protected area. Personnel working within the collectively protected areas inside the vehicles and aircraft are unencumbered by individual protective equipment during or after a CBR attack.
  - ***Shipboard Collective Protection Systems (CPS).*** Shipboard CPS is an integral part of the heating, ventilating, and air conditioning (HVAC) systems on new construction ships. The system is also retrofitted during shipyard availabilities by the JPEO-CBD CPS Backfit Program. CPS provides each protected, overpressurized zone on the ship with clean, breathable air. CPS is modular and is based on the 200 cubic feet per minute M98 Gas-Particulate Filter Unit Set. The main components of CPS include filters, filter housings, high-pressure fans, airlocks, pressure control valves, low-pressure alarm system, and personnel decontamination stations.
  - ***Fixed Collective Protection Systems (FCPS).*** FCPS provide CP against CBR contamination to buildings and installations. FCPS allows the warfighter to perform mission critical tactics by filtering all the air that is supplied to the facilities and installations and by over pressurization to prevent contamination from penetrating or leaking into the protected area. Personnel working within the protected areas are unencumbered by individual protective equipment during or after a CBR attack. The

main components of CPS include M98 filters, filter housings, high-pressure fans, airlocks, pressure control valves, and a low-pressure alarm system.

In addition, the Joint Program Manager for Collective Protection (JPM-CP) and JSTO-CBD conducted a CP Technology Readiness Evaluation (TRE) from FY 2005 to FY 2006. This was the first TRE conducted outside the biological defense area. The TRE consists of four focus areas: air purification processes, CB barrier material and quick CP erect technologies, CP support equipment, and whole CP systems. The CP TRE will present mature applicable CP technologies for transition into various acquisition programs. These include the JECP, Expeditionary Fighting Vehicle (EFV), Future Combat Systems (FCS), and Littoral Combat Ship (LCS).

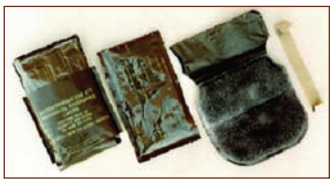
Sustain: Decontamination - Advanced Development Products

To meet near-term needs, numerous decontamination systems and decontaminant technologies are being optimized while alternative systems mature. The Army is rebuilding the M12A1 Power-Driven Decontamination Apparatus (PDDA) and enhancing the M17A3 Lightweight Decontamination Apparatus with COTS technology.

- ***M17 Lightweight Decontamination Apparatus.*** The Marine Corps and Navy have procured and fielded an M17 Lightweight Decontamination Apparatus that can be operated with standard military fuels.

- ***M291 Skin Decontamination Kit.*** The M291 skin decontamination kit was fielded as a replacement for the M258A1 decontamination kit for all Services.

- ***M295 Decontamination Kit.*** The M295 decontamination kit has been fielded for improved personal equipment decontamination and provides the warfighter with a fast and non-caustic decontamination system for personal gear.



- ***Joint Service Personnel/Skin Decontamination System (JSPDS).*** The JSPDS is a FDA cleared, individually carried skin decontamination kit. The JSPDS provides the warfighter with the ability to decontaminate the skin after exposure to CBW agents, in support of immediate and thorough personnel decontamination operations. Reactive Skin Decontamination Lotion (RSDL), selected as JSPDS Increment I in 2007, provides the warfighter with improved capability over the existing M291 skin decontamination kit to reduce lethal and performance degrading effects of CWAs on unbroken skin. Additionally it can be used to decontaminate individual equipment, weapons, and casualties.

- ***Joint Service Transportable Decontamination System - Small-Scale (JSTDS-SS).*** The JSTDS-SS will consist of applicator(s) and accessories that apply decontaminant (DF 200 and/or hot soapy water) to conduct operational and thorough decontamination of non-sensitive military materiel, limited facility decontamination at logistics bases, airfields, and critical airfield assets, ports, key C2 centers, and other fixed facilities.

- ***Joint Material Decontamination System (JMDS).*** The JMDS program is planned to field a modular and scalable system; however, Joint Service Sensitive Equipment Decontamination (JSSED) and Joint Platform Interior Decontamination (JPID) will still exist with separate requirements and funding lines.
- ***Joint Portable Decontamination System (JPDS).*** The JPDS will be used to support operational and thorough decontamination operations. The system will enhance decontamination capabilities by using the latest technology to reduce or eliminate chemical and biological hazards in a safe and effective manner. This program is pre-milestone B.
- ***Human Remains Decontamination System (HRDS).*** The HRDS will provide the capability to ensure the safety of personnel handling and processing CBR contaminated human remains (CHR) and the capability to repatriate CBR CHR. This system is pre-milestone B.

Annex D: List of Acronyms and Abbreviations Used in the Report

–A–

AAE – Army Acquisition Executive
AAS – Advanced Anticonvulsant System
ACAA – Automatic Chemical Agent Alarm
ACADA – Automatic Chemical Agent Detector and Alarm
ACAT – Acquisition Category
ACD&P – Advanced Component Development and Prototypes
AChE – Acetylcholinesterase
ACTD – Advanced Concept Technology Demonstration
AEFRP – Army Emergency First Responder Program
AEL – Allowance Equipage Lists
AFRRI – Armed Forces Radiobiology Research Institute
AFS – Alternative Footwear Solutions
AHRT – All-Hazard Response Training
AMC – U.S. Army Materiel Command
ANDA – Abbreviated New Drug Application
APB – Acquisition Program Baseline
ARC – Annual Report to Congress
ARS – Acute Radiation Syndrome
ASC – Active Standoff Chamber
ATD – Advanced Technology Demonstration
ATNAA –Antidote Treatment Nerve Agent Autoinjector
ATSD(NCB) – Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs
AWAR – Advanced Warning, Analysis, and Reporting

–B–

BA – Budget Activity
BAA – Broad Agency Announcement
BIDS – Biological Integrated Detection System
BLA – Biologic License Application
BoNT – Botulinum Neurotoxins
BW – Biological Warfare or Biological Weapons
BWA – Biological Warfare or Biological Weapon Agent
BWC – Biological and Toxin Weapons Convention
BPI – Business Process Improvement

–C–

C4ISR – Command, Control, Communication, Computer, Intelligence, Surveillance, and Reconnaissance
C2 – Command and Control
CANA – Convulsant Antidote Nerve Agent
CANUKUS – Canada, United Kingdom, and United States
CAM – Chemical Agent Monitor
CAPO – Capability Area Program Officers
CB – Chemical and Biological
CBA – Capabilities Based Assessment
CBART – Chemical, Biological Agent Resistance Test
CBDP – Chemical and Biological Defense Program

cBioScavenger – Catalytic BioScavenger
CBIRF – Chemical Biological Incident Response Force
CBMS – Chemical Biological Medical Systems
CBMS II – Chemical/Biological Mass Spectrometer Block II
CBPS – Chemical and Biological Protective Shelter
CBR – Chemical, Biological, and Radiological
CBR MOU – Australia, Canada, United Kingdom, and the United States Memorandum of Understanding on Research, Development, and Acquisition of Chemical, Biological and Radiological Defence Materiel
CBRN – Chemical, Biological, Radiological, and Nuclear
CBRN-IRC – CBRN Information Response Center
CBRNE – Chemical, Biological, Radiological, Nuclear, and (High-Yield) Explosives
CBT – JSTO-CBD Physical Science and Technology Division
CBW – Chemical and Biological Warfare
CBWA – Chemical and Biological Warfare Agent
CCMRF – CBRNE Consequence Management Response Force
CDC – Centers for Disease Control and Prevention
CDTF – Chemical Defense Training Facility
CENTCOM – Central Command
CERFP – CBRNE Enhanced Response Force Package
CHR – Contaminated Human Remains
CJCS – Chairman of the Joint Chiefs of Staff
CJCSI – Chairman of the Joint Chiefs of Staff Instruction
CJCSN – Chairman of the Joint Chiefs of Staff Notice
CLS – Contractor Logistics Support
COCOM – Combatant Command
CONOPS – Concept of Operations
CONUS – Continental United States
COP – Common Operational Picture
COTS – Commercial off-the-shelf
CP – Collective Protection
CPC – CBRN Pharmaceutical Countermeasures
CPD – Capability Production Document
CP DEPMEDS – Chemically Protected Deployable Medical System
CPE – Collective Protection Equipment
CP EMEDS – Collectively Protected Expeditionary Medical Support
CP EMF – Chemically Protected Expeditionary Medical Facility
CPFH – Collectively Protected Field Hospitals
CPI – Continuous Process Improvement
CPRC – Counterproliferation Program Review Committee
CPS – Collective Protection Systems
CRADA – Cooperative Research And Development Agreement
CRG – Compliance Review Group
CTR – Cooperative Threat Reduction
CW – Chemical Warfare or Chemical Weapons
CWA – Chemical Warfare or Chemical Weapon Agent
CWC – Chemical Weapons Convention
CWIWG – Chemical Weapons Agreements Implementation Working Group
CMWD – Combating Weapons of Mass Destruction

–D–

DAE – Defense Acquisition Executive
DAIG – Department of the Army Inspector General
DARPA – Defense Advanced Research Projects Agency
DCMA – Defense Contract Management Agency
DEARE – Delayed Effects of Acute Radiation Exposure
DFU – Dry Filter Unit
DHS – Department of Homeland Security
DHHS – Department of Health and Human Services
DLA – Defense Logistics Agency
DMRTI – Defense Medical Readiness Training Institute
DMSMS – Diminishing Manufacturing Sources and Material Shortages
DNA – Deoxyribonucleic Acid
DOC – Department of Commerce
DoD – Department of Defense
DoDD – Department of Defense Directive
DoDI – Department of Defense Instruction
DOTMLPF – Doctrine, Organization, Training, Materiel, Leadership and Education, Personnel, and Facilities
DPE – Demilitarization Protective Ensemble
DPIA – Dry Powder Inhaler Atropine
DTC – Dynamic Test Chamber
DTIRP – Defense Treaty Inspection Readiness Program
DTO – Defense Technology Objective
DTRA – Defense Threat Reduction Agency

–E–

E2C2 – Expendable Equipment Combat Consumption
ECBC – Edgewood Chemical and Biological Center
ECL – Electrochemical Luminescence
EEE – Eastern Equine Encephalitis
EFV – Expeditionary Fighting Vehicle
EO – Executive Office
ETIC – Education and Training Integration Council

–F–

FAR – Federal Acquisition Regulations
FBCB2 – Force XXI Battle Command, Brigade and Below
FCPS – Fixed Collective Protection System
FCS – Future Combat Systems
FDA – Food and Drug Administration
FO/GO – Flag Officer/General Officer
FOUO – For Official Use Only
FUE – Field User Evaluations
FY – Fiscal Year

–G –

GAO – Government Accountability Office
GCP – Good Clinical Practice
GI – Gastrointestinal
GLP – Good Laboratory Practice
GMP – Good Manufacturing Practice
GtW – Go-to-War (items)

– H –

HAZMAT – Hazardous Material
HAZWOPER – Hazardous Waste Operations and Emergency Response
HFV – Hemorrhagic Fever Viruses
HMMWV – High Mobility Multi-purpose Wheeled Vehicle
HPAC – Hazard Prediction and Assessment Capability
H.R. – House Report
HRDS – Human Remains Decontamination System
HSARPA – Homeland Security Advanced Research Projects Agency
HSO – Heath and Safety Orientation (Course)
HSPD – Homeland Security Presidential Directive
HuBChE – Human Butyrylcholinesterase
HVAC – Heating, Ventilating, and Air Conditioning

–I–

IAB – Interagency Board for Equipment Standardization and Interoperability
IBP – Intercellular Bacterial Pathogens
ICAM – Improved Chemical Agent Monitor
IFS – Integrated Footwear System
INATS – Improved Nerve Agent Treatment System
IND – Investigational New Drug
IP – Individual Protection
IPDS – Improved Point Detection System
IPE – Individual Protective Equipment
IPE-SIM – Individual Protective Equipment Strategic Inventory Management
IPP – Installation Protection Program
IOC – Initial Operational Capability
IST – Information Systems Technology
IT – Information Technology
ITF – Interagency Task Force

–J–

JABT – Joint Ambient Breeze Tunnel
JACKS – Joint Acquisition CBRN Knowledge System
JACKS-RW – Joint Acquisition CBRN Knowledge System Reporting Warehouse
JB1GU – JSLIST Block 1 Glove Upgrade
JBAIDS – Joint Biological Agent Identification and Diagnostic System
JBPDS – Joint Biological Point Detection System
JBSDS – Joint Biological Standoff Detection System
JBTDS – Joint Biological Tactical Detection System
JCAD – Joint Chemical Agent Detector
JCBRAWM – Joint Chemical, Biological, and Radiological Agent Water Monitor
JCBRNFC MTT – Joint Chemical, Biological, Radiological, and Nuclear Mobile Training Team
JCD-CBRND – Joint Combat Developer for Experimentation for Chemical, Biological, Radiological, and Nuclear Defense
JCIDS – Joint Capabilities Integration and Development System
JCTD – Joint Capability Technology Demonstration
JEAP – Joint Equipment Assessment Program
JECP – Joint Expeditionary Collective Protection
JEF – Joint Expeditionary Forces
JEM – Joint Effects Model
JFCOM – Joint Forces Command
JKDDC – Joint Knowledge Development and Distribution Capability

JLAC-CBD – Joint Logistics Advisory Council for Chemical and Biological Defense
JLSP – Joint Logistics Support Plan
JMDS – Joint Material Decontamination System
JMPAB – Joint Materiel Prioritization Allocation Board
JMR – Joint Materiel Release
JNBCRS – Joint Nuclear, Biological, and Chemical Reconnaissance System
JOEF – Joint Operational Effects Federation
JP – Joint Publication
JPACE – Joint Protective Aircrew Ensemble
JPDS – Joint Portable Decontamination System
JPEO-CBD – Joint Program Executive Office for Chemical and Biological Defense
JPID – Joint Platform Interior Decontamination
JPM – Joint Program Manager or Joint Project Manager
JPM-CBMS – Joint Project Manager for Chemical and Biological Medical Systems
JPM-CP – Joint Program Manager for Collective Protection
JPME – Joint Professional Military Education
JPM NBC CA – Joint Project Manager for Nuclear, Biological, and Chemical Contamination Avoidance
JPS – Joint Portal Shield
JROC – Joint Requirements Oversight Council
JRO-CBRND – Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense
JSAM – Joint Service Aircrew Mask
JSCESM – Joint Service Chemical Environment Survivability Mask
JSGPM – Joint Service General Purpose Mask
JSLIST – Joint Service Lightweight Integrated Suit Technology (individual protection)
JSLSCAD – Joint Service Lightweight Standoff Chemical Agent Detector
JSMLT – Joint Service Mask Leakage Tester
JSPDS – Joint Service Personnel/Skin Decontamination System
JSSED – Joint Service Sensitive Equipment Decontamination
JSTDS-SS – Joint Service Transportable Decontamination System - Small Scale
JTF – Joint Task Force
JSTO-CBD – Joint Science & Technology Office for Chemical and Biological Defense
JTAVRW – Joint Total Asset Visibility Reporting Warehouse
JVAP – Joint Vaccine Acquisition Program
JWARN – Joint Warning And Reporting Network

–K–

No acronyms.

–L–

LAV – Light Armored Vehicle
LCS – Littoral Combat Ship
LVA – Low Volatility Agent

–M–

M&S – Modeling & Simulation
MAGTF – Marine Air Ground Task Force
MAGTF CBRN CM - Marine Air Ground Task Force Chemical, Biological, Radiological, and Nuclear Consequence Management
MCPS – Mobile Collective Protection System
MCS – Maneuver Control System
MDA – Milestone Decision Authority
MDAP – Major Defense Acquisition Programs
MEF – Marine Expeditionary Force
MEU – Marine Expeditionary Unit

MICAD – Multi-purpose Integrated Chemical Agent Detector
MILCON – Military Construction
MIPR – Military Interdepartmental Purchase Request
MIST – Man-In-Simulant Test
MITS – Medical Identification and Treatment Systems
MMB4 – Oxime Candidate
MOA – Memorandum of Agreement (also, Mechanism of Action)
MRDP – Medical Radiological Defense Program
MTTP – Multi-service Tactics, Techniques, and Procedures

–N–

NAE – Naval Aviation Enterprise
NATO – North Atlantic Treaty Organization
NAVSEA – Naval Sea Systems Command
NBC – Nuclear, Biological, and Chemical
NBCRV – Nuclear, Biological, and Chemical Reconnaissance Vehicle
NBIC – Nanotechnology, Biotechnology, Information Technology, and Cognitive Sciences
NDA – New Drug Application
NDAA – National Defense Authorization Act
NDC – National Drug Company
NDU – National Defense University
NET – New Equipment Training
NGB WMD-CST – National Guard Bureau Weapons of Mass Destruction Civil Support Teams
NHP – Non-Human Primates
NIAID – National Institute of Allergies and Infectious Diseases
NICP – National Inventory Control Points
NORTHCOM – Northern Command
NSTM – Naval Ships' Technical Manual
NTA – Novel Threat Agent or Non-Traditional Agent or Non-Traditional Chemical Agent
NTRP – Navy Tactical Reference Publication

–O–

O&M – Operations and Maintenance
O&S – Operations and Sustainment
OCONUS – Outside of Continental United States
OIPT – Overarching Integrated Product Team or Overarching Integrated Process Team
OPAA – Organophosphorous Acid Anhydrase
OPCW – Organization for the Prohibition of Chemical Weapons
ORM – Operational Risk Management
OSD – Office of the Secretary of Defense

–P–

PA – Project Assessment or Project Arrangement
PAIO – Program Analysis and Integration Office
PB – Pyridostygmine Bromide
PBPK – Physiologically Based Pharmacokinetic/Pharmacodynamic
PCR – Polymerase Chain Reaction
PDDA – Power-Driven Decontamination Apparatus
PD TESS – Product Director, Test Equipment, Strategy, and Support
PME – Professional Military Education
pNPA – Carboxyl Acid Ester
PO – Program Office
PON1 – Human Serum Paraoxonase

POM – Program Objective(s) Memorandum
POR – Program of Record
PSC – Prime Systems Contractor

–Q–

QDR – Quadrennial Defense Review
QSAR – Quantitative Structure Activity Relationship

–R–

R&D – Research and Development
RA – Readiness Assessment
RADIAC – Radiation Detection, Indication, And Computation
RAV – Readiness Assist Visit
RDA – Research, Development, and Acquisition
RDT&E – Research, Development, Test, and Evaluation
RFI – Request For Information
RFP – Request For Proposal
rHuBChE – Recombinant Human Butyrylcholinesterase
RIP – Readiness Improvement Program
RSCAAL – Remote Sensing Chemical Agent Alarm
RSDL – Reactive Skin Decontamination Lotion

–S–

S&T – Science and Technology
SA(CBD&CDP) – Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs
SBA – Simulation Based Acquisition or Simulation Based Analysis
SBIR – Small Business Innovative Research
SCPE – Simplified Collective Protection Equipment
SDD – System Development and Demonstration
SMARTMAN – Simulated Agent Resistance Test Mannequin
SME – Subject Matter Expert
SNAPP – Soman Nerve Agent Pretreatment Pyridostigmine
SoP – Standards of Proficiency
SOW – Statement of Work
SRF – Sample Receipt Facility
SSE – Sensitive Site Exploitation
STANAG – Standardization Agreement
STTR – Small Business Technology Transfer
SUPCOM – 20th Support Command
SWE – Surface Warfare Enterprise

–T–

TAS – Threat Agent Science
T&E – Test and Evaluation
TEI – Technical Equipment Inspection
TIC – Toxic Industrial Chemical
TIM – Toxic Industrial Material
TLCSM – Total Life Cycle Systems Management
TMTI – Transformational Medical Technologies Initiative
TPP – Target Product Profile
TRAC – Threat Reduction Advisory Committee
TRE – Technology Readiness Evaluation

TRL – Technology Readiness Level
TS – OPCW Technical Secretariat
TSI – The Salk Institute
TSR – Total Service Requirement
TSWG – Technical Support Working Group
TTA – Technology Transition Agreement
TTP – Tactics, Techniques, and Procedures

–U–

UID/RFID – Unique Identification/Radio Frequency Identification
UNS – Urgent Needs Statement
USACBRNS – U.S. Army CBRN School
USAR – U.S. Army Reserve
U.S.C. – United States Code
USD(AT&L) – Under Secretary of Defense for Acquisition, Technology and Logistics
USD(P&R) – Under Secretary of Defense for Personnel and Readiness
USG – United States Government

–V–

VEE – Venezuelan Equine Encephalitis
VIG – Vaccine Immune Globulin
VIGIV – Vaccinia Immune Globulin Intravenous
VLSTRACK – Vapor, Liquid, and Solid Tracking

–W, X, Y & Z–

WBT – Web-Based Training
WEE – Western Equine Encephalitis
WMD – Weapons of Mass Destruction
WMD-CST – Weapons of Mass Destruction Civil Support Teams
WMD/E – Weapons of Mass Destruction/Effects
WSLAT – Whole System Live Agent Test